LUISS

Master's degree in Corporate Finance

Course of Financial Statement Analysis

How female leadership drives risk management and long-term sustainability in the Italian pharma industry

Prof. Barbara Sveva Magnanelli

SUPERVISOR

Prof. Saverio Bozzolan

CO-SUPERVISOR

Giuseppe Guida - 773951

CANDIDATE

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Abstract

Over recent decades, leadership studies have progressively emphasized the potential benefits arising from gender diversity within corporate governance, particularly in relation to risk management effectiveness and strategic sustainability orientation (Palvia et al., 2020). In highly regulated and risk-intensive sectors, such as the pharmaceutical industry, leadership styles critically influence organizational responses to complex operational, financial, and regulatory risks. However, despite growing female representation within the pharmaceutical workforce, the specific impact of female leadership on corporate risk management practices remains empirically underexplored, particularly within the Italian context. As a result, the main objective of this thesis is to analyze how female leadership influences risk management and long-term sustainability within the Italian pharmaceutical industry. Specifically, the study aims to explore whether and to what extent leadership styles associated with women and men may contribute to more effective and sustainability-oriented approaches to risk management in a sector marked by complex market dynamics, regulatory frameworks, safety and efficacy protocols that involve specific, long and costly business processes (Simonetti, 2020). Chapter 1 analyzes leadership theories in relation to the specific risk environment of the Italian pharmaceutical industry, with the aim of identifying the most suitable leadership styles required to address risk-sensitive contexts of pharma companies' operations that may critically affect the public welfare. By focusing on the link between gender and leadership, the research outlines the distinctive characteristics of leadership styles adopted by men and women as explored by academic literature, that clearly associate women with transformational leadership traits oriented toward ESG risk management, long-term sustainability and stakeholder engagement, while men are more frequently associated with transactional, performance-driven leadership oriented toward short-term profitability and shareholders' value creation. Chapter 2 provides a detailed analysis of the eight major risk categories affecting pharmaceutical companies—namely supplier, operational, financial, market, logistical, political/regulatory, technological, and environmental risks—and explores how each of these risks are addressed through effective risk management strategies, as well as the critical role of leadership as a driver of risk management effectiveness and the differences between men and female leaders related to risk management orientation. As pharmaceutical companies face increasing pressure to adopt ESG corporate strategies, driven by regulatory requirements, investor expectations and the urgent need to transition toward environmentally and socially responsible business models, Chapter 3 presents the empirical analysis aimed at understanding the extent to which in the context of Italian pharmaceutical industry female leaders adopt a transformational leadership style and are more likely to focus on prudent and conservative risk management strategies that increase firms' commitment to ESG performance to reduce the negative impact of pharmaceutical business operations on the environment and society at large, while male leaders adopt a transactional leadership style and are more likely to focus on aggressive profit-seeking business-oriented risk management strategies less focused on ESG priorities.

Introduction

Risk management has become a key priority for executive teams and boards of directors globally, particularly within the pharmaceutical industry. Most companies operate in a highly complex and industry-specific risk environment, where they must navigate both geopolitical and macroeconomic uncertainties while addressing various risks inherent to their business models (Gius, Mieszala, Panayiotou, & Poppensieker, 2018). In certain industries, companies have developed sophisticated risk management strategies tailored to their unique financial and operational frameworks (Gius, Mieszala, Panayiotou, & Poppensieker, 2018). As the political and economic landscape grows more volatile, pharmaceutical companies face increasing risks related to global commercial operations, clinical-trial development, product quality, and regulatory compliance (Dhankhar et al., 2018). Specifically, the Italian pharmaceutical industry is marked by considerable complexity regarding regulations, market dynamics, safety and efficacy protocols, which demand lengthy, intricate, and expensive research and development phases (Simonetti, 2020). The necessity of balancing the private commercial corporate interests with public health protection further complicates the framework, as these two objectives are frequently, if not always, in conflict (Simonetti, 2020). The COVID-19 pandemic has starkly revealed this dichotomy, exposing the inefficient allocation of funds for medical and pharmaceutical research, along with the challenges of managing long and complex supply chains that create dependencies on shocks and ongoing developments in Asian countries, particularly China (Simonetti, 2020). These dependencies extend beyond economic factors, encompassing technological and geopolitical dimensions as well. As a result, there has been a growing recognition of the need to rethink supply chain structures to better prevent and, in worst-case scenarios, effectively manage the many risks stemming from global interconnectivity, thereby strengthening the resilience of companies (Simonetti, 2020). One clear sign of this escalating risk environment is the sharp decline in the market valuations of specialty companies (a 35% drop), generic-drug manufacturers (a 25% drop), and biotechnology firms (Dhankhar et al., 2018). Pharma companies aim to mitigate the downside risk of substantial investments in their product pipelines while simultaneously ensuring product quality and patient safety to meet stringent regulatory requirements (Gius, Mieszala, Panayiotou, & Poppensieker, 2018). According to McKinsey research pharma companies suffering from quality issues lose annual revenue equal to 4 to 5% of cost of goods sold (McKinsey & Company, 2017). Within the operational processes of pharmaceutical corporations, Quality Risk Management (QRM) has become an essential mandatory regulatory requirement for healthcare and pharmaceutical companies (Reddy, Gupta, Raghunandan, & Kashyap, 2014). QRM is a systematic and ongoing process of risk assessment, control, communication, and review aimed at minimizing risks to product quality throughout the entire product life cycle (Reddy, Gupta, Raghunandan, & Kashyap, 2014). This framework is designed to prevent unforeseen consequences that could negatively impact both the patients and the company's reputation and profitability. In the coming years, pharmaceutical companies are expected to encounter heightened industry-specific risks in the following critical areas (Dhankhar et al., 2018):

- Pricing and market access risks: Traditional pricing models are becoming obsolete due to growing public scrutiny and the rise of outcome-based reimbursement structures.
- Clinical trial and drug approval risks: High attrition rates in late-stage trials and difficulties in achieving market success, even after clinical approvals.
- Regulatory and compliance risks: Challenges in adhering to a wide array of regulatory frameworks across different global markets.
- Operational and supply chain risks: Increasingly complex global supply chains and a growing reliance on third-party suppliers, which affect product quality and operational efficiency.

The role of female leadership in risk management

As the pharmaceutical industry navigates increasingly complex and multifaceted risks, leadership style plays a vital role in shaping how risks are managed. Female leadership has been increasingly recognized for its potential to enhance risk management practices (Weaver-Pronk, 2023). Research has shown that transitioning from a single-gender office to a gender-balanced one can be associated with a 41% increase in revenue (Weaver-Pronk, 2023). Furthermore, women in leadership positions have been proven to help mitigate risk. For instance, companies with a higher number of female directors on their boards have demonstrated stronger resilience in maintaining firm value during mergers and acquisitions (Weaver-Pronk, 2023). This evidence highlights how gender diversity in senior management teams is not only essential for equity and inclusion, but also crucial for enhancing a firm's financial success and sustainability. In the context of the pharmaceutical industry, where patient safety, regulatory compliance, and operational efficiency are critical, female leaders may offer a distinctive advantage (Weaver-Pronk, 2023). Female leaders tend to adopt a collaborative leadership style, which fosters diverse perspectives and promotes ethical decision-making (Burke & Collins, 2001). Their focus on long-term sustainability and a heightened awareness of the ethical implications of business decisions can contribute to more robust risk mitigation strategies (Weaver-Pronk, 2023). In addition, one key area where female leadership can have a profound impact is in decision-making under pressure. Contrary to the outdated belief that women become more emotional and less rational in stressful situations, neuroscientific research has debunked this stereotype (Weaver-Pronk, 2023). Studies have shown that when experiencing stress, men tend to make impulsive decisions based on high-risk rewards, even when the likelihood of success is low. In contrast, women tend to be more risk-averse, taking time to carefully assess the available options and focusing on smaller, more reliable rewards (Weaver-Pronk, 2023). This difference in decision-making styles highlights the importance of gender diversity in leadership, as a balanced approach between risk-taking and risk-averse behaviors proves to be the most effective, especially when high-stakes decisions are involved (Burke & Collins, 2001). To harness the full potential of female leadership, companies must also address the retention and attraction of female talent. A survey conducted by EY on gender parity within the life sciences sector revealed that many executives acknowledge their companies' struggles to retain women in leadership positions (EYGM

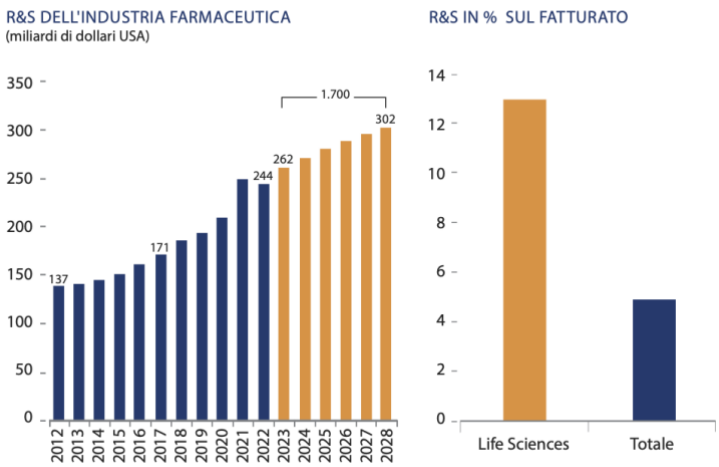
Limited, 2016). This issue is particularly concerning given that 72% of industry leaders believe that increasing gender diversity within leadership teams would enhance overall company performance. Despite this, 53% of these leaders feel that their organizations are underutilizing the skills and potential of women (EYGM Limited, 2016). In conclusion, women's collaborative decision-making in the pharma industry, ethical focus, and measured risk-taking provide a unique approach to navigating complex risks, implying that female leadership may offer advantages in risk management (Weaver-Pronk, 2023). By fostering a more inclusive environment and ensuring that women are represented at the highest levels of leadership, pharmaceutical companies may better manage risk, improve financial performance, and ensure long-term sustainability (Henderson, 2023).

Chapter 1 – Theoretical framework of female leadership and its relevance within the Italian pharma industry

1.1. The strategic role of Italy in the global pharmaceutical industry

Pharmaceutical research is a strategic investment in health, growth, and security. The pharmaceutical industry ranks first globally in R&D investments, both in absolute terms and as a percentage of revenue (Farmindustria, 2024). Between 2023 and 2028, pharma companies are projected to invest €1.7 trillion, with 80% of this amount allocated to a research network based on the Open Innovation model (Farmindustria, 2024). This network involves a variety of stakeholders, including businesses, public institutions, start-ups, science parks, and clinical centers. For Italy, this presents a significant opportunity to boost employment and attract further investment. In the last three years, an average of 75 new active pharmaceutical ingredients (APIs) have been approved globally each year, compared to 50 per year in the previous decade (Farmindustria, 2024). This growth, along with the 23,000 products currently under study which will become future therapies, brings tangible hope for patient treatments and represents a growing trend toward more personalized medicine (Farmindustria, 2024). Investing in research not only improves the health and life expectancy of citizens but also attracts new resources and talent, driving economic and social development (Farmindustria, 2024). For this reason, it is crucial to create an attractive environment for basic research, clinical trials, patent registration and protection, as well as the technological and digital transfer of data, to further strengthen the innovation ecosystem.

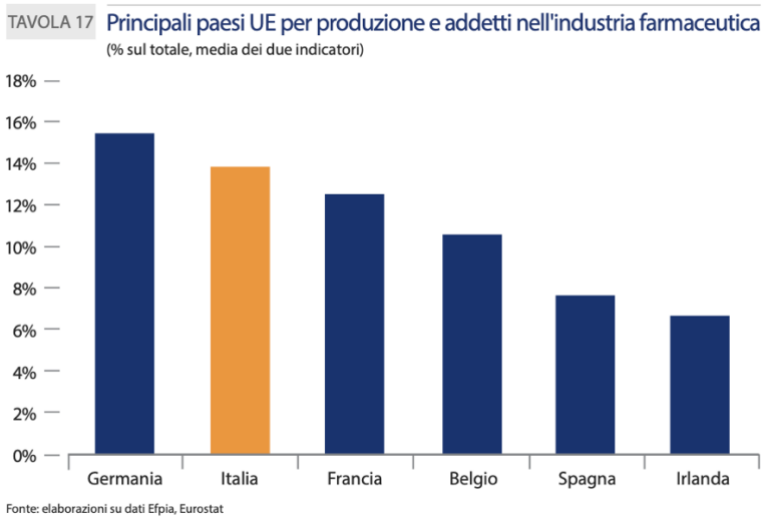
TAVOLA 5 Dati sulla Ricerca e Sviluppo a livello mondiale



Fonte: EvaluatePharma, Commissione Europea

Digitalization is one of the primary and cross-cutting forces of our era, and especially in the pharmaceutical industry, various transformations are already taking place in processes – both in R&D and production – as well as in organizational structures (Farmindustria, 2024). On the product side, medications are increasingly integrated into a holistic therapeutic and care pathway, combined with digital devices, companion diagnostics, and remote care systems, ensuring seamless continuity between hospital, outpatient, and home care (Farmindustria, 2024). In 2023, the global pharmaceutical industry invested $12.8 billion in AI-driven R&D projects, covering both fundamental research, where AI is expected to reduce the time for identifying new molecules by up to 40%, but especially clinical trials (Farmindustria, 2024). In Italy, data from ISTAT highlights that the use of digital tools in the pharmaceutical industry is more widespread compared to other industries: 84% of pharmaceutical companies use enterprise management software (compared to 39% in other sectors), 54% use cloud services (vs 28%), and 32% leverage AI technologies (vs 16%) (Farmindustria, 2024). Additionally, findings from the Politecnico di Milano show that 38% of Italian pharmaceutical companies have already integrated AI applications into their drug and vaccine R&D processes, particularly during the drug discovery phase (Farmindustria, 2024). Moreover, a considerable number of patients and healthcare professionals rely on digital services, although data collection and usage are not yet fully systematized: 45% of patients use at least one health app, 39% of doctors conduct tele-visits, and 42% use the Electronic Health Record system (Farmindustria, 2024). Italy has established itself as one of the leading pharmaceutical hubs worldwide. In 2023, the industry achieved a production value of €52 billion, with €49 billion generated from exports, employing around 70,000 people (Farmindustria, 2024). This highlights the sector's crucial contribution to the growth of the European Union. The strength of Italian pharmaceutical companies lies in their ability to integrate innovation, investment, and productivity. A diversified and resilient supply chain, including a variety of companies and production stages, has played a central role in driving the industry forward and attracting significant investments (Farmindustria, 2024). Labor productivity in the sector is 7% higher than the average of the EU Big Five and even competes with that of Germany (Farmindustria, 2024). Additionally, over the past decade, the average export value has increased by 87%, far exceeding the 47% growth rate of the EU Big Five, reflecting the high quality and

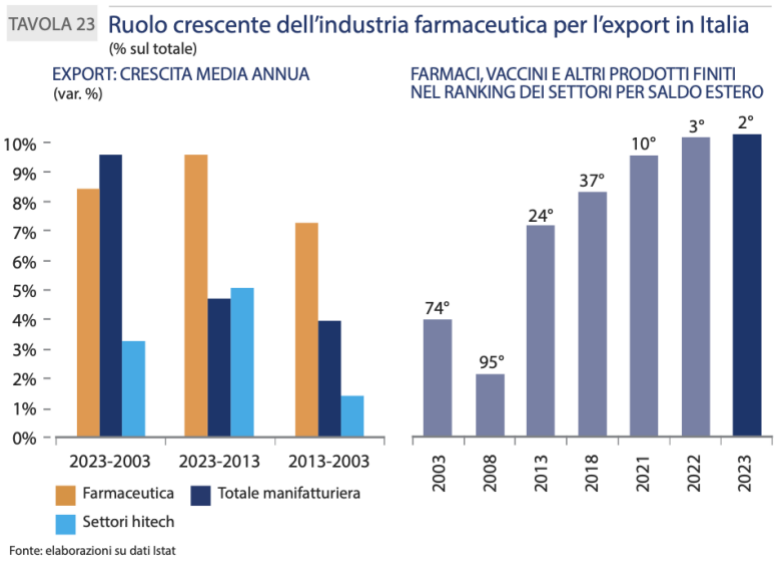
innovation of Italian pharmaceutical products (Farmindustria, 2024). In terms of patent activity, there has been a 32% rise in Life Sciences and a 35% increase in the pharmaceutical field over the past five years, outstripping the growth seen in the European Big Five (23%) and other Italian sectors (16%) (Farmindustria, 2024). Despite these achievements, enhancing Italy's competitiveness remains critical to maintaining its leading role in Europe and bolstering its position on the global stage.



Source: Farmindustria Centro Studi. *(2024). Indicatori farmaceutici*. Roma: Farmindustria

In 2023, the global pharmaceutical market is valued at approximately $1.6 trillion in industry revenue, with North America accounting for 53%, Europe 23%, and China 8% (Farmindustria, 2024). Italy ranks as one of the leading markets worldwide, holding the 7th spot in the global ranking, contributing around 3% of the global pharmaceutical revenue (Farmindustria, 2024). Projections for 2028 anticipate Italy rising to the 6th position. The competition for attracting pharmaceutical industry investments has intensified globally, with new attraction policies shaping the landscape for the coming years. To prevent Europe from losing more ground to its global competitors, it is crucial to boost its attractiveness to investors by securing sufficient funding, offering targeted incentives for pharmaceutical industry investments, and implementing updated regulatory frameworks that are tailored to the current challenges and opportunities in the global pharmaceutical market (Farmindustria, 2024). These efforts should focus on fostering innovation, accelerating product development, and strengthening Europe's role as a competitive hub for high-quality drug manufacturing and healthcare solutions. The pharmaceutical industry in Italy has emerged as one of the key specializations of the "Made in Italy" excellence. In 2023, the total trade surplus amounted to €11 billion; when including pharmaceuticals, vaccines, and other finished products, this figure rises to approximately €17 billion, positioning the pharmaceutical sector second only to the mechanical engineering industry among Italy's manufacturing sectors (Farmindustria, 2024). This strong specialization is further reflected in the consistently positive trade balance of chemically synthesized drugs, as well as the substantial growth in the biotechnological product segment over the past two years (Farmindustria, 2024). This outstanding performance is driven by a recent surge in pharmaceutical exports, with growth rates exceeding

the long-term average (Farmindustria, 2024). Between 2021 and 2023, Italy became the global leader in pharmaceutical export value growth, surpassing major competitors such as the USA and Germany.



Source: Farmindustria Centro Studi. *(2024). Indicatori farmaceutici*. Roma: Farmindustria

These figures confirm the international excellence of Italy's pharmaceutical industry, a fact further supported by the increase in the average export value from 2013 to 2023 (Farmindustria, 2024). This indicator, which serves as a proxy for the innovation and quality of Italy's pharmaceutical production, shows that the industry not only closed the gap with the European Big Five but also outperformed them in the last five years. Given the complexity and competitive nature of this sector, the need for effective leadership, particularly in fostering innovation and managing risks, becomes increasingly crucial, setting the stage for exploring the influence of female leadership in driving sustainable growth.

1.2. Why leadership is essential in managing Italian pharma industry-specific risks

The pharmaceutical industry is currently facing unique risks that go beyond the global economic slowdown, inflation, and geopolitical instability. The COVID-19 pandemic revealed vulnerabilities in the pharma industry's international supply chain, and although consumer trust is gradually improving, it has not yet returned to pre-pandemic levels (Ahmed, 2021). In fact, pharma industry has historically struggled with low levels of trust worldwide, although a 2021 Accenture survey found that 15% of U.S. consumers now trust pharmaceutical companies more than they did before the pandemic (Ahmed, 2021). Flynn (2021) identifies six crucial risks that the pharmaceutical sector is currently grappling with, each of which poses significant stumbling blocks to the industry's operational stability and long-term viability:

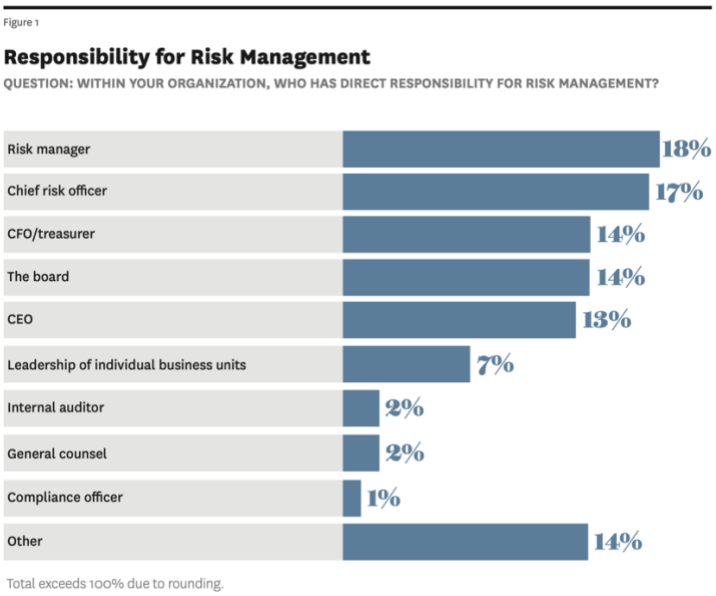
1. Reduced demand for prescription medicine: Due to reduced purchasing power and lower consumer trust post-COVID, the demand for prescription medicine has dropped. People deferred treatments during the pandemic, which caused a temporary decline in sales and consumption.
2. Growing competition from generic pharmaceuticals: As patents for many blockbuster drugs expire, the market is flooded with generic alternatives, threatening the profitability of established companies.

This increased competition from generics can lead to drastic revenue loss for big pharmaceutical firms, as generics are sold at significantly lower prices.

3. Pharmaceutical fraud: The pandemic created an environment ripe for fraudulent activities, including counterfeit medications and false claims about drug efficacy. Fraudulent actors take advantage of the public's desperation, which can undermine trust in legitimate pharmaceutical companies and erode confidence in healthcare industry.
4. Rising consumer expectations and difficulties managing brand health: Customers now demand more transparency about drug pricing, efficacy, and accessibility. Additionally, the shift toward personalized medicine has created expectations for treatments tailored to individual genetic profiles, increasing pressure on pharmaceutical companies to innovate and customize their value propositions.
5. Cybersecurity threats: The rise of digital health technologies, including the use of AI and big data in drug development, exposes the industry to cyberattacks. Pharmaceutical companies are main targets for hackers due to the value of intellectual property and sensitive data, such as clinical trial information and patient records. A breach can compromise a company's reputation and financial stability.
6. Supply chain disruptions: The global nature of pharmaceutical supply chains makes them vulnerable to disruption. Events such as natural disasters, trade restrictions, or pandemics like COVID-19 can delay the production and distribution of essential drugs, a situation that erodes public confidence in the pharma sector's ability to meet healthcare needs.

In a global context where uncertainty is increasing both in frequency and manifestation of unpredictable economic and financial events, the crucial role of leadership in risk management becomes essential, particularly in the pharmaceutical sector, which is considered strategic from a national public interest perspective (Henderson, 2023). Effective leadership in the pharma industry requires the ability to navigate through complex regulatory frameworks while ensuring patient safety and maintaining operational efficiency (Henderson, 2023). According to a recent survey conducted by Harvard Business Review Analytic Services, in collaboration with Zurich, the Federation of European Risk Management Associations (FERMA), and the Public Risk Management Organization (PRIMO), there has been a notable increase in C-suite involvement in overseeing risk management efforts at European companies, reflecting the growing importance of risk management after years of financial and economic uncertainty. At the same time, businesses are stressing the need for stronger board involvement to guide decisions on strategic and company-wide risks, while also encouraging the spread of a risk-aware culture across the organization. The survey found that 35% of organizations have delegated the responsibility for risk management directly to a Chief Risk Officer (CRO) or a risk manager, while 27% place this responsibility in the hands of the CEO or CFO/treasurer (Harvard Business Review Analytic Services, n.d.). In 14% of cases, the board itself holds direct responsibility for managing risk. Moreover, most companies have established training programs and review processes that

ensure both the board and top executives remain well-informed about the organization's exposure to key risks. At 70% of organizations, critical risks are regularly communicated to the C-suite, underscoring the importance of continuous risk monitoring at the highest levels of leadership (Harvard Business Review Analytic Services, n.d.). However, only 17% of respondents indicated that communication between top executives and the CRO was comprehensive, while 40% of companies had not yet established a cross-functional risk committee (Harvard Business Review Analytic Services, n.d.).



Source: Harvard Business Review Analytic Services. (n.d.). *Leadership in risk management*. Harvard Business Review. Retrieved from https://www.ferma.eu/app/uploads/2013/08/leadership-and-risk-management-executive-summary.pdf

In addition, most companies in the survey have education and review processes in place that keep the board and the C-suite regularly informed about their risk exposures. As underlined above, key risks are communicated to the C-suite regularly at 70% of organizations. At more than half (59%) of organizations, the board reviews risk management policies and procedures annually, and at almost three out of four (72%), it reviews top risk exposures and treatment actions at least biannually (Harvard Business Review Analytic Services, n.d.). More than half (56%) of organizations have increased the resources they devote to risk-related education and training over the past three years, at least for the CRO level and higher (Harvard Business Review Analytic Services, n.d.). In recent years, European companies have faced an increasingly complex risk landscape driven by global events such as the COVID-19 pandemic, the Russia-Ukraine war, multiple geopolitical tensions and the acceleration of digital transformation. These challenges, combined with growing concerns around cybersecurity, supply chain disruptions, and climate change, have made risk management a top priority for businesses. Companies are now under pressure to respond not only to financial volatility but also to regulatory shifts and rising expectations from stakeholders regarding environmental, social, and governance (ESG) issues. Top management and boards are taking a more active role in integrating risk management into corporate strategy, recognizing that today's risks are more interconnected and far-reaching than ever before (Harvard Business Review Analytic Services, n.d.). For

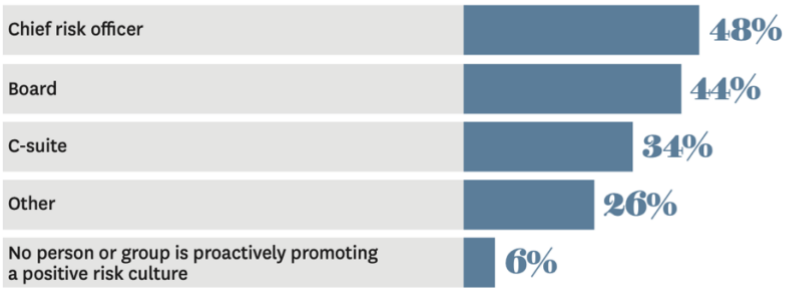
example, cybersecurity incidents, which have surged in the wake of increased remote work and digital dependency, have placed IT risk at the forefront of boardroom discussions. Similarly, reputational risk, exacerbated by the rapid spread of information through social media, is prompting companies to adopt proactive risk management strategies to safeguard their brand value. Reflecting this new prioritization of risks, executives at major companies and leading thinkers on risk management emphasize the BoD and the C-suite's pivotal role in providing continued leadership and direction (Harvard Business Review Analytic Services, n.d.). "It's important that the C-suite be talking as much about risk management as it does about profit, growth, and customers because they are interdependent. The point is that you can't optimize profit if you do not manage, leverage or mitigate risk exposures as appropriate", said Linda Conrad, Director of Strategic Business Risk at Zurich, at a May 2013 Harvard Business Review webinar (Harvard Business Review Analytic Services, n.d.). In this context, leadership plays a pivotal role in not only responding to these risks but also in anticipating them through strategic foresight and the implementation of advanced risk management frameworks. Leaders who can cultivate a culture of risk awareness across the companies are more likely to ensure that risk management is embedded in daily operations and decision-making processes (Harvard Business Review Analytic Services, n.d.). This is particularly true in the pharmaceutical industry, as it is considered strategic for its public relevance, and the consequences of poor risk management can directly impact patient safety, regulatory compliance, financial stability, but especially the social welfare (European Commission, 2020). To give specific examples, moving our attention to the specific risks of Italian pharma industry, the complexity of operational risks inherent to the production processes of pharmaceutical companies requires specialized and high-skilled leadership (Brusco et al., 2011). In the Italian pharma industry these risks are especially pronounced due to the highly regulated nature of production, the strict standards for safety, and the use of complex machinery and hazardous substances (Brusco et al., 2011). According to Brusco et al. (2011), the main operational risks include worker exposure to toxic chemicals during the handling of active pharmaceutical ingredients (APIs), potential contamination during production processes, and accidents related to the use of industrial equipment such as granulators, mixers, and autoclaves. Specifically, Brusco et al. (2011) emphasize how handling of APIs presents a significant health risk to workers, requiring high specific skills: these substances often require stringent control measures, including the use of personal protective equipment (PPE) and containment systems to prevent direct exposure. Additionally, the storage and transportation of these substances further amplify the risks, especially when dealing with volatile or flammable chemicals like solvents used in the production process (Brusco et al., 2011). The accidental release of such substances not only poses immediate health risks but also environmental hazards, potentially leading to costly regulatory penalties and remediation efforts (Brusco et al., 2011). Moreover, the risk of contamination during the production process is one of the most critical operational concerns in the pharmaceutical industry. According to Brusco et al. (2011), even minor contamination can render entire batches of products unusable, leading to significant financial losses and potential shortages in essential medications. The complexity of maintaining sterile environments,

particularly in the production of injectable drugs or other sterile formulations, requires constant vigilance and adherence to strict protocols, such as Cleaning in Place (CIP) and Sterilizing in Place (SIP) systems (Brusco et al., 2011). Any lapse in these procedures can lead to contamination, risking the safety of patients and undermining the company's compliance with regulatory bodies such as the European Medicines Agency (EMA) (Brusco et al., 2011). In addition to chemical and contamination risks, Brusco et al. (2011) highlight the industry-specific physical risks associated with the use of industrial equipment like mixers, granulators, and autoclaves. These machines, essential for the large-scale production of pharmaceutical products, require highly skilled operators who are trained in both safety protocols and emergency procedures. Accidents involving such equipment, including mechanical failures or improper usage, can result in severe injuries or even fatalities (Brusco et al., 2011). Therefore, leadership in the pharmaceutical sector is essential to prioritize comprehensive training programs and regular safety audits to ensure that all equipment is operated safely and maintained to the highest standards (Brusco et al., 2011). Finally, the waste generated by pharmaceutical production processes, particularly toxic or hazardous waste, represents a main environmental risk. Brusco et al. (2011) note that improper disposal of chemical waste can lead to environmental contamination, which not only damages ecosystems but also exposes companies to legal liabilities and reputational damage. Leaders must ensure that their organizations comply with environmental regulations by implementing robust waste management systems and fostering a culture of environmental responsibility. Given the abovementioned operational industry-specific risks shaping the Italian pharma industry, ranging from worker safety and contamination control to equipment handling and waste management, risk management of Italian pharma companies demand highly skilled leadership. Leaders who effectively integrate risk management into every aspect of the production process can mitigate these risks, ensuring not only the safety of workers and patients but also the long-term sustainability of the company (Brusco et al., 2011). In any effective risk management framework, but especially in a strategic industry such as pharma, communication is the backbone that ensures informed and well-grounded decision-making by leadership (Harvard Business Review Analytic Services, n.d.). A well-structured communication process allows leaders at all levels of the organization to thoroughly understand the risks the company faces, enabling them to make decisions that are not only strategic but also conscious of all potential risk implications (Harvard Business Review Analytic Services, n.d.). The abovementioned Harvard survey analyzed the crucial role of the chief risk officer (CRO) in developing and communicating an affirmative risk culture, with nearly half (48%) of survey respondents affirming their involvement in promoting an affirmative risk culture, surpassing even the board (44%) and the C-suite (34%).

Figure 2

Involvement in Communicating an Affirmative Risk Culture

QUESTION: WITHIN YOUR ORGANIZATION, WHO IS INVOLVED IN DEVELOPING AND COMMUNICATING AN AFFIRMATIVE "RISK CULTURE"?



Source: Harvard Business Review Analytic Services. (n.d.). Leadership in risk management. Harvard Business Review. Retrieved from https://www.ferma.eu/app/uploads/2013/08/leadership-and-risk-management-executive-summary.pdf

Moreover, 75% of respondents stated that the risk function is the primary channel through which the C-suite gathers crucial information and advice on risk, more than any other source. This underscores how essential it is for risk functions to ensure that detailed, real-time information flows seamlessly from every level of the organization to the top leadership. However, effective communication is not just about the flow of information but also about ensuring its depth and accuracy. As underlined above, only 17% of respondents described communication between the C-suite and the CRO as being comprehensive (Harvard Business Review Analytic Services, n.d.). Additionally, 40% reported that their organization has not yet established a cross-functional risk committee, an essential component for ensuring that risk profiles are discussed thoroughly across the management chain. This lack of comprehensive communication hinders the leadership's ability to make fully informed decisions that consider every possible risk implication for the company. In a sector as highly regulated and complex as the pharmaceutical industry, clear and structured communication processes are critical (Brusco et al., 2011). Leaders need to be equipped with detailed, precise, and actionable insights on the company's risk landscape to make decisions that not only mitigate immediate risks but also safeguard the organization's long-term sustainability. By ensuring that communication flows effectively from the operational to the strategic level, pharmaceutical companies can create a culture of risk awareness that empowers leaders to make informed, forward-thinking decisions (Brusco et al., 2011). As we are aware, the pharmaceutical sector, like many other industries, is undergoing a profound digital transformation, commonly referred to as Industry 4.0 (Endress+Hauser, 2023). This revolution is taking place behind the scenes of the world's leading industrial and manufacturing organizations, where companies are progressively digitizing essential functions within their entire value chains (Endress+Hauser, 2023). Products are being enhanced with digital functionalities, and new data-driven services are being introduced. One of the most significant trends and innovations in pharmaceutical risk management is the development of smart monitoring systems, especially in relation to temperature control of valuable pharma products, a critical factor in ensuring product quality and compliance

(Endress+Hauser, 2023). According to Endress+Hauser (2023), the advent of Industry 4.0 has introduced a new level of interconnectedness between devices, commonly known as the Internet of Things (IoT). In addition to communication advancements, e-maintenance has emerged as a transformative approach to asset management. Defined as the ability to monitor production assets in real time, connect production and maintenance management systems, and integrate remote production data with higher-level information systems to support decision-making, e-maintenance represents the future of smart monitoring (Endress+Hauser, 2023). By leveraging internet connectivity and data integration, pharmaceutical companies can now monitor the status of their equipment and systems from virtually anywhere, significantly improving maintenance response times and reducing operational downtime. Key components of e-maintenance include real-time monitoring and intelligent diagnostics (Endress+Hauser, 2023). Real-time monitoring provides up-to-the-minute data streaming from devices, enabling continuous oversight of the production process and allowing for immediate interventions when necessary. This capability provides a competitive advantage, as companies can react swiftly to potential issues, minimizing disruptions and ensuring the smooth operation of the production line. On the other hand, intelligent diagnostics enable devices to autonomously analyze operational flows, predict deviations, monitor activity states, and alert management when maintenance is required (Endress+Hauser, 2023). As the technological advancements in the pharmaceutical industry clearly create a new hard-to-manage risk environment, effective risk management, whether related to operational, financial or regulatory, requires highly skilled leadership that is not only completely aware of the specific pharma industry environment to understand and manage the industry-specific risks by guaranteeing a positive impact on internal and external stakeholders, but also proactive in identifying potential risks before they materialize and reactive to immediate risk manifestations (Brusco et al., 2011). As discussed, the increasing integration of Industry 4.0 technologies has transformed the pharma industry landscape by providing real-time data and predictive capabilities (Endress+Hauser, 2023). However, the true value of these technological innovations lies in the ability of leadership to exploit them effectively and to the fullest for forward-looking quality risk management. Leaders must bridge the gap between technological innovation and effective decision-making, ensuring that new technological innovations contribute meaningfully to the company’s overall approach to risk mitigation (Endress+Hauser, 2023). This is where well-structured communication processes become indispensable. As noted, structured and clear communication channels allow leaders to make well-informed, timely decisions based on the comprehensive, real-time risk profile of the company (Endress+Hauser, 2023). Whether it involves ensuring that temperature sensors in critical production systems are functioning optimally or preempting disruptions in the global supply chain, top management must facilitate the seamless flow of information from the operational level to the strategic level (Endress+Hauser, 2023). By doing so, leaders ensure that every aspect of risk, down to the most technical details, is accounted for in the broader organizational strategy, enhancing both operational efficiency and long-term resilience. The Italian pharmaceutical industry, particularly in response to the COVID-19 pandemic, has shown how innovative leadership can drive rapid technological advancements and foster

collaboration across sectors, from research centers to large multinational corporations (Jefferson Wells, 2022). The sector's ability to quickly mobilize resources, adapt to flexible production and regulatory processes, and accelerate the development of life-saving treatments exemplifies the power of strong leadership in times of crisis (Jefferson Wells, 2022). The Italian pharma industry's resilience and innovation oriented to the protection of the public health is demonstrated by its positive outcomes over time. Over the past decade, the number of cancer survivors has increased by 1.2 million, with two out of three individuals diagnosed with cancer now surviving beyond five years, compared to just one in three in 1990 (Jefferson Wells, 2022). Innovative treatments for hepatitis C have already cured more than 240,000 patients, and mortality rates from chronic diseases have also decreased, as many conditions now benefit from more effective treatments. Despite the COVID crisis in 2020, Italy's pharmaceutical sector has solidified its position as a global leader, with a production value of €34.4 billion in 2021, sharing the European podium with Germany and France (Jefferson Wells, 2022). This economic success has been fueled by growing investments, with €3.1 billion allocated in 2021 alone across production and research & development, marking a 15% increase compared to the previous five-year period. One of the most striking aspects of this growth is the sector's commitment to gender equality. 2021 data of Italian pharma industry show that women now represent 43% of the workforce, a significant increase compared to the 29% national industrial average, and play a critical role in research & development, where they make up 51% of the workforce (Jefferson Wells, 2022). Moreover, the growing presence of female leadership in the Italian pharmaceutical industry is reshaping how companies approach risk management. According to Enrica Giorgetti, General Director of Farmindustria, more than 35% of the sector's revenue comes from companies led by women, including entrepreneurs, managers of small and medium-sized enterprises, and leaders of multinational corporations like Pfizer, MSD, and BMS (Jefferson Wells, 2022). This significant contribution set the stage for exploring how female leaders are driving not only innovation but also the strategic approaches needed to manage the complex risks of the Italian pharmaceutical industry.

1.3. Female leadership in pharma: overcoming systemic barriers

A "pink wave" is sweeping through the Italian pharmaceutical industry, marking a significant revolution in corporate governance best practices, as noted by recent reports on gender dynamics within the pharma industry (Manca, 2024). Over the last decade, the presence of women in pharmaceutical companies has risen substantially, driven by a mix of policies that promote gender inclusion and work-life balance (Farmindustria, 2024). 2024 Data from Farmindustria underscores that women now represent 53% of the workforce in Research & Development and 44% of the total workforce in the Italian pharma sector, marking a 13.4% increase in female employment over the past five years (Farmindustria, 2024). These numbers reflect not only the growing presence of women in the industry but also a shift toward higher levels of responsibility, with many holding managerial and executive roles, especially among professionals under 35 (Manca, 2024). The upward trajectory is further evidenced by a 15% rise in female employment in the Italian pharma industry between 2016 and 2022 (Avitalta, 2023). This growing female presence is further

encouraged by corporate welfare models that prioritize family-friendly policies. Measures such as flexible working hours, part-time positions, and smart working opportunities are common, with 73% of companies providing these options (Manca, 2024). Additionally, on-site services such as daycare facilities and other conveniences contribute to fostering an inclusive work environment for women (Manca, 2024). The growing female workforce also extends to the broader Italian healthcare industry. 2023 Data from the National Federation of Orders of Doctors (Fnomceo) reveals that 52% of the 329,263 medical professionals under the age of 69 in Italy are women (Avitalta, 2023). Between the age 40-44, the number of female doctors almost doubles that of their male colleagues (Avitalta, 2023). On a global scale women's representation is crucial to healthcare and pharmaceutical industries, overseeing the well-being of 5 billion individuals and contributing around $3 billion each year to global health, with half of this amount coming from unpaid work (Avitalta, 2023). Despite their substantial involvement, women remain significantly underrepresented in leadership positions. According to the 2023 report "The Status of Women and Leadership in Global Health" by Women in Global Health, women hold only 25% of leadership positions within the global health sector (Avitalta, 2023). Furthermore, a 2020 survey revealed that 85% of the 115 national Covid-19 task forces were composed predominantly of male participants (Avitalta, 2023). This disparity in leadership is mirrored within the Italian pharmaceutical industry, where, despite growing female representation in the workforce and in research and development, women still face challenges in ascending to executive positions (Avitalta, 2023). While female representation is steadily increasing in the workforce, systemic barriers in leadership advancement remain a critical issue to address if the pharmaceutical industry is to fully benefit from the diverse perspectives that women may bring to strategic decision-making and risk management (Manca, 2024). The 2020 Pharmaceutical Strategy for Europe, together with the legal framework provided by the EU's Gender Equality Strategy 2020-2025, emphasizes the importance of promoting diverse leadership within the pharmaceutical sector, highlighting how greater inclusion of women in leadership positions can strengthen the sector's resilience and innovation (European Commission, 2020). While the European pharmaceutical industry remains a key strategic sector of the EU economy, especially for its commitment and success on research and development, there are still remarkable gaps in fully attracting female talent, particularly in senior leadership roles (European Commission, 2020). European Commission encourages the adoption of concrete measures to remove structural barriers preventing women from reaching leadership positions, as an integral part of strengthening the pharma sector's innovative capacity and its preparedness to face future global health challenges, acknowledging that including women in leadership roles is not only a priority of diversity and inclusion policies, but also a strategy to enhance the long-term competitiveness and sustainability of European pharmaceutical companies. It encourages Member States and businesses to implement gender mainstreaming practices, establish transparent pay systems, and ensure equal opportunities for career progression. One of the key actions laid out in the strategy includes mandatory measures on pay transparency, aimed at addressing the gender pay gap, which continues to limit women's economic independence and career advancement (European Commission, 2020). The strategy also calls for

the enforcement of the Work-Life Balance Directive, ensuring that both men and women have equal opportunities to thrive in their professional and personal lives, particularly in sectors like pharmaceuticals, where work schedules are often inflexible (European Commission, 2020). Following the European Commission's commitment for greater gender equality in the pharmaceutical sector, Italy has introduced specific legislative measures and national policies to promote gender equality in the workplace, closely tied to its National Recovery and Resilience Plan (NRRP). One of the most significant milestones is the introduction of the UNI/PdR 125:2022 certification, a gender equality certification framework developed through a collaborative process involving multiple Italian governmental bodies such as the Department for Equal Opportunities, who had a main role in its implementation (SGS, 2022). This certification serves as an essential tool to assess and enhance gender equality in the workplace, requiring companies to adhere to several key criteria, including (SGS, 2022):

- Measurement of organizational maturity of the company through the calculation of specific KPIs.
- Formalization of gender equality policies, ensuring that policies related to equal treatment and opportunities are embedded within the company's culture.
- Development and implementation of a strategic plan aimed at achieving gender equity.
- Establishment of a management system that oversees the company's progress on gender equality initiatives.

Companies that comply with these standards and obtain the UNI/PdR certification can not only enhance their accountability and public image with bot external and internal stakeholders, but also benefit from tax incentives and a competitive edge in public procurement, according to Italy's National Recovery and Resilience Plan (NRRP) Mission 5 objectives (SGS, 2022). Two notable examples of Italian pharmaceutical complying with the abovementioned Italian Gender Equality framework are Fidia Farmaceutici and Chiesi. Fidia Farmaceutici has set a benchmark in the industry by becoming the first mid-sized pharmaceutical company to obtain the National Certification for Gender Equality (Fidia Farmaceutici, 2024). This accomplishment reflects Fidia's commitment to fostering an inclusive environment, with 49.5% of its workforce being women and 37% of its top management positions held by women in Europe. Similarly, Chiesi, one of Italy's leading biopharmaceutical companies, obtained the same gender equality certification in 2023, reinforcing its long-standing commitment to diversity and inclusion (Chiesi, 2023). With nearly 52% of its employees being women and 44% of managerial roles occupied by females, Chiesi exemplifies how a diverse workforce can drive innovation, improve decision-making, and strengthen the company's long-term sustainability (Chiesi, 2023).

Leadership in the pharmaceutical sector plays a crucial role in navigating the multifaceted risk environment of this highly regulated industry. The increasing regulatory pressures, rapidly evolving market dynamics, and the critical importance of public health demand leaders who can adapt quickly and make strategic decisions grounded in effective risk management (Aydogdu & Asikgil, 2011). In this context, leadership cannot simply

be understood as an exercise of authority; it must be seen as a dynamic and evolving function, capable of responding to unpredictable and shifting risky events that can undermine the satisfaction of internal and external stakeholders (Aydogdu & Asikgil, 2011). This section will analyze the main theoretical implications of leadership with the aim of identifying the most suitable leadership styles for the pharmaceutical sector. Given the specific complexity of the industry's risk environment, the analysis will focus on those styles that best align with the need for both adaptability and precision in decision-making (Brusco et al., 2011). Subsequently, the relationship between leadership and gender will be examined, highlighting both the obstacles and opportunities that arise from gender dynamics within leadership roles. The main research objective is to analyze how female leadership brings distinctive qualities that can potentially enhance risk management strategies and long-term sustainability of Italian pharmaceutical companies. By examining these dynamics, the research will provide a comprehensive understanding of how leadership styles, combined with greater gender diversity, particularly female leadership, can influence critical strategic decisions at the highest levels of the corporate hierarchy, ultimately contributing to public healthcare safety and corporate resilience. While traditional leadership models have largely been developed within male-dominated corporate structures, recent research suggests that female leadership styles bring unique advantages in risk mitigation, decision-making, and long-term sustainability (Weaver-Pronk, 2023). According to Catalyst (2019), the pharmaceutical sector has been considered a nontraditional industry for women within the STEM fields. Many women have sought traditional industries for occupations, for example in nursing and teaching. In such careers, women are more likely to be considered equal to men in their achievement of degrees and in promotional opportunities. The fact that females are earning more undergraduate and graduate degrees than men should help women attain high-level leadership positions, but that is not the case within the pharmaceutical industry (Catalyst, 2019). During the 1980s and 1990s, the rapid expansion of the pharmaceutical industry led to a significant increase in female representation within sales roles, as companies required a larger sales force. However, this surge did not extend proportionately to higher managerial positions, as women still occupy less than one-fifth of senior management roles in the sector (Smith, 2008). Various theories have been proposed to explain the barriers preventing women from advancing in leadership positions (Aydogdu & Asikgil, 2011). These include concepts such as the glass ceiling, sticky floor, and labyrinth metaphors. While the first two suggest a one-dimensional obstruction, the labyrinth—described by Carli and Eagly (2016)—illustrates that although the path is complex, women can ultimately reach leadership positions, gaining clarity on their trajectory once they navigate through the challenges. The roles of men and women within organizations are deeply shaped by systemic gender inequality and cultural conditioning, which often hinder women's career progression. Established corporate policies and structures continue to favor men, enabling them to retain positions of power and authority (Harmon & Williams, 2020). As a result, women face significant structural obstacles that restrict upward mobility within organizations. One of the major factors contributing to this disparity is implicit bias, particularly in hiring and promotion practices. Research has shown that unstructured interviews, where

subjective judgment plays a significant role, tend to disadvantage women (Harmon & Williams, 2020). However, using structured and standardized interview processes—including blind evaluations and diverse interview panels—reduces bias and leads to increased hiring of women. Studies also suggest that limiting interview panels to a small group of diverse evaluators, implementing structured questioning, and immediately rating candidates post-interview can further minimize gender biases (Harmon & Williams, 2020). Beyond hiring practices, broader cultural and institutional factors contribute to the underrepresentation of women in leadership roles. Gender-based discrimination, lack of familiarity with dominant corporate cultures, and differences in professional socialization impact women's ability to advance in their careers (Carnes and Radojevich-Kelley, 2011). Workplace socialization processes differ for men and women, influencing leadership expectations and opportunities. Success in pharmaceutical leadership requires recognizing the distinct leadership approaches employed by men and women. Women are more likely to adopt transformational leadership styles, emphasizing collaboration, mentorship, and empowerment, whereas men often favor transactional leadership, which focuses on structured tasks, rewards, and authority-based decision-making (Carli & Eagly, 2016). Unless female leaders are well represented at all levels of the organization, transformational leadership remains underappreciated in favor of the more traditionally male-dominated transactional approach. In the STEM and pharmaceutical industries, this discrepancy presents an opportunity to raise awareness of the advantages of transformational leadership in fostering innovation and resilience. Despite diversity initiatives, organic and grassroots efforts to increase female representation at the executive level have not yielded significant results (Terjesen & Sealy, 2016). In response, some countries have implemented boardroom quotas to accelerate change. For instance, in 2002, Norway introduced a policy requiring that 40% of corporate board seats be occupied by women, a measure that significantly increased female representation (Terjesen & Sealy, 2016). Many other nations have followed suit, implementing similar mandates to foster gender diversity at the executive level. However, such policies remain a topic of debate due to concerns over meritocracy and corporate autonomy (Terjesen & Sealy, 2016). Despite progress in some areas, women continue to face difficulties in reaching executive roles within the pharmaceutical sector, highlighting the need for more effective career advancement strategies. The lack of female leadership at higher organizational levels strongly impacts business performance and strategic decision-making. Women play a crucial role as healthcare decision-makers within their families and offer valuable consumer insights, which can better inform corporate strategy and market positioning (Hewlett et al., 2013). This is particularly relevant for pharmaceutical companies, as research suggests that firms with higher female representation in executive leadership tend to achieve stronger financial performance (Hewlett et al., 2013; Taneja et al., 2012). Furthermore, the absence of female role models, mentors, and sponsors hinders the formation of supportive professional networks, which are essential for women's career progression (Hewlett et al., 2013). The structural and systemic barriers that hinder women's advancement to senior corporate positions lay the groundwork for exploring the theoretical foundations of leadership and its implications in the Italian pharmaceutical industry. This analysis aims to identify the most

effective leadership styles for navigating the sector's inherent risks and complexities while simultaneously fostering greater female representation in senior positions, thereby strengthening strategic decision-making and industry-specific risk management practices.

1.4. Theoretical framework of leadership for effective risk management in the pharma industry

The concept of leadership has been extensively explored in academic literature and is widely referenced by political experts, business executives, and scholars alike. Despite numerous theoretical frameworks introduced over the years, there remains no universal consensus on its definition. Leadership has often been interpreted as both a behavior and a process. For instance, Bowers and Seashore (1966) described leadership as "a beneficial organizational behavior exhibited by one member toward another within the same organizational structure." Tannenbaum and Massrick (1957) viewed leadership as a dynamic function, emphasizing its fluidity, where the role of leader could shift among individuals depending on the situation. Other scholars, such as Mescon (1958), highlighted the transformative nature of leadership, asserting that "true leadership transforms a group of individuals into a cohesive force capable of achieving collective goals, unattainable for an unstructured group." This perspective aligns with theories emphasizing the influence leaders wield in motivating subordinates to pursue shared objectives. Tannenbaum and Massrick (1957) also underscored leadership as "an interpersonal influence executed through communication to achieve specific goals." Bennis (1959) further argued that a leader's primary tool is the ability to inspire and influence others. Bass (1990) posited that leaders possess unique traits, such as sanctity and heroism, which set them apart as exemplars for followers. Conversely, Jago (1982) proposed a dual perspective, defining leadership as both a property and a process. According to Jago, leaders use noncoercive influence to align organizational members' activities toward achieving collective objectives, differentiating leadership from managerial roles that rely on authority or coercion. Understanding leadership theories provides a foundational framework for analyzing risk management practices in the pharmaceutical industry. Leadership plays a fundamental role in shaping risk management strategies within the pharmaceutical industry, influencing regulatory compliance, corporate governance, and crisis response mechanisms (Henderson, 2023). The complexity and high-stakes nature of this sector demand leaders who can adapt to evolving challenges while ensuring organizational resilience and sustainability. Over the years, various leadership theories have been developed to explain the dynamics of effective leadership. These theories provide a foundational understanding of how leadership styles and behaviors can impact organizational performance, particularly in industries with critical risk factors such as pharmaceuticals. By exploring these theories, we gain insights into the qualities and approaches that contribute to successful leadership in managing risks. In the pharmaceutical industry, the stakes are uniquely high due to factors such as stringent regulatory oversight, the complexity of global supply chains, and the direct impact on public health. Effective leadership in this sector requires not only the ability to mitigate operational and financial risks but also to foster innovation and maintain compliance with constantly evolving standards. This section will provide the

necessary theoretical framework to assess which leadership styles are best equipped to address the multifaceted risk landscape of the pharmaceutical industry.

In the 19th century, studies on leadership primarily centered around the inherent traits of individuals deemed to be natural leaders. Researchers sought to identify the specific personality traits and qualities that differentiated exceptional leaders from the rest. The foundational idea of the *Great Man theory* was that leadership abilities are innate and cannot be developed through training or experience (Benmira & Agboola, 2021). According to this perspective, only a select few individuals possess the extraordinary characteristics required to achieve leadership excellence, often viewed as a result of divine or natural design. This theory was deeply rooted in historical and philosophical contexts, where leaders were often perceived as extraordinary figures predestined to rise during times of need (Organ, 1996). Figures such as Napoleon Bonaparte and Abraham Lincoln were frequently cited as examples, embodying the belief that these individuals were naturally equipped with unparalleled vision, decisiveness, and charisma that set them apart from their contemporaries. While the Great Man theory provided an early framework for understanding leadership, it faced significant limitations. Critics argue that it neglects the impact of external factors such as social, economic, and cultural influences that shape leadership opportunities and effectiveness (Organ, 1996). Furthermore, it disregards the potential for leadership skills to be cultivated through education, experience, and deliberate practice. The Great Man theory, though largely outdated in contemporary leadership studies, offers insights into how visionary and decisive leadership can be instrumental in navigating crises and ensuring organizational resilience. Pharmaceutical executives who exhibit characteristics associated with the Great Man theory—such as decisiveness, confidence, and strategic foresight—often play pivotal roles in responding to industry challenges. Leaders with these traits have historically guided organizations through drug safety crises, regulatory scrutiny, and financial downturns, making critical decisions under pressure that impact both business sustainability and public health (Brusco et al., 2011). Moreover, in the context of pharmaceutical risk management, this leadership perspective underscores the importance of individuals who naturally excel in high-stakes environments. While modern leadership development emphasizes training and experience, there remains a need for leaders who instinctively rise to the occasion, particularly in moments of crisis such as product recalls, pandemic response, or regulatory interventions. Despite its shortcomings, the Great Man theory paved the way for subsequent leadership studies, influencing trait-based approaches that sought to systematically identify the characteristics associated with effective leadership (Organ, 1996).

The *Trait theory of leadership*, which evolved from the Great Man theory, posits that certain inherent characteristics distinguish leaders from non-leaders. This perspective suggests that individuals possess specific traits that predispose them to leadership roles (Benmira & Agboola, 2021). Research in this domain has primarily focused on identifying these distinguishing characteristics (Nanjundeswaraswamy et al., 2024).

Early studies in the 19th and early 20th centuries emphasized the identification of innate qualities that set leaders apart. Researchers sought to determine the specific traits that made individuals effective leaders, often focusing on personal attributes such as intelligence, assertiveness, and self-confidence. For instance, Stogdill's (1948) seminal work identified traits like alertness, insight, responsibility, initiative, persistence, self-confidence, and sociability as significant for effective leadership. Similarly, Mann (1959) highlighted factors such as intelligence, masculinity, adjustment, dominance, extraversion, and conservatism as pertinent to leadership effectiveness. As research progressed, scholars expanded the list of potential leadership traits, incorporating factors like endurance, stability, and vision (Nanjundeswaraswamy et al., 2024). However, this expansion led to challenges in reaching a consensus on a definitive set of leadership traits. The diversity of identified traits underscored the complexity of leadership and suggested that effective leadership characteristics might vary depending on context and position. This realization prompted a shift in focus from solely inherent traits to include behaviors and situational factors, leading to the development of behavioral and contingency theories of leadership. In the pharmaceutical industry, recognizing and developing specific traits can enhance leaders' ability to manage risks effectively, ensuring both organizational success and public safety. (Henderson, 2023). Leaders possessing traits such as intelligence, diligence, and vision are better equipped to navigate these challenges. For instance, a leader's self-confidence and sociability can foster a culture of open communication, essential for identifying and mitigating risks early. Moreover, traits like persistence and responsibility ensure that leaders remain committed to compliance and ethical standards, thereby safeguarding public health and the organization's reputation. While the Trait theory of leadership has significantly contributed to understanding leadership by identifying key characteristics, it also has limitations, particularly concerning the variability of effective traits across different contexts (Benmira & Agboola, 2021).

The *behavioral leadership theory* emerged in the mid-20th century as a departure from trait-based leadership theories, emphasizing that leadership is not an inherent quality but rather a set of behaviors that can be learned, developed, and refined (Bass, 1990; Stogdill, 1974). Unlike trait theories, which focus on innate characteristics, behavioral theories argue that leadership effectiveness is determined by actions rather than inherent personal attributes (Yukl, 2013; Benmira & Agboola, 2021). This approach underscores that anyone can develop leadership capabilities through structured training, experience, and reinforcement of specific leadership behaviors (Northouse, 2021). A foundational study in this area was conducted at Ohio State University in the 1940s, where researchers identified two primary dimensions of leadership behavior: consideration and initiating structure (Fleishman, 1953). Consideration refers to leaders who demonstrate empathy, foster open communication, and prioritize team well-being, while initiating structure describes leaders who focus on setting goals, defining roles, and maintaining efficiency in task execution (Fleishman, 1953; Stogdill, 1974). This two-dimensional framework laid the foundation for subsequent research in leadership effectiveness, particularly within high-stakes industries such as pharmaceuticals. Unlike trait-

based theories, behavioral leadership theory offers a practical approach by focusing on observable and learnable actions, which can be adapted to industry-specific risks within the pharmaceutical sector. For example, leaders who excel in consideration behaviors—demonstrating empathy, prioritizing communication, and ensuring team cohesion—are especially valuable in research and development settings (Spanu, 2024). These environments often involve cross-functional teams working under significant pressure to meet milestones or resolve complex scientific challenges. By fostering a culture of trust and collaboration, these leaders can enhance team dynamics, improve morale, and drive innovative problem-solving, which is critical for success in competitive pharmaceutical markets (Spanu, 2024). On the other hand, initiating structure behaviors, which emphasize setting clear goals, defining roles, and maintaining operational efficiency, are indispensable in managing the operational and regulatory complexities of pharmaceutical production. From ensuring compliance with Good Manufacturing Practices (GMP) to meeting stringent deadlines for clinical trials, these behaviors help establish a framework of accountability and precision. For instance, during the scale-up of a new drug, leaders who focus on structured processes can minimize errors and maintain the high-quality standards required to meet regulatory approval (Brusco et al., 2011). The practical relevance of behavioral leadership theory in the pharmaceutical sector is evident in its application to risk management. Effective leaders in pharma must navigate a range of risks, from regulatory non-compliance to supply chain disruptions, each requiring a tailored response (Brusco et al., 2011). Leaders who integrate consideration behaviors—such as promoting transparency and encouraging open reporting of potential issues—create an environment where risks can be identified and addressed proactively. At the same time, initiating structure behaviors ensure that risk management frameworks are well-defined and rigorously implemented, reducing the likelihood of oversight or process failures. A study by Amayreh (2020) highlights the positive influence of strategic leadership on ethical practices within pharmaceutical organizations, emphasizing the importance of clear communication and accountability in effective risk management. The adaptability of behavioral leadership theory also makes it particularly relevant for addressing crises, which are inevitable in the pharmaceutical industry. Whether dealing with product recalls, clinical trial setbacks, or sudden regulatory changes, leaders who can switch between collaborative and directive styles are better equipped to guide their teams through uncertainty. For example, a leader managing a product recall might initially adopt a directive approach to ensure rapid containment of the issue but later transition to a more collaborative style to rebuild team confidence and stakeholder trust. Holdford (2003) discusses how different leadership approaches can be applied effectively in various situations within the pharmaceutical sector, underscoring the need for flexibility in leadership styles. Furthermore, behavioral leadership theory aligns with the growing emphasis on ethical leadership in pharmaceuticals. Leaders who exhibit consistent, observable ethical behaviors, such as prioritizing patient safety and maintaining transparency with regulators, not only fulfill their professional responsibilities but also enhance the industry's credibility. This is particularly important in a sector where public trust is fragile, and ethical lapses can lead to severe reputational and financial consequences. An article in Pharmaceutical Executive (2023) emphasizes the

critical role of ethical leadership in maintaining public trust and navigating the complex ethical dilemmas inherent in the pharmaceutical industry (Henderson, 2023). In the end, behavioral leadership theory provides a foundation for understanding the impact of gender diversity in leadership roles within the pharmaceutical sector. Research suggests that female leaders are more likely to adopt transformational and participative leadership styles, which align with the consideration dimension of behavioral leadership (Carli & Eagly, 2016). These leadership approaches emphasize collaboration, ethical responsibility, and long-term vision—qualities that are particularly valuable in managing industry-specific risks such as supply chain vulnerabilities and patient safety concerns (Weaver-Pronk, 2023).

As leadership research evolved beyond behavioral theories, scholars recognized that leadership effectiveness is not solely dependent on a leader's inherent traits or learned behaviors, but also on the situational context in which leadership is exercised. This shift in perspective led to the emergence of *situational and contingency leadership theories* during the 1960s, which emphasized that no single leadership style is universally effective; instead, leadership effectiveness depends on the specific circumstances and the dynamic interplay between the leader, the followers, and the external environment (Benmira & Agboola, 2021). *Situational leadership theory* posits that effective leaders must adapt their leadership style based on the readiness, competence, and motivation of their subordinates (Vecchio, 1987). This model categorizes leadership behaviors into four main styles: directing (high directive, low supportive), coaching (high directive, high supportive), supporting (low directive, high supportive), and delegating (low directive, low supportive). Leaders must assess the capabilities and willingness of their team members and adjust their approach accordingly to maximize performance and engagement (Vecchio, 1987). Similarly, Fred Fiedler's *contingency model* introduced the idea that leadership effectiveness is determined by the match between a leader's fixed style and the specific situation in which they operate (Peters et al., 1985). Fiedler's model suggests that leaders cannot easily change their inherent style, so organizations should focus on placing leaders in environments that align with their leadership approach. This theory considers three key situational variables: leader-member relations (the degree of trust and confidence between leader and followers), task structure (the clarity and specificity of tasks), and leader position power (the authority and influence a leader holds within the organization) (Peters et al., 1985). Depending on the combination of these variables, either a task-oriented or relationship-oriented leadership style will be more effective.

Situational leadership theory provides a useful framework for navigating the complex and highly regulated environment of the pharmaceutical industry, where leadership must be flexible to address industry-specific challenges such as stringent compliance requirements, innovation-driven competition, and crisis management (Brusco et al., 2011), by allowing leaders to tailor their approach to the needs of their teams and the external pressures they face. For instance, in R&D settings, where innovation and collaboration are critical, a supporting or delegating leadership style is often more effective, as experienced scientists and

researchers require autonomy and intellectual freedom to drive discoveries (Holdford, 2003). However, during regulatory audits or quality assurance processes, a more directive leadership style may be necessary to ensure strict adherence to compliance protocols and minimize risks (Brusco et al., 2011). Additionally, situational leadership plays a crucial role in crisis management, such as responding to drug recalls, supply chain disruptions, or public health emergencies like the COVID-19 pandemic. In such high-stakes situations, leaders must swiftly assess the context and adopt an appropriate leadership style. A directive style may be required in the initial stages of a crisis to implement immediate corrective actions, followed by a more supportive and participative approach in the recovery phase to rebuild trust and morale among employees and stakeholders (Endress+Hauser, 2023). It is crucial to recognize that the growing presence of female leadership in the pharmaceutical industry aligns with the principles of situational leadership, as studies suggest that women leaders tend to exhibit higher adaptability and emotional intelligence, allowing them to adjust their leadership style based on situational demands (Weaver-Pronk, 2023). Female leaders are often more likely to employ coaching and supporting leadership styles, fostering collaboration, ethical decision-making, and long-term sustainability—elements that are particularly relevant in managing industry-specific risks and ensuring patient safety (Carli & Eagly, 2016). Situational leadership theory underscores the importance of adaptability in leadership, particularly in industries as dynamic and risk-sensitive as pharmaceuticals. By assessing the needs of their teams, the specific challenges at hand, and external regulatory pressures, leaders can effectively tailor their approach to maximize efficiency, innovation, and compliance. The integration of situational leadership principles with ethical leadership practices and gender-diverse leadership teams present an opportunity for pharmaceutical companies to enhance their resilience, strengthen risk management strategies, and drive sustainable growth in an increasingly volatile and competitive industry.

With the increasing complexity of modern organizations and the rapid pace of technological advancements, traditional leadership theories have evolved to accommodate more dynamic and adaptive models. The *New Leadership Era*, emerging in the 1990s and 2000s, marked a significant departure from earlier top-down leadership structures (Nelson, 2006). Scholars and practitioners recognized that leadership is not solely about authority or situational adaptability but also about fostering engagement, innovation, and long-term strategic vision (Benmira & Agboola, 2021). This shift led to the development of transactional and transformational leadership theories (Bass, 1990; Yukl, 2013), which have become particularly relevant in industries facing high levels of complexity and regulatory oversight, such as pharmaceuticals. *Transformational leadership* is centered around the idea that leaders inspire, motivate, and elevate their followers beyond immediate self-interest to achieve collective goals (Bass, 1990). This leadership style is particularly effective in environments requiring innovation, adaptability, and ethical decision-making—all critical aspects of pharmaceutical industry leadership. Unlike transactional leadership, which operates through structured reward and punishment systems, transformational leadership fosters a deeper connection between leaders

and their teams, emphasizing vision, ethical responsibility, and long-term strategic thinking (Benmira & Agboola, 2021). Transformational leaders are characterized by their ability to serve as role models, setting high ethical standards and creating a compelling vision that inspires employees. They encourage creativity, challenge existing assumptions, and cultivate a culture of innovation, which is essential in an industry where scientific breakthroughs and regulatory adaptation play a critical role (Aydogdu & Asikgil, 2011).

Within the pharmaceutical sector, transformational leadership has proven to be particularly effective in areas such as drug innovation, regulatory adaptation, and crisis management (Aydogdu & Asikgil, 2011). The rapid development and deployment of COVID-19 vaccines serve as a prime example of how transformational leaders guided pharmaceutical firms through an unprecedented global health crisis. These leaders were able to mobilize cross-functional teams, navigate evolving regulatory landscapes, and prioritize patient safety while ensuring business continuity (Aydogdu & Asikgil, 2011). Moreover, the emphasis on ethical leadership within the transformational framework aligns closely with the pharmaceutical industry's need to maintain public trust, a crucial asset in a field where regulatory failures can lead to severe reputational and financial damage (Henderson, 2023). In this context, research has shown that women in leadership positions are more likely to exhibit transformational leadership traits, particularly individualized consideration and ethical responsibility (Eagly & Johannesen-Schmidt, 2001; Carli & Eagly, 2016). In the pharmaceutical sector, this leadership style aligns with the need for:

- Long-term strategic vision, especially regarding corporate sustainability and patient-centered innovation.
- A collaborative leadership approach, which is essential for cross-functional research teams in R&D.
- A heightened awareness of ethical implications, crucial in decision-making for clinical trials, drug pricing, and public health (Weaver-Pronk, 2023).

Unlike transformational leadership, *transactional leadership* is based on structured reward and punishment systems to maintain order and efficiency within an organization (Bass, 1990). Unlike transformational leadership, which emphasizes long-term growth and employee empowerment, transactional leadership is based on structured task delegation, performance monitoring, and adherence to pre-established protocols (Avolio et al., 1999). The core premise of transactional leadership is that subordinates perform best when they are provided with well-defined responsibilities, clear objectives, and contingent rewards based on their level of performance (Avolio et al., 1999). Leaders establish explicit performance expectations and reward employees for meeting predefined objectives. These rewards may include monetary incentives, promotions, or public recognition. This form of leadership reinforces motivation by linking effort to tangible outcomes, creating a structured and predictable work environment (Sarros & Santora, 2001). Leaders proactively monitor performance and intervene when necessary to correct deviations from expected results. They establish strict quality control measures and performance tracking systems to minimize inefficiencies and

ensure adherence to company policies (Sarros & Santora, 2001). Given its structured and directive nature, transactional leadership is most effective in stable and highly regulated environments where compliance, consistency, and efficiency are essential for organizational success (Bass, 1990).

The pharmaceutical industry operates within one of the most highly regulated environments, where compliance with international standards, quality assurance, and operational efficiency are critical for success (Brusco et al., 2011). Given the complexity of drug development, clinical trials, regulatory approvals, and supply chain management, transactional leadership plays a vital role in ensuring that pharmaceutical companies meet legal, ethical, and industry-specific requirements while maintaining operational stability (Bass, 1990; Brusco et al., 2011). A key strength of transactional leadership in this sector lies in its emphasis on clear expectations, structured processes, and strict adherence to guidelines (Henderson, 2023). Regulatory frameworks such as Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), and Good Laboratory Practices (GLP) require stringent adherence to protocols, making task-oriented leadership styles particularly effective (Henderson, 2023). Leaders who employ transactional methods ensure that employees follow compliance procedures, document findings accurately, and meet regulatory milestones set by institutions such as the FDA (Food and Drug Administration), EMA (European Medicines Agency), and AIFA (Agenzia Italiana del Farmaco). However, despite its effectiveness in maintaining compliance, operational efficiency, and risk mitigation, transactional leadership alone is insufficient for ensuring long-term innovation and strategic growth. Given the increasing complexity of the pharmaceutical sector—where breakthrough therapies, digital transformation, and personalized medicine are reshaping the industry—companies cannot rely solely on rigid structures and compliance-driven leadership (Henderson, 2023; Endress+Hauser, 2023). This is where a hybrid approach, combining transactional and transformational leadership, becomes essential for pharmaceutical firms aiming to balance regulatory rigor with innovation-driven competitiveness (Jefferson Wells, 2023). The future of pharmaceutical leadership will likely involve an increased emphasis on dynamic leadership models, where structured oversight is balanced with visionary leadership, ensuring that companies not only meet industry standards but also pioneer groundbreaking advancements in global healthcare.

Given the complexity and high-risk nature of the pharmaceutical sector, selecting the appropriate leadership style is critical for ensuring regulatory compliance, operational efficiency, crisis management, and innovation-driven competitiveness (Aydogdu & Asikgil, 2011). While no single leadership model guarantees success in all circumstances, a hybrid and adaptive approach, drawing from multiple leadership theories, has been recognized as the most effective strategy for risk mitigation, decision-making, and long-term sustainability (Bass, 1990; Yukl, 2013). Pharmaceutical executives must navigate an intricate landscape that includes global regulatory frameworks, supply chain complexities, ethical considerations, and the increasing influence of digital transformation in healthcare (Henderson, 2023; Brusco et al., 2011). As a result, a

combination of leadership styles—strategic, transformational, visionary, bureaucratic, collaborative, and situational—has proven to be the most effective in managing risks in this industry (Parsity Group, 2023).

Strategic leadership plays a pivotal role in risk management by enabling pharmaceutical executives to anticipate, assess, and mitigate potential threats while aligning risk strategies with long-term industry objectives (Parsity Group, 2024). This leadership style is characterized by critical thinking, problem-solving, and proactive decision-making, ensuring that organizations remain competitive in a volatile market while maintaining regulatory compliance. Strategic leaders in the pharmaceutical sector develop robust risk management frameworks that integrate financial, operational, and regulatory considerations. For example, during the COVID-19 pandemic, pharmaceutical firms employing strategic leadership effectively navigated disruptions in supply chains, regulatory adjustments for expedited drug approvals, and public health demands while maintaining corporate integrity (Cavaliere et al., 2021).

Transformational leadership, as previously discussed, is particularly effective in environments that require adaptability and long-term vision. Given that the pharmaceutical industry operates under rapidly evolving scientific, technological, and regulatory landscapes, transformational leaders are instrumental in guiding organizations through change while maintaining ethical and risk-aware practices (Aydogdu & Asikgil, 2011; Bass, 1990). In the pharmaceutical sector, transformational leadership is particularly beneficial for risk management in research and development (R&D), where leaders must foster innovation while ensuring compliance with Good Clinical Practices (GCP) and Good Manufacturing Practices (GMP) (Aydogdu & Asikgil, 2011). By inspiring and motivating teams, transformational leaders ensure that quality control and risk prevention measures remain a priority without compromising scientific progress.

Visionary leadership is critical in preparing pharmaceutical firms for emerging risks by aligning organizational efforts with future industry trends. Visionary leaders anticipate technological disruptions, regulatory shifts, and potential crisis scenarios, ensuring that risk management strategies remain adaptive and forward-thinking (Parsity Group, 2024). For example, pharmaceutical firms that successfully integrated AI-driven predictive analytics into their risk management frameworks have demonstrated superior forecasting of supply chain vulnerabilities and regulatory compliance risks (Cavaliere et al., 2021; Endress+Hauser, 2023). Visionary leadership is essential in guiding teams through digital transformation, ensuring that risk assessment and mitigation frameworks evolve alongside technological advancements.

Bureaucratic leadership is particularly relevant in pharmaceutical risk management due to the highly regulated nature of the industry. Leaders operating under a bureaucratic framework emphasize strict adherence to legal and regulatory requirements, ensuring that processes in drug delivery, approval, manufacturing, and supply chain management comply with FDA, EMA, and AIFA regulations (Parsity

Group, 2024). Bureaucratic leadership fosters a structured, rules-based environment, reducing the likelihood of compliance failures, legal liabilities, and financial penalties. However, its rigid nature can hinder adaptability and responsiveness to unexpected crises. To mitigate this limitation, bureaucratic leadership must be integrated with transformational elements, ensuring that efficiency and compliance do not stifle innovation or ethical considerations (Aydogdu & Asikgil, 2011).

Given the multi-disciplinary nature of pharmaceutical risk management, *collaborative leadership* has become increasingly relevant. Leaders who promote cross-functional teamwork and interdepartmental collaboration create an environment where risk identification and mitigation efforts are more comprehensive (Parsity Group, 2024). For instance, successful risk management strategies in pharmaceutical firms often involve integrated risk assessment teams, composed of experts in regulatory affairs, quality assurance, legal compliance, and financial risk management (Cavaliere et al., 2021). Collaborative leaders ensure that these teams work cohesively, fostering information-sharing and proactive problem-solving. Moreover, research suggests that female leaders excel in collaborative leadership roles, as they are more likely to facilitate knowledge exchange, encourage team cohesion, and prioritize transparency in risk-related decision-making (Carli & Eagly, 2016).

Situational leadership, as previously discussed, is one of the most effective leadership models in risk management, as it emphasizes flexibility, adaptability, and agility (Hersey et al., 1979). Given that different risk scenarios require different leadership approaches, situational leaders excel in modifying their leadership style based on evolving challenges (Parsity Group, 2024). For example, in a regulatory audit scenario, a pharmaceutical executive may adopt a bureaucratic leadership approach, ensuring strict compliance with documentation and procedural requirements. However, in an R&D innovation context, the same leader may shift to a transformational leadership style, inspiring creative problem-solving while maintaining quality control (Aydogdu & Asikgil, 2011). The adaptability inherent in situational leadership ensures that pharmaceutical firms are equipped to manage both predictable risks and unforeseen crises, such as supply chain disruptions or drug recalls (Henderson, 2023).

Effective risk management in the pharmaceutical industry requires a multifaceted leadership approach, as no single leadership style can comprehensively address the industry's regulatory, operational, and innovation-related risks (Henderson, 2023). The integration of strategic, transformational, visionary, bureaucratic, collaborative, and situational leadership models allow pharmaceutical executives to balance compliance with adaptability, efficiency with innovation, and risk mitigation with long-term sustainability (Parsity Group, 2024). In addition, despite the recognized need for diverse leadership approaches, women remain underrepresented in senior leadership positions within the pharmaceutical sector (McKinsey & Company, 2023). While women constitute a significant portion of the healthcare workforce, their representation diminishes at higher organizational levels. For instance, according to a 2023 report by McKinsey &

Company, although women hold 75% of entry-level roles and 70% of managerial positions, their presence drops to 32% at the C-suite level. This decline is even more pronounced for women of color, who represent 26% of entry-level positions but only 4% of C-suite roles. This disparity highlights the importance of examining the unique contributions of female leadership to risk management and organizational success. The following section will provide an extensive literature review on female leadership, exploring its defining characteristics, the challenges faced by women in leadership positions, and the characteristics, impact, and differences between male and female leadership styles on organizational outcomes. This analysis will lay the groundwork for understanding how female leadership can influence risk management practices in the Italian pharmaceutical industry.

1.5. Leadership and gender: distinctive characteristics of female leaders for pharma risk management

Leadership is a fundamental driver of organizational success, yet female representation in senior corporate positions remains disproportionately low despite the increasing participation of women in the workforce (Carli & Eagly, 2016). Studies have explored whether women's leadership styles differ from men's, whether these styles are more or less effective, and whether perceptions of leadership effectiveness are fact-based or socially constructed (Eagly & Johannesen-Schmidt, 2001; Gardiner & Tiggemann, 1999; Burke & Collins, 2001). According to Appelbaum et al. (2003), female leadership has historically been hindered by structural barriers, gender biases, and societal expectations that favored traditional male leadership models. However, contemporary research suggests that women's leadership styles—characterized by consensus-building, collaboration, and transformational leadership—are particularly suited for modern, team-based corporate environments (Burke & Collins, 2001). This section will examine:

- The differences between male and female leadership styles.
- The effectiveness of female leadership in corporate settings.
- The barriers that still hinder women's advancement to senior leadership roles.
- The relevance of these insights to the pharmaceutical industry, particularly in Italy.

The study of leadership has long been shaped by theories that attempt to explain the differences (or lack thereof) between male and female leadership styles (Burke & Collins, 2001). While early research tended to assume male leadership superiority, more recent studies have challenged this notion, arguing that leadership effectiveness is not inherently gendered but rather shaped by structural, cultural, and attitudinal factors. According to Appelbaum et al. (2003), the debate on gender and leadership can be categorized into four key theoretical schools of thought, each offering a different lens through which leadership differences (or similarities) are analyzed:

- Biological theories
- Gender role theories
- Causal factor theories
- Attitudinal theories

Each of these perspectives plays a role in shaping corporate expectations, hiring biases, and leadership development programs, particularly in industries like pharmaceuticals, where regulatory complexity and innovation-driven strategies require adaptive leadership styles (Henderson, 2023).

The biological approach suggests that leadership ability is inherently tied to sex differences, meaning that men are naturally predisposed to leadership roles due to biological and evolutionary advantages (Appelbaum et al., 2003). For a long time, leadership was thought to be an inherently male trait, something biologically ingrained and naturally suited to men. This belief, rooted in traditional theories of leadership, suggested that men were predisposed to leadership roles due to their evolutionary history—being hunters, warriors, and decision-makers in hierarchical societies (Appelbaum et al., 2003). As a result, leadership studies historically focused on male subjects, reinforcing the idea that effective leadership required qualities like assertiveness, competitiveness, and dominance—traits often associated with men (Donnel & Hall, 1980; Dobbins & Platz, 1986). However, as research evolved, this perspective started to lose ground. Studies began to show that the assumption of male superiority in leadership was not backed by solid evidence (Kolb, 1999). While some research has identified differences in leadership styles between men and women (Helgesen, 1990; Hennig & Jardim, 1977; Rosner, 1990), the broader scientific consensus indicates that men and women are equally capable leaders when given the same opportunities and resources (Shimanoff & Jenkins, 1991). In other words, leadership is not a biological trait, but rather a skill shaped by experience, social roles, and organizational culture. This shift in thinking led researchers to explore leadership through a different lens, focusing less on biology and more on the impact of social expectations and gender roles. For example, Kolb (1999) and Shimanoff & Jenkins (1991) found that the leadership behaviors of men and women are far more similar than different, and that both genders are equally effective in leadership roles. Similarly, Powell (1993) and Oakley (2000) highlighted that there are no significant innate differences in leadership abilities between male and female managers. Despite these findings, stereotypes persist that portray women as less capable leaders than men (Appelbaum et al., 2003).

As research on leadership moved beyond biological determinism, scholars began to focus on gender role theories, which argue that leadership styles and effectiveness are shaped more by societal expectations and learned behaviors than by inherent biological differences (Eagly & Karau, 2002). This perspective suggests that leadership is not dictated by sex, but rather by the adoption of traits and behaviors that society traditionally associates with either men or women (Kent & Moss, 1994). For decades, masculine leadership traits—such as assertiveness, decisiveness, and competitiveness—were regarded as essential for executive success, while feminine traits—such as empathy, collaboration, and consensus-building—were often undervalued (Appelbaum et al., 2003). However, research on gender and leadership suggests that a balanced combination of both masculine and feminine leadership traits leads to higher perceived leadership

effectiveness (Kolb, 1997; Appelbaum et al., 2003). Androgynous leadership is characterized by (Appelbaum et al., 2003):

- A balance between directive and participatory leadership styles—leaders are both decisive and inclusive in their decision-making.
- A combination of strategic thinking and interpersonal engagement, enabling leaders to navigate complex challenges while fostering collaboration.
- The ability to adapt to different contexts, demonstrating assertiveness when needed while also prioritizing ethical considerations and team dynamics.

Despite the growing recognition of androgynous leadership as an ideal model, women continue to face systemic barriers in reaching executive positions. One of the most well-documented challenges is the "double bind" dilemma, where women are often forced to navigate contradictory expectations (Oakley, 2000; Jamieson, 1995). If a woman embraces a more traditionally "feminine" leadership style, prioritizing collaboration and emotional intelligence, she may be perceived as too soft or ineffective for executive roles. If she adopts a more "masculine" approach, demonstrating assertiveness and authority, she risks being labeled as too aggressive or unfeminine, leading to potential backlash from colleagues and subordinates (Jamieson, 1995). This paradox significantly impacts promotion and leadership selection processes, as the same leadership behaviors tend to be evaluated more favorably when exhibited by men rather than women, thereby contributing to the underrepresentation of women in senior corporate positions (Kolb, 1997).

While gender role theories have provided a strong framework for understanding leadership, additional factors such as *attitude*, *self-confidence*, *experience*, and *corporate environment* play a crucial role in shaping leadership emergence (Kolb, 1999). These elements often act as barriers or enablers for women pursuing executive roles, particularly in industries like pharmaceuticals, where leadership decisions directly impact regulatory compliance, innovation, and risk management (Henderson, 2023). Research suggests that attitude toward leadership is a stronger predictor of leader emergence than masculinity itself (Kolb, 1999). However, women may face disadvantages due to gendered socialization, which often encourages them to adopt more submissive or conciliatory behaviors that may be perceived as lacking leadership potential (Claes, 1999; Lipsey et al., 1990). This is compounded by the "second-class" perception, which stems from traditional expectations that women should prioritize communal and supportive roles rather than assertive leadership (Kolb, 1997). Additionally, self-confidence plays a crucial role in leadership emergence. Studies indicate that higher self-confidence significantly improves a leader's perceived effectiveness, yet many women internalize societal messages that undermine their confidence in pursuing leadership roles (Jackson, 1989; Kirchmeyer, 1998). This is particularly evident in promotion and selection processes, where women may be less likely to self-nominate for leadership positions, reinforcing their underrepresentation in executive roles. Experience is another critical factor influencing leadership emergence. While both experience and masculinity are correlated with leadership success, research suggests that experience is a

more significant predictor (Kolb, 1997). This finding underscores the need for structured leadership development programs that ensure women have equal access to career advancement opportunities (Cassirer & Reskin, 2000). However, the challenge remains that women often receive fewer high-visibility assignments or strategic responsibilities, limiting their ability to accumulate the same leadership experience as their male counterparts (Cassirer & Reskin, 2000). Beyond individual traits and experience, the corporate environment itself plays a fundamental role in shaping leadership outcomes. Women often encounter male-dominated corporate cultures that reward traditionally masculine leadership styles, making it more difficult for women to be recognized as competent leaders (Wicks & Bradshaw, 1999). Key challenges include (Appelbaum et al., 2003):

- The persistence of gender stereotypes, where assertive women are viewed as aggressive, while men displaying the same traits are seen as strong leaders.
- The "old boys' network", which continues to limit access to informal mentorship and promotion opportunities for women (Oakley, 2000).
- Workplace structures designed to favor men, including rigid career paths that do not accommodate work-life balance, often disproportionately impacting women (Jamieson, 1995).

Despite increasing awareness, these systemic barriers remain deeply embedded in corporate structures, slowing progress toward gender parity in leadership. However, research suggests that companies that proactively address these biases by fostering inclusive cultures and implementing transparent promotion processes can significantly improve female representation in executive roles (Cassirer & Reskin, 2000).

Over the past few decades, leadership studies have observed a shift in the perception of what constitutes effective leadership. Traditional masculine leadership models, characterized by authority, competition, and transactional management, have long dominated corporate environments. However, contemporary research suggests that feminine leadership values—such as collaboration, inclusivity, and emotional intelligence—are increasingly recognized as key drivers of organizational success (Claes, 1999). Studies have consistently shown that women tend to excel in transformational leadership, a style that prioritizes (Bass, 1990; Avolio et al., 1999; Burke & Collins, 2001):

- Consideration for employees and stakeholders, fostering a work culture that values diverse perspectives.
- Participative decision-making, ensuring that leadership is inclusive and adaptive.
- A people-oriented approach, emphasizing employee engagement and team cohesion (Hare et al., 1997).

According to Claes (1999), new values—often referred to as feminine values—have emerged in the business world, contrasting with the traditional masculine management style, which is typically characterized by competitiveness and authority. These emerging principles emphasize collaborative relationships and promote a more inclusive approach to communication, leadership, negotiation, organization, and control.

Increasingly, companies recognize that this shift in leadership dynamics is a key factor in achieving business success. Various studies have analyzed the differences between male and female leadership approaches, highlighting how each tends to adopt distinct management and decision-making styles (Appelbaum et al., 2003). The following are some of the key characteristics attributed to each (Appelbaum et al., 2003):

Male	*Female*
Structure	Consideration
Transactional	Transformational
Autocratic	Participative
Instruction-giving	Socio-expressive
Business-oriented	People-oriented

Modern perspectives on leadership increasingly define a feminine leadership style as distinct from its masculine counterpart. Some scholars, such as Helgesen (1990), argue that certain feminine traits provide women with a leadership advantage. These qualities include strong communication skills, particularly the ability to listen attentively and demonstrate empathy; advanced negotiation and conflict resolution abilities; well-developed interpersonal competencies; and a more diplomatic approach to managing teams (Stanford et al., 1995). Furthermore, extensive research supports this view, suggesting that "feminine leadership attributes" align more closely with transformational leadership, while "masculine traits" are typically associated with transactional leadership (Hare et al., 1997). Kabacoff (1998) found that women tend to receive higher ratings in terms of empathy, demonstrating a strong awareness of people's needs and forming close, supportive relationships. They also excel in communication, as they are more likely to clearly articulate expectations, express ideas effectively, and ensure smooth information flow compared to men. Additionally, women score higher in interpersonal skills, displaying greater sensitivity, approachability, active listening abilities, and the capacity to build strong professional relationships with colleagues and supervisors (Appelbaum et al., 2003). However, women are not necessarily perceived as more extroverted, socially outgoing, or inclined toward informal leadership styles. Interestingly, contrary to conventional assumptions, women often score higher on leadership metrics related to productivity, demonstrating a strong drive for achievement, high expectations for both themselves and others, and a strong focus on results (Appelbaum et al., 2003). In contrast, men tend to be rated higher in strategic planning and long-term organizational vision, while women excel in people-oriented leadership, and men in business-oriented leadership (Appelbaum et al., 2003). Overall, supervisors view men and women as equally effective leaders, though peer and direct assessments often rate women slightly higher (Claes, 1999; Kabacoff, 1998). These findings challenge outdated perceptions that women are inherently less suited for leadership roles. While gender biases persist, research suggests that female managers must navigate a delicate balance in how they present their leadership style (Appelbaum et al., 2003). As Kirchmeyer (1998) points out, if women are widely perceived as lacking the attributes necessary for executive roles, openly displaying traditionally feminine leadership traits may reinforce misconceptions of incompetence in the eyes of decision-makers (Appelbaum et al., 2003). Addressing this challenge requires rethinking leadership evaluation criteria to

focus on effectiveness rather than conformity to traditional masculine or feminine norms. Feminist leadership theories adopt different approaches, ranging from advocating for equal treatment and opportunities (*Liberal theory*) to recognizing and valuing gender differences (*Radical theory*) and analyzing how society constructs gender roles (*Social Constructionist and Post-Structuralist Feminist theory*) (Ozdenerol et al., 2023). Each perspective provides a distinct viewpoint on how women can thrive in leadership positions and overcome gender-related obstacles. *Liberal feminism* is based on the idea that men and women share the same fundamental abilities, and therefore, gender differences should not act as a barrier to leadership or professional advancement (Ozdenerol et al., 2023). Women aim for self-improvement and they are equally capable of excelling in various fields, including business and politics. This perspective encourages challenging societal biases and dismantling prejudices that may limit women's access to leadership roles. Liberal feminists advocate for equal opportunities, emphasizing that women can succeed in leadership by demonstrating the same professional competencies and decision-making skills as men (Ozdenerol et al., 2023). Radical feminism argues that men and women are equal but inherently different, and rather than conforming to traditional male leadership styles, women should embrace their unique leadership strengths (Ozdenerol et al., 2023). Feminine traits—such as emotional intelligence, collaboration, and a focus on consensus-building—should be seen as assets rather than limitations in leadership (Rinehart & Lorber, 2002). Radical feminists highlight that leadership can be enriched by integrating both masculine and feminine qualities, creating a balanced and diverse leadership style that benefits organizations (Ozdenerol et al., 2023). This perspective challenges traditional leadership norms by promoting a reevaluation of leadership effectiveness, emphasizing the importance of feminine leadership attributes in achieving strategic and ethical outcomes (Ozdenerol et al., 2023). Unlike the previous theories, which either strive for equality or recognize gender-based leadership strengths, the *Social Constructionist and Post-Structuralist Feminist theory* examines how society shapes perceptions of leadership. According to this perspective, masculine leadership traits are not inherently superior but have been historically favored due to societal biases (Jogulu & Wood, 2006). Leadership qualities associated with men—such as assertiveness and decisiveness—are often perceived as more desirable, while those linked to women—such as empathy and collaboration—are undervalued (Rinehart & Lorber, 2002). This theory encourages deconstructing leadership stereotypes and reshaping corporate culture to ensure that leadership effectiveness is measured by performance and strategic impact, rather than gendered expectations (Ozdenerol et al., 2023). Women in leadership can play a crucial role in challenging these norms and reshaping perceptions by breaking down stereotypes and promoting leadership diversity within organizations (Ozdenerol et al., 2023). According to 2023 Deloitte statistics, in biotechnology and pharmaceutical companies, women constitute nearly half (46.4%) of the workforce. Despite this, only 8% of these organizations are led by women, according to an analysis of approximately 200 companies. In the medical technology sector, women make up about 40% of the workforce but hold only 23% of executive positions among the world's 100 largest medical device companies. Currently, six of these companies are headed by women, an increase of one from 2021.

Leadership roles in the broader healthcare field are also predominantly occupied by men. In 2021, 15.3% of health system CEOs were women, and 15.8% of health plans were led by women. In contrast, approximately 90% of chief nursing officers and more than 70% of human resources executives in health systems are women (Deloitte, 2023). In Italy, the pharmaceutical industry has a higher percentage of female employees than many other industrial sectors. Women constitute approximately 44% of the workforce, and this figure rises to 53% in research and development (R&D), one of the most strategic areas in pharma (Farmindustria, 2023). However, despite this strong presence in technical and scientific roles, less than a quarter of senior leadership positions are held by women, and only a handful of major pharmaceutical firms in Italy have female CEOs or Board Presidents (Farmindustria, 2023). These statistics highlight an underrepresentation of women in leadership positions within the pharmaceutical and broader healthcare industries, despite their substantial presence in the workforce. This disparity aligns with the classic definition of the glass ceiling, which refers to artificial barriers, rooted in corporate biases and structural limitations, that prevent women from advancing into top management roles (Purcell et al., 2010). Unlike general workplace discrimination, which affects women at all levels, the glass ceiling specifically refers to gender-based disparities that become more pronounced at higher levels of an organization's hierarchy (Elliott & Smith, 2004). Scholarly research has identified several factors that contribute to maintaining the glass ceiling in corporate settings. Cotter et al. (2001) proposed four defining characteristics of the glass ceiling, which distinguish it from general workplace gender disparities:

1. The inequality cannot be attributed to job-relevant differences such as skills, education, experience, or performance.
2. It becomes more pronounced at higher organizational levels, meaning that gender disparities in promotion and earnings grow as one advances in their career.
3. It creates systemic barriers to upward mobility, specifically in terms of managerial attainment and executive decision-making positions.
4. The disadvantage compounds over time, meaning that gender-based discrepancies in promotions accumulate and persist across different career stages.

Empirical research confirms that these conditions hold true in corporate settings, and the pharmaceutical industry is no exception (Deloitte, 2023). Studies show that while entry-level and mid-level positions tend to be relatively gender-balanced, the presence of women diminishes dramatically at senior levels, reinforcing the idea that a systemic filtering mechanism is at play rather than individual career choices (Maume, 2004). Purcell et al. (2010) extensively outlines the six main determinants of the glass ceiling effect as:

1. Opting out
2. Cultural capital and homophily
3. Networking
4. Gendering and gender stereotypes
5. Discrimination and segregation

6. Characteristics of organizations

One of the most pervasive explanations for gender disparities in leadership is the assumption that women voluntarily "*opt out*" of career advancement due to personal preferences, family responsibilities, or a lack of ambition (Purcell et al., 2010). However, research challenges this narrative by demonstrating that many women are actually "forced out" rather than choosing to leave the workforce (Stone, 2007). Strong ideologies of caregiving place disproportionate expectations on women to invest in child-rearing and elder care. Societal norms dictate that women should prioritize their families over career ambitions, leading many to reduce their working hours or exit the labor market entirely. The result is a self-reinforcing cycle: fewer women in the workforce means fewer women in the pipeline for executive roles, thereby perpetuating gender disparities at higher levels (Purcell et al., 2010). Even when women attempt to balance work and family, they encounter unsupportive workplace policies that make long-term career growth difficult. For instance, "family-friendly" policies often come with significant career penalties, as employers may view female employees who utilize them as less committed to their roles (Stone, 2007). Additionally, many women receive only symbolic support from their partners in balancing work and family life, while men continue to prioritize their own career progression. Thus, the notion that women simply "opt out" is misleading. Instead, workplace structures, cultural expectations, and unequal domestic responsibilities work together to push women out of the career advancement pipeline before they ever reach the glass ceiling.

Cultural capital and homophily—the tendency of people to associate with those who share similar backgrounds and experiences—are significant yet often invisible barriers that contribute to the persistence of the glass ceiling (Purcell et al., 2010). According to Bourdieu's (2001) theory of cultural capital, the ability to navigate professional networks, demonstrate social competence, and acquire symbolic credentials are key determinants of career advancement. Research shows that men, particularly those in leadership positions, tend to mentor and sponsor individuals who resemble them in terms of social background, professional experience, and cultural identity (Purcell et al., 2010). This process, known as homosocial reproduction (Kanter, 1977), results in male executives disproportionately selecting male successors, reinforcing the gender imbalance at the top levels of organizations. In certain industries, firm-related cultural capital plays a critical role in advancement (Kay & Hagan, 1995). For example, being publicly recognized by a professional organization, having access to prestigious social networks, or demonstrating "executive presence" can significantly impact career prospects. However, these forms of capital often favor men, as they are more likely to have access to the elite circles where such credentials are valued. Women, by contrast, are required to overperform to gain the same level of recognition and must often demonstrate exceptional cultural and professional competence to break into exclusive networks (Purcell et al., 2010).

Closely related to homophily, *networking* is another major determinant of the glass ceiling, as career advancement is often dependent on informal relationships rather than formal qualifications (Purcell et al.,

2010). Workplace networks provide access to mentorship, sponsorship, information sharing, and career opportunities, yet they remain largely male-dominated (Ibarra, 1997). Among Wall Street professionals, research shows that male colleagues frequently engage in networking activities such as after-work drinks, golf outings, or corporate retreats—opportunities where high-stakes career decisions are often made (Roth, 2004a). Women, on the other hand, are often excluded from these networks due to gender norms that dictate what is considered "appropriate" social interaction between male and female colleagues. Even when women do gain access to these networks, they often find that they receive less informal help than men (Purcell et al., 2010). While men in leadership roles actively mentor junior male employees, women are less likely to benefit from such sponsorship. This disadvantage compounds over time, leading to fewer women in leadership pipelines and widening the gender gap at the executive level.

Gender stereotypes play a crucial role in shaping how men and women are perceived in the workplace. Organizations are inherently gendered institutions where values, qualifications, and leadership traits are defined in a way that privileges masculinity (Acker, 1990; Ridgeway, 1997). Men are typically associated with traits such as assertiveness, decisiveness, and strategic thinking, which are seen as essential for leadership. Women, on the other hand, are often perceived as empathetic, nurturing, and risk-averse, leading to doubts about their ability to handle high-pressure executive roles (Erickson et al., 2000). This results in a double standard in performance evaluations: women must outperform men to receive the same level of recognition (Botelho & Abraham, 2017). Additionally, men who have children are often seen as more committed to their careers, while women with children are assumed to be less dedicated to their jobs (Kay & Hagan, 1998). The cumulative effect of these biases is that women are held to stricter standards and are often overlooked for promotions due to perceptions of their leadership potential rather than their actual performance.

Discrimination and workplace segregation further reinforce the glass ceiling (Purcell et al., 2010). Research shows that women's earnings and promotion rates suffer in gender-segregated industries and workplaces (Cotter et al., 2003). In many organizations, women are systematically funneled into lower-revenue roles or positions with limited career advancement opportunities (Cotter et al., 2003). For instance, in finance, women are often assigned to client accounts that generate less revenue, while men are given high-profile deals that lead to faster career progression (Roth, 2004a). This segregation results in wage disparities, as even women who reach senior management positions earn less than their male counterparts (Cotter et al., 2003). Moreover, when women are excluded from high-status leadership roles, it increases the gender wage gap across all levels of an organization (Cohen & Huffman, 2007).

The *structure of organizations* plays a crucial role in sustaining the glass ceiling. Recruitment methods, promotion pathways, and company policies all influence occupational mobility (Reskin & McBrier, 2000).

Informal hiring practices, such as network-based referrals, tend to favor men, while open recruitment methods, such as job postings, help reduce gender bias (Purcell et al., 2010). Additionally, organizational changes like mergers and restructuring often disproportionately harm female managers, as they tend to hold lower-status jobs that are more vulnerable to layoffs (Haveman et al., 2009). Even when women are promoted, they are often placed in less powerful leadership roles, limiting their ability to drive change (Purcell et al., 2010). Research suggests that gender diversity initiatives are most effective when they target structural inequalities within organizations rather than focusing solely on individual career development programs (Kalev et al., 2006). Addressing these barriers requires comprehensive reforms, including transparent promotion criteria, formalized mentorship programs, and corporate policies that actively dismantle gender-based disparities. Without systemic change, leadership opportunities will continue to be disproportionately concentrated in the hands of men, limiting both gender equality and corporate innovation (Purcell et al., 2010).

Despite the growing interest in leadership theories across industries, the pharmaceutical sector remains underexplored in academic literature when it comes to gender-based leadership dynamics (Henderson, 2023). The absence of research on gendered leadership dynamics in this sector represents a significant gap, given the industry's unique and highly complex environment, including stringent regulatory requirements, high-stakes risk management, and the demand for continuous innovation (Henderson, 2023; Brusco et al., 2011). While female leadership in healthcare management and corporate governance has received some scholarly attention (Henderson, 2023; Aydogdu & Asikgil, 2011), there is a significant gap in research analyzing how female leaders contribute to risk management and long-term sustainability in pharmaceutical firms. However, as previously established in the theoretical framework of this study, certain leadership styles are particularly effective for managing risk in the pharmaceutical sector—namely, strategic, transformational, visionary, bureaucratic, collaborative, and situational leadership (Parsity Group, 2023; Aydogdu & Asikgil, 2011). The objective of this analysis is to bridge this research gap by demonstrating that female leaders are more likely than male leaders to embody these leadership styles, making them better equipped to manage risk, ensure compliance, and foster sustainable growth in pharmaceutical companies.

The pharmaceutical industry is an innovation-driven sector that requires leaders capable of managing uncertainty, fostering collaboration, and maintaining ethical standards while driving long-term growth (Henderson, 2023; Brusco et al., 2011). Strategic leadership, which focuses on long-term planning, adaptability, and sustainable decision-making, has been identified as a key leadership style for pharmaceutical executives (Parsity Group, 2023). Research suggests that female leaders are more likely than male leaders to adopt long-term strategic approaches, prioritizing corporate stability, regulatory compliance, and stakeholder trust over short-term financial gains (Carli & Eagly, 2016; Adams-Harmon & Greer-Williams, 2020).

The pharmaceutical industry thrives on innovation, requiring leaders who can anticipate trends, embrace technological advancements, and navigate uncertain regulatory landscapes (Parsity Group, 2023; Henderson, 2023). Visionary leadership is essential for identifying emerging risks and opportunities, ensuring that companies remain resilient and competitive in a rapidly evolving market (Bennis, 1959; Brusco et al., 2011). Evidence suggests that female executives demonstrate stronger visionary leadership than their male counterparts, particularly in their ability to:

- Foster innovation while maintaining corporate responsibility, preventing unethical research practices and compliance breaches (Hewlett, Marshall, & Sherbin, 2013).
- Promote interdisciplinary collaboration (Eagly & Carli, 2007), crucial for risk mitigation in complex pharmaceutical R&D projects (Brusco et al., 2011).
- Implement forward-looking risk assessment models, ensuring that companies adapt to evolving regulations while maintaining sustainable growth (Teodósio et al., 2021).

Given that corporate sustainability in the pharmaceutical sector depends on balancing innovation with compliance and patient safety (Brusco et al., 2011), transformational leadership's emphasis on long-term strategic thinking and ethical responsibility is critical (Jamieson, 1995; Henderson, 2023). Studies on leadership styles suggest that transformational leadership—a model characterized by vision, inspiration, intellectual stimulation, and individualized consideration—is particularly effective in industries that demand high adaptability and strategic foresight (Bass, 1990; Avolio et al., 1999; Aydogdu & Asikgil, 2011), such as the pharmaceutical industry. Research indicates that women exhibit transformational leadership qualities more frequently than their male counterparts (Eagly et al., 2003; Kabacoff, 1998; Burke & Collins, 2001), making them particularly well-suited to leadership roles in dynamic and highly regulated environments such as pharmaceuticals (Aydogdu & Asikgil, 2011). Transformational female leaders in the pharmaceutical industry may enhance risk management through:

- Consensus-building and participatory decision-making, reducing the likelihood of regulatory breaches (Eagly & Johannesen-Schmidt, 2001).
- Ethical leadership practices, preventing compliance failures, financial fraud, and reputational risks (Brusco et al., 2011).
- Greater transparency in corporate governance, reinforcing trust among regulatory bodies and investors (Deloitte, 2023; Dhankhar et al., 2018).

Transformational leadership has already proven successful in leading pharmaceutical companies through crises such as drug recalls, supply chain failures, and regulatory investigations (Aydogdu & Asikgil, 2011). Given that female executives display transformational leadership behaviors more frequently than men (Eagly & Carli, 2003), their contributions to risk mitigation strategies should be further analyzed and promoted within pharmaceutical firms. However, the evaluation of transformational leadership is not gender-neutral, as research suggests that the same behaviors can be perceived differently depending on whether they are exhibited by male or female leaders (Stempel et al., 2015). A study by Mohr and Wolfram (2008) found that

while male leaders demonstrating verbal consideration were associated with reduced strain among employees, the same effect was not observed for female leaders. Similarly, Wolfram and Mohr (2010) demonstrated that transformational leadership was positively correlated with job satisfaction only when performed by male leaders. These findings suggest that there is a systematic bias in how leadership behaviors are perceived, potentially disadvantaging female leaders despite their effectiveness (Stempel et al., 2015). This phenomenon is linked to deep-rooted gender stereotypes. According to Heilman and Haynes (2005), men tend to receive greater recognition for their performance compared to women, even when their contributions are identical. In the context of transformational leadership, this means that female leaders may not receive the same level of acknowledgment as their male counterparts because behaviors such as collaboration, empathy, and consensus-building are socially expected from women and therefore do not appear as "exceptional" when exhibited by them (Heilman & Chen, 2005). Conversely, when men display these traits, they stand out as extraordinary leaders, reinforcing a gendered perception of leadership effectiveness (Stempel et al., 2015). Historically, leadership roles have been predominantly occupied by men, leading to a strong association between effective leadership traits and traditionally masculine attributes (Schein, 1975, 2001; Schein et al., 1996). This bias, often referred to as the "think manager, think male" phenomenon, has been consistently observed across various cultural contexts, including the United States, the United Kingdom, Germany, China, and Japan (Schein, 2001). Other meta-analyses conducted over time, such as those by Koenig et al. (2011) and Ryan et al. (2011), confirm that leadership qualities continue to be predominantly linked to male characteristics. The role congruity theory (Eagly & Karau, 2002) provides insight into this persistent bias, suggesting that leadership expectations align more closely with traditionally male traits than with female traits. The central premise of role congruity theory is that various social roles exhibit differing levels of alignment, with some being more congruent than others. In the context of gender and leadership, extensive research has demonstrated that leadership roles traditionally align more closely with male gender roles than with female ones (Embry et al., 2008; García-Retamero & López-Zafra, 2006; Willemsen, 2002). This is largely because the attributes commonly associated with effective leadership—such as assertiveness, decisiveness, and strategic thinking—are the same agentic traits typically attributed to men. When there is congruence between the role expectations of a leader and those of the male gender, observers' preconceptions are reinforced, solidifying gender role stereotypes (Hart et al., 2009). Conversely, since leadership expectations do not naturally align with traditional female gender roles—which emphasize communal characteristics such as empathy, collaboration, and nurturing—women tend to be perceived as less naturally suited for leadership. This incongruence results in female leaders receiving lower evaluations for identical leadership behaviors compared to their male counterparts (Eagly & Carli, 2003). This misalignment creates additional challenges for women in leadership, as they are often perceived as less suited for executive roles simply because their qualities do not conform to long-established male-oriented leadership norms (Stempel et al., 2015). Despite these entrenched perceptions, leadership models have evolved over time. The demands of modern organizations have led to a shift in leadership expectations, with

greater emphasis on adaptability, collaboration, and long-term strategic vision. Within this context, transformational leadership—part of the full range leadership theory (Bass, 1999)—has gained prominence as an effective leadership style. A comprehensive meta-analysis by Eagly et al. (2003) found that female leaders tend to employ transformational leadership strategies, as well as contingent reward systems, more frequently than their male counterparts: women receive higher ratings in key transformational leadership dimensions, including charisma, idealized influence, inspirational motivation, intellectual stimulation, and individualized consideration. Several of these dimensions—particularly individualized consideration, intellectual stimulation, and idealized influence—reflect communal qualities such as fostering employee well-being, encouraging participation, and emphasizing shared goals (Eagly et al., 2003). Interestingly, idealized influence and charisma are less directly tied to either communal or agentic attributes, as they largely pertain to the leader's ability to inspire and the way they are perceived by others. Even though women were rated higher on inspirational motivation (Eagly et al., 2003), this dimension contains more agentic elements, as it focuses on goal-setting and performance orientation (Vinkenburg et al., 2011). Conversely, research on gender differences in leadership styles has highlighted that male leaders are more inclined to adopt management by exception and laissez-faire approaches, which are generally associated with a less engaged and more reactive leadership style (Stempel et al., 2015). A meta-analysis by Eagly, Johannesen-Schmidt, and van Engen (2003), which examined 45 studies on transformational, transactional, and laissez-faire leadership, found that male leaders tend to exhibit management by exception (both active and passive) more frequently than female leaders. They also demonstrate a greater tendency toward laissez-faire leadership, which is characterized by a hands-off approach, minimal intervention, and limited proactive engagement with subordinates. This leadership style often implies a reduced level of direct involvement in daily management and decision-making processes, instead intervening only when performance deviations become significant. On the other hand, female leaders tend to focus more on inspiring, motivating, and actively recognizing the achievements of their subordinates, in contrast to the more reactive, intervention-based approach observed in male leaders (Eagly et al., 2003; Stempel et al., 2015). The laissez-faire style is often linked to a disengaged leadership approach that may lead to lower employee motivation and organizational commitment. The quality of leadership fundamentally shapes the culture and strategic direction of an organization (Yukl, 2013). Transformational leadership extends beyond traditional transactional management by fostering a shared vision and motivating employees to transcend basic contractual obligations in favor of long-term organizational advancement (Bass, 1999). Unlike transactional leadership, which primarily focuses on short-term incentives and performance monitoring, transformational leaders instill a sense of belonging and pride in employees, inspiring them to proactively contribute to corporate objectives and innovation-driven goals (Sikhounchanh & Nijjar, 2024). One of the critical advantages of transformational leadership is its ability to enhance employee well-being—that includes job satisfaction, stress management, mindfulness, trust, performance, and engagement. Research indicates that transformational leaders, through their ability to cultivate a positive work culture, play a significant role in

fostering resilience among employees (Sikhounchanh & Nijjar, 2024). Resilience, defined as the capacity to recover from challenges and sustain productivity under pressure, is particularly crucial in the pharmaceutical industry, where long working hours, regulatory scrutiny, and high-stakes decision-making contribute to elevated stress levels (Sikhounchanh & Nijjar, 2024). Recent studies underscore the link between resilience, burnout, and workplace performance (Weiss et al., 2023). A 2023 study on the pharmaceutical sector revealed that employees with higher resilience demonstrated superior job performance and lower burnout rates, both of which are key determinants of long-term organizational success (Weiss et al., 2023). Burnout—characterized by emotional exhaustion, disengagement, and reduced professional efficacy—not only leads to employee turnover but also compromises the quality of decision-making, increasing the likelihood of costly regulatory breaches and compliance failures (Weiss et al., 2023). Transformational leadership mitigates these risks by fostering a culture of engagement, adaptability, and psychological safety, ensuring that employees remain motivated despite workplace challenges (Sikhounchanh & Nijjar, 2024). Gender differences in leadership styles also extend to *decision-making approaches*, which play a crucial role in corporate governance, particularly in risk management and strategic planning (Blais & Weber, 2001). Research suggests that women are more likely than men to incorporate social support and relational considerations into their decision-making processes (Blais & Weber, 2001). Studies indicate that, under stressful conditions, female leaders tend to seek advice from peers who have faced similar situations, whereas their male counterparts are more inclined to rely on authoritative sources or credentials when making high-stakes decisions (Matuszek, Nelson, & Quick, 1995; Frisch & O'Brien, 1990). This female relational approach aligns with collaborative and participatory leadership models, which are increasingly recognized as effective in managing complex risks within pharmaceutical companies (Parsity Group, 2023). Women also demonstrate a heightened ability to perceive and interpret emotions—both their own and those of their colleagues—when making decisions (Brody & Hall, 1993). This capacity for emotional intelligence allows female leaders to recognize potential conflicts, anticipate employee concerns, and facilitate consensus-driven decision-making processes, all of which contribute to stronger organizational cohesion and more effective risk mitigation (Blais & Weber, 2001). While there is a stereotype that women are inherently more attuned to emotions than men, empirical evidence suggests that this ability translates into a preference for affect-based processing, particularly in leadership settings where interpersonal dynamics play a critical role (Brody & Hall, 1993). However, it is important to acknowledge that gendered decision-making styles do not always yield uniform outcomes. While some studies indicate that women are more prone to affect-driven decision-making, findings on impulse-based behaviors remain mixed (Dittmar, Beattie, & Friese, 1996). In corporate environments, particularly in high-stakes industries like pharmaceuticals, objectivity and analytical reasoning are essential for ensuring sound strategic decision-making (Brusco et al., 2011). Some research suggests that, contrary to common assumptions, women may actually be more inclined than men to use structured, objective decision-making frameworks (Frisch & O'Brien, 1990; Blais & Weber, 2001). This contradicts traditional notions that men are inherently more rational in leadership roles while women rely on

emotional intuition (Blais & Weber, 2001). A study conducted by Epstein et al. (1996) examined differences in intuitive-experiential and analytical-rational thinking styles and found no significant gender-based disparities in either domain. This indicates that both men and women can effectively employ analytical reasoning when making executive decisions. These findings hold important implications for leadership effectiveness in pharmaceutical risk management. As regulatory pressures and market volatility continue to shape the industry, pharmaceutical firms require leaders who can balance analytical rigor with adaptive, relational leadership approaches (Henderson, 2023; Aydogdu, S., & Asikgil, B., 2011). Female executives—who often emphasize team collaboration, stakeholder engagement, and consensus-driven governance—may be particularly well-positioned to implement multi-dimensional risk assessment models that integrate both quantitative analysis and human-centered considerations (Burke & Collins, 2001). An essential factor in understanding gender differences in leadership effectiveness within pharmaceutical risk management lies in the variations in risk perception and risk-taking behavior between male and female leaders. Research consistently demonstrates that women tend to perceive risks as higher than men do, particularly in domains involving financial, health, and safety risks (Powell & Ansic, 1997; Schubert et al., 1999). This heightened risk awareness and aversion to excessive risk-taking has important implications for corporate governance, compliance, and strategic decision-making, particularly in industries like pharmaceuticals, where regulatory risks, patient safety, and ethical considerations are paramount (Henderson, 2023). Women are generally more cautious and deliberate in assessing risks, a tendency that has been widely documented in financial decision-making (e.g., investment and gambling), where female investors exhibit lower risk tolerance than their male counterparts (Powell & Ansic, 1997). The same pattern extends to corporate leadership, where female executives have been found to prioritize long-term stability, regulatory adherence, and ethical considerations over high-risk, short-term profit-seeking strategies (Blais & Weber, 2001; Burke & Collins, 2001). Beyond financial risks, health and safety risks also demonstrate clear gender-based differences. Flynn, Slovic, and Mertz (1994) conducted a national survey analyzing perceptions of environmental hazards and workplace health risks, finding that women consistently perceived these risks to be greater than men did. This suggests that female leaders may be more attuned to potential compliance pitfalls, ethical dilemmas, and reputational threats, which is particularly critical in pharmaceutical risk management, where regulatory breaches can have severe financial and legal repercussions (Brusco et al., 2011; Henderson, 2023). A crucial finding in behavioral risk research is that women's heightened risk perception does not simply reflect caution—it actively translates into safer, more responsible behaviors (Hersch, 1996). In an analysis of over 18,000 individuals, Hersch (1996) found that women consistently exhibited more prudent health and safety habits than men, including lower rates of smoking, better adherence to hygiene protocols, and higher levels of compliance with safety regulations. This pattern remained consistent even after controlling for factors such as education, marital status, and personal income, reinforcing the notion that gender differences in leadership extend beyond cultural conditioning and are reflected in concrete behavioral outcomes (Blais & Weber, 2001). From a corporate leadership perspective, this insight is particularly relevant in the pharmaceutical

sector, where risk mitigation is essential for regulatory compliance, clinical trial oversight, and patient safety. Female executives—who inherently exhibit more cautious, calculated approaches to risk management—may be better positioned to anticipate regulatory challenges, prevent compliance violations, and foster a safety-first corporate culture (Burke & Collins, 2001). In addition, research indicates that women generally exhibit a higher level of environmental concern and pro-environmental behaviors compared to men (Li et al., 2022; Zhao et al., 2021). For instance, a study in China found that females reported a higher level of environmentalism, including greater concern for environmental problems and stronger intentions to engage in sustainable practices (Li et al., 2022). Women, on average, demonstrate higher levels of altruism and a greater concern for future generations, which in turn makes them more receptive to sustainability initiatives (Leonidou & Leonidou, 2011; Cholette et al., 2013). Moreover, behavioral studies have found that women are more likely to incorporate ethical considerations into their purchasing decisions, supporting brands that prioritize environmental responsibility and social impact (Mohai, 1997; McCright & Sundström, 2013). Research suggests that pro-environmental behaviors are often associated with femininity, while traditionally masculine traits—such as competitiveness and ambition—are less aligned with sustainability efforts (Brough et al., 2016; Swim et al., 2020). Consequently, men tend to exhibit a more passive approach to sustainability, often requiring external incentives—such as financial benefits or regulatory compliance—to actively participate in environmental initiatives (Nanggong & Bandu, 2018; Swim et al., 2020). The pharmaceutical industry, given its reliance on complex supply chains and energy-intensive production processes, faces unique sustainability challenges (De Soete et al., 2017). While firms have increasingly adopted green initiatives—such as reducing carbon emissions and optimizing waste management—there remains a critical need to integrate sustainability into corporate decision-making at a strategic level (De Soete et al., 2017). In this context, female leadership can play a transformative role. Research has shown that firms with greater gender diversity in leadership positions demonstrate stronger environmental performance and corporate social responsibility practices (Zelezny et al., 2000; Vainio & Paloniemi, 2014). Furthermore, studies on gender differences in environmental psychology suggest that women are more likely than men to view sustainability as a moral and ethical imperative rather than merely a regulatory obligation (Stern, 2000; Frantz & Mayer, 2009; Alibeli & White, 2011). The purpose of this research is to analyze the impact of female leadership on risk management in the Italian pharmaceutical sector. To establish a strong theoretical foundation, we have conducted a literature review on leadership theories, gender differences in leadership styles, decision-making approaches, risk perception, and sustainability-oriented corporate governance. This body of research provides compelling evidence that female leadership possesses distinctive attributes that are particularly relevant for managing risk in highly regulated and high-stakes industries like pharmaceuticals. The pharmaceutical industry operates within a complex risk landscape, where regulatory oversight, corporate governance, financial stability, and ethical considerations play a critical role in ensuring long-term corporate sustainability (De Soete et al., 2017). Given these challenges, the leadership style adopted at the executive level significantly influences how risks are perceived, mitigated, and managed (Aydogdu, S., &

Asikgil, B., 2011). Our literature review suggests that female leadership, compared to male leadership, offers a unique set of characteristics that align with the needs of effective risk management in the pharmaceutical industry. The literature consistently highlights that women tend to adopt transformational leadership behaviors more frequently than men (Eagly et al., 2003; Kabacoff, 1998; Burke & Collins, 2001). Another defining trait of female leadership is a participatory, relational, and consensus-driven approach to decision-making (Eagly & Johannesen-Schmidt, 2001; Blais & Weber, 2001). This is particularly relevant in pharmaceutical risk management, where corporate decisions must balance financial, regulatory, and ethical considerations while incorporating diverse stakeholder perspectives (Dhankhar et al., 2018; Aydogdu & Asikgil, 2011). Female leaders are more likely to seek input from diverse teams and stakeholders before making strategic decisions, ensuring a well-rounded, risk-conscious approach (Frisch & O'Brien, 1990). Research shows that women leaders demonstrate higher levels of emotional intelligence, which enables them to navigate complex corporate environments, anticipate resistance to change, and foster cohesive teams (Brody & Hall, 1993). In pharmaceutical risk management, where collaboration between regulatory agencies, investors, and healthcare providers is crucial (Aydogdu, S., & Asikgil, B., 2011), female leadership's inclusive decision-making style may enhance corporate resilience, regulatory compliance, and long-term sustainability. The literature consistently finds that women leaders demonstrate higher risk awareness and lower tolerance for excessive risk-taking, particularly in industries that involve financial, health, and safety risks (Powell & Ansic, 1997; Schubert et al., 1999; Blais & Weber, 2001). Women perceive financial and compliance risks more acutely than men, leading to a more prudent and proactive approach to risk mitigation (Schubert et al., 1999; Blais & Weber, 2001). Female executives are more likely to integrate regulatory risk assessment into corporate decision-making, reducing exposure to legal penalties, compliance failures, and reputational crises (Burke & Collins, 2001). Unlike high-risk, short-term profit-seeking strategies often favored by male leaders, female executives tend to prioritize long-term stability, regulatory adherence, and ethical business practices (Burke & Collins, 2001). These characteristics reinforce the importance of female leadership in ensuring risk-conscious corporate governance, particularly in an industry where regulatory breaches and product safety failures can have severe financial, legal, and ethical repercussions (Henderson, 2023; Aydogdu & Asikgil, 2011; Brusco et al., 2011). In addition, female leaders are recognized as strong advocates for corporate sustainability, ESG policies, and long-term stakeholder value (Li et al., 2022; Paolone et al., 2024). Given the resource-intensive nature of pharmaceutical production, the complexity of global supply chains, and the strict environmental regulations governing the industry, integrating sustainability into corporate strategy is essential for mitigating long-term risks (De Soete et al., 2017). Female leadership can play a crucial role, as women are more likely to prioritize environmental responsibility, social impact, and ethical governance, reinforcing corporate resilience and long-term sustainability (Swim et al., 2020; Paolone et al., 2024). Additionally, female leaders take a proactive stance on environmental and ethical risk mitigation, embedding environmental concerns into corporate policies to anticipate regulatory changes and reduce exposure to compliance-related risks (Zhao et

al., 2021; Paolone et al., 2024). Their emphasis on long-term environmental planning minimizes the likelihood of reputational damage and strengthens firms' standing in an increasingly ESG-conscious market (Paolone et al., 2024). Beyond their direct contributions to sustainable governance, women in leadership positions also enhance firms' reputations (Bear et al., 2010; Brammer et al., 2009). Their presence on boards contributes to greater diversity of thought, broader perspectives, and improved strategic oversight (Daily & Dalton, 1994; Hillman et al., 2001). Female directors are noted for their wisdom and diligence, attributes that contribute to greater board independence and stronger corporate governance structures (Huse & Solberg, 2006; Fondas, 2000). Research further suggests that women directors can shift firms' strategic direction, fostering long-term ESG commitments (Selby, 2000). The impact of female leadership on corporate performance extends beyond qualitative governance improvements. Empirical evidence suggests that gender diversity at the board level can enhance financial performance and corporate sustainability outcomes (Garcia-Meca et al., 2015). Recent research has increasingly focused on the role of women on boards in shaping ESG strategies, with findings indicating that greater gender diversity improves decision-making quality and governance effectiveness (Khan et al., 2019; Nguyen et al., 2020). Boards with a higher representation of women benefit from diverse approaches, improved deliberation, and stronger oversight functions (Adams & Ferreira, 2009; Huse & Solberg, 2006). Furthermore, women board members play a critical role in fostering transparent communication and maintaining strong relationships with stakeholders (Liu et al., 2014). Their ability to mediate conflicts, facilitate dialogue, and promote accountability strengthens ESG reporting and enhances corporate sustainability performance. In line with theoretical perspectives, higher female representation on boards has been associated with a reduction in stakeholder conflicts, leading to more responsible corporate reporting and improved sustainability performance (Nicolò et al., 2021; Zampone et al., 2024). The presence of women in executive and board positions is expected to positively influence ESG performance, with empirical research suggesting that board gender diversity is a key determinant of a firm's ESG score and overall sustainability strategy (Paolone et al., 2024). While much of the existing research has examined gender diversity in global and European contexts (Paolone et al., 2024), the specific impact of female leadership on ESG outcomes in Italian pharmaceutical firms remains underexplored (Henderson, 2023). The literature reviewed theoretically demonstrates that female leadership may be uniquely positioned to enhance risk management strategies in the pharmaceutical industry through:

- *Transformational leadership*, which fosters ethical governance, long-term strategic thinking, and crisis adaptability.
- *Participatory decision-making*, which ensures well-informed, consensus-driven strategies that align with stakeholder interests.
- *Risk-averse and compliance-focused approach*, which reduces financial volatility, regulatory violations, and reputational threats.
- *Sustainability-driven corporate leadership*, which integrates ESG considerations into pharmaceutical governance, enhancing long-term industry resilience.

This conclusion synthesizes the key characteristics of female leadership, emphasizing their relevance to pharmaceutical risk management and providing a theoretical framework that justifies the empirical investigation of female leadership as a determinant of corporate risk outcomes in the Italian pharmaceutical sector.

Having established the theoretical foundation of female leadership and its relevance to corporate governance and decision-making, the next step in our research is to transition from leadership theory to a structured analysis of the pharmaceutical industry's risk environment. The pharmaceutical sector operates within an exceptionally complex landscape, where decision-making is shaped by a combination of regulatory constraints, financial pressures, operational challenges, and reputational considerations (Sikhounchanh & Nijjar, 2024). To fully understand how female leadership influences corporate outcomes in this industry, it is first necessary to define the broader risk dynamics that pharmaceutical firms face. The ability to effectively manage risk is one of the most critical aspects of corporate strategy in this sector, as it determines regulatory compliance, financial stability, patient safety, and long-term corporate resilience (Brusco et al., 2011). Without a clear framework for understanding risk, it is impossible to accurately assess the extent to which different leadership styles contribute to more effective risk mitigation. In the next chapter, we will conduct a detailed examination of risk in the pharmaceutical sector, defining its nature and distinguishing its various forms. We will analyze the different types of risks that pharmaceutical firms must address, including regulatory risks, financial risks, operational risks, and reputational risks, exploring their causes, implications, and strategic significance. In addition, we will investigate how pharmaceutical companies develop risk management frameworks, identifying the strategies used to mitigate uncertainty, ensure compliance, and maintain corporate stability in an environment characterized by high levels of volatility and regulatory oversight. Beyond establishing a general understanding of risk management in the pharmaceutical sector, we will then focus on the relationship between leadership and risk governance, specifically examining how different leadership styles influence corporate approaches to risk mitigation. We will assess the extent to which female leadership differs from male leadership in risk management, identifying the advantages, disadvantages, and key differences in how executives approach risk-related decision-making. This study is aimed at understanding whether female executives, given their greater risk awareness, long-term strategic orientation, and emphasis on compliance, contribute to a more structured, ethical, and sustainable risk management model compared to their male counterparts. To bridge the gap between theoretical and empirical analysis, we will also identify the key measurable variables that define risk management effectiveness, allowing us to construct a systematic framework for evaluating how leadership impacts corporate risk governance. This will involve defining the core elements that constitute risk management performance, as well as determining how these variables can be quantified in an empirical setting. By doing so, we will establish a foundation for testing whether female-led pharmaceutical firms demonstrate superior risk management outcomes compared to those led by male executives.

Chapter 2 - Risk management in the Italian pharmaceutical industry

2.1. What is risk in the pharmaceutical industry

The concept of risk has been extensively explored across various scientific and technological disciplines (Aven, 2010). However, despite its widespread application, there is no universally accepted framework or commonly agreed-upon definition of its fundamental principles within the field of risk assessment (Covello & Mumpower, 1985; Flato, 1977; Outreville, 1998). Scholars have pointed out that risk-related studies often lack a unified theoretical foundation capable of providing a consistent interpretation across different sectors (Haimes, 2009; Jo & Na, 2012). While risk assessment has demonstrated considerable success in areas such as environmental and ecological analysis, industrial and workplace safety, financial and investment evaluation, as well as security and defense, there remains a noticeable absence of a standardized definition that is universally recognized, even among experts in the field (Andretta, 2013; Artzner et al., 1999). Moreover, the term "risk" is frequently debated within the risk management community, yet there is little consensus on its precise definition (Outreville, 1998; Aven, 2010; Andretta, 2013). A significant gap in the literature is not only the lack of agreement on what constitutes risk (Andretta, 2013), but also the absence of a dedicated framework specifically addressing its definition and applications in the pharmaceutical sector. Establishing a clear definition of risk within the pharmaceutical industry represents a main research objective of this thesis, as it is essential to understand how pharma companies identify, manage and mitigate the increasingly complex industry-specific risks, such as the sector's reliance on complex global supply chains, extensive R&D investments, and strict regulatory oversight (Simonetti, 2020; Dhankhar et al., 2018). Given the complexity and variability of risk, scholars and regulatory bodies have proposed multiple definitions to conceptualize its nature. Some typical definitions of risk are provided by the scientific literature (Aven, 2010; Artzner et al., 1999):

1. Risk is a measure of the probability and severity of adverse effects (Flato, 1977)
2. Risk is the combination of probability of an event and its consequences (Artzner et al., 1999)
3. Risk is equal to the triplet (s_i, p_i, c_i), where s_i is the *i*th scenario, p_i is the probability of that scenario, and c_i is the consequence of the *i*th scenario, $i = 1, 2, \ldots, N$ (Kaplan & Garrick, 1981)

Despite the differences in how risk is defined, a common element across all definitions is that risk consists of three key components: initiating events (A), consequences (C), and associated probabilities (P) (Aven, 2010). Uncertainty is represented through probability, while the severity of a risk is determined by the extent of its consequences. This framework is often formalized as (Aven, 2010):

$$Risk = (A, C, P)$$

where:

- *A (Initiating events)* refers to specific occurrences that set a risk scenario in motion (Aven, 2010). In the pharmaceutical industry, this could include a disruption in the supply chain of active pharmaceutical ingredients (APIs), contamination during drug manufacturing, or unexpected adverse reactions observed in clinical trials (Brusco et al., 2011).

- *C (Consequences)* represents the outcomes of the initiating events (Aven, 2010). For example, a delay in API delivery could lead to production shortages, contamination in manufacturing might result in large-scale product recalls, and adverse drug reactions could lead to regulatory restrictions, financial losses, or harm to patients (Brusco et al., 2011).
- *P (Probability)* quantifies the likelihood of each event occurring (Aven, 2010). However, the interpretation of probability in risk assessment is not straightforward and can follow two main approaches:
    1. The probability is interpreted as a relative frequency, by defining it as the proportion of times an event would occur if the situation were hypothetically repeated an infinite number of times (Artzner et al., 1999).
    2. The probability is interpreted according to Bayesian (subjective) perspective, by treating it as measure of uncertainty based on the available background knowledge of an assessor. Unlike the frequency-based view, which relies on observed data, the Bayesian approach considers expert judgment, prior information, and evolving industry conditions to assess risk (Aven, 2010).

Risk, at its core, is often associated with *uncertainty*, particularly regarding the outcomes of actions and events (Tversky & Fox, 1995; Knight, 1921). Despite the multitude of interpretations across various disciplines, a unifying theme is that risk refers to uncertainty concerning the occurrence and severity of potential adverse effects (Aven, 2010; Artzner et al., 1999). While earlier definitions emphasized risk as the combination of probability and consequences (Flato, 1977; Artzner et al., 1999), more recent conceptualizations have introduced the multi-dimensional nature of risk, considering both the magnitude of its impact and the degree of uncertainty surrounding it (Aven, 2017; Levinson et al., 2011).
Several definitions found in the scientific literature highlight the different ways in which risk can be perceived (Aven, 2010; Knight, 1921; Haimes, 2009; Covello & Mumpower, 1985):

- Risk refers to *the uncertainty of the outcome of actions and events* (Knight, 1921). This definition aligns with the probabilistic interpretation of risk, emphasizing that risk is inherently tied to unpredictability.
- Risk is *a situation or event where something of human value is at stake, and the outcome remains uncertain* (Rosa, 1998). This interpretation broadens the scope beyond mere probability and consequences, integrating the societal and ethical implications of risk (Rosa, 2003), particularly relevant in the pharmaceutical industry, where patient safety is paramount.
- Risk is an *uncertain consequence of an event or an activity with respect to something that humans value* (Aven, 2010)
- Risk is equal to the *two-dimensional combination of events/consequences and associated uncertainties* (Artzner et al., 1999)

The theoretical conceptualization of risk, as previously discussed, establishes that risk is fundamentally tied to uncertainty and the potential for adverse consequences, making it a crucial aspect of decision-making across numerous domains (Aven, 2010; Artzner et al., 1999; Knight, 1921). The probability-based models proposed by frequentist interpretations, which define risk as an objective function of likelihood and severity (Kaplan & Garrick, 1981), have long provided a structured framework for risk quantification. However, such traditional approaches often fail to fully capture the complexities of dynamic and highly uncertain environments, particularly in the pharmaceutical sector, where risks arise not only from scientific and technological unpredictability but also from systemic vulnerabilities linked to supply chain dependencies, operational disruptions, financial volatility, and regulatory pressures (Mittal et al., 2008; Moktadir et al., 2018; Truong Quang & Hara, 2019). The COVID-19 pandemic has further underscored the industry's exposure to multidimensional risks, as pharmaceutical firms struggled to navigate raw material shortages, transportation bottlenecks, fluctuating demand for essential medicines, and unprecedented R&D acceleration pressures (Dadhich & Gurbani, 2021). The pharmaceutical industry is one of the largest global investors in research and development (R&D), allocating billions of dollars annually toward the discovery, testing, and commercialization of new therapeutic agents (Schuhmacher et al., 2021). While this extensive commitment to scientific advancement has driven substantial medical progress, it is also accompanied by an exceptionally high level of risk, permeating every stage of the pharmaceutical value chain (Dadhich & Gurbani, 2021). This reality has been starkly illustrated in recent years, as seen in cases such as Vertex Pharmaceuticals, whose stock value plunged by 20% following safety concerns in a Phase 2 trial for its alpha-1 antitrypsin deficiency treatment, and Eli Lilly, which suffered a 10% drop in market capitalization after releasing inconclusive Phase 3 trial results for donanemab, an experimental Alzheimer's therapy (Schuhmacher et al., 2021). These examples highlight how risk in the pharmaceutical industry is not merely confined to clinical outcomes but also extends to investor sentiment, regulatory interpretation, and competitive positioning. These risks, if not properly managed, do not merely affect individual companies but can have far-reaching consequences for global healthcare systems, impacting the availability of life-saving treatments and compromising public health outcomes (Schuhmacher et al., 2021; Rimin et al., 2021). Given the multifaceted and interdependent nature of risks in the pharmaceutical industry, a systematic approach to risk identification and mitigation is essential for ensuring supply chain resilience, financial stability, regulatory compliance, and the sustainability of R&D investments (Brusco et al., 2011; Urushihara et al., 2014). The complexity of risk assessment in this sector is heightened by *interdependencies among various risk categories*, where disruptions in one domain can create cascading effects across the entire value chain (Sharma et al., 2023). For instance, regulatory delays can lead to financial instability, which in turn affects R&D funding allocation, while supply chain disruptions can impact clinical trial timelines, delaying market entry and eroding investor confidence (Moktadir et al., 2018; Dadhich & Gurbani, 2021). In this context, the causality and prominence of specific risk factors must be systematically evaluated to enable pharmaceutical firms to implement targeted risk mitigation strategies. Addressing this need, scientific research has

emphasized the importance of identifying primary risks and sub-risks that, if mitigated, would inherently reduce the impact of other dependent risks (Schuhmacher et al., 2021). In order to identify the most critical risks in the pharmaceutical industry and establish a categorization that allows us to distinguish those that are most relevant and manageable directly by leadership, it is necessary to review the scientific literature on risks in the pharmaceutical sector. These risks are broadly categorized into *supplier risks*, *operational risks*, *financial risks*, *market risks*, *logistical risks*, *political risks*, and *technology-related risks* (Cowan, 2015; Sharma et al., 2023). Kumar et al. (2018) applied the fuzzy-AHP technique to systematically prioritize the risks and sub-risks in the pharmaceutical industry. Their study identified *cold chain technology* as the most critical risk, highlighting the industry's heavy reliance on controlled storage and transportation for pharmaceutical products (Sharma et al., 2023). Within cold chain technology, *infrastructure failure* was determined to be the most critical sub-risk, emphasizing the vulnerability of temperature-sensitive medications to logistical disruptions. Additional key risks identified in their research included supply risks, operational risks, *environmental risks*, financial risks, *government and organizational risks*, and *product recovery risks*. Similarly, Silva et al. (2020) utilized the Orders-of-Magnitude AHP technique to identify and prioritize risks from multiple industry stakeholders' perspectives, including pharmaceutical manufacturers, distributors, and buyers. Their study revealed that *R&D incapability* was the most critical risk within the industry, reflecting the substantial financial and technological risks associated with pharmaceutical innovation. Additionally, *quality issues* and *poor inventory management* ranked as the second and third most important risks, respectively, demonstrating the importance of maintaining strict quality control measures and efficient supply chain operations (Sharma et al., 2023). Moktadir et al. (2018) classified pharmaceutical risks into four primary categories, each containing four sub-risks. Their study determined that *supply risks* were the most significant, followed by organizational risks, financial risks, and demand risks. Among the sub-risks, *machine*, *equipment*, or *facility failure* was found to be the most critical, illustrating the operational vulnerabilities in pharmaceutical production facilities. Jaberidoost et al. (2013) conducted a comprehensive review of pharmaceutical industry risks and ranked supplier risks as the most pressing concern. This was followed by organization and strategy risks, financial risks, logistical risks, and market-related risks. In a subsequent study, Jaberidoost et al. (2015) expanded their risk categorization into seven key areas, applying the AHP technique to rank them. Their results emphasized that financial and economic risks were the most critical, followed by political and government-related risks, which can significantly impact pharmaceutical companies through regulatory changes, pricing controls, and trade restrictions. From the literature review, the primary risks affecting the pharmaceutical industry can be classified into the following seven categories (Sharma et al., 2023):

1. **Supplier risks**: Disruptions in raw material availability, API (Active Pharmaceutical Ingredient) shortages, dependency on international suppliers, and price volatility.

2. **Operational risks**: Equipment malfunctions, workforce inefficiencies, quality control failures, and regulatory compliance challenges.

3. **Financial risks**: Fluctuations in R&D investment returns, unstable market valuations, capital constraints, and high costs of drug development.

4. **Demand/market risks**: Changes in consumer behavior, drug patent expirations, market competition from generics, and healthcare policy shifts.

5. **Logistical risks**: Supply chain vulnerabilities, transportation delays, and inefficiencies in inventory management.

6. **Political and regulatory risks**: Policy uncertainty, changing drug approval processes, government interventions in drug pricing, and geopolitical factors affecting global operations.

7. **Technology-related risks**: Cybersecurity threats, failures in digital health infrastructure, challenges in AI-driven drug discovery, and integration issues with emerging pharmaceutical technologies.

Among the various risk categories, *supplier risks* are particularly critical due to the pharmaceutical industry's heavy reliance on raw materials, APIs (Active Pharmaceutical Ingredients), and supply chain stability (Kumar et al., 2018). These risks can be further divided into *key sub-risks* that impact manufacturing efficiency, regulatory compliance, and business continuity. The following sub-categories highlight the most significant *supplier-related risks* (Sharma et al., 2023):

1.1 Key supplier failure

Key supplier failure can be determined by disruptions caused by unforeseen events, such as fires, worker strikes, geopolitical instability, or logistical bottlenecks, preventing the timely delivery of crucial raw materials like APIs. These disruptions hinder production, lead to unfulfilled demand, and create ripple effects across the supply chain (Forghani et al., 2018; Moktadir et al., 2018; Jaberidoost et al., 2013; Mehralian et al., 2012; Enyinda et al., 2010).

1.2 Raw material issues

This sub-risk encompasses the poor quality or unavailability of raw materials, leading to substandard drug production or complete supply shortages (Forghani et al., 2018; Moktadir et al., 2018; Jaberidoost et al., 2013, 2015; Elleuch et al., 2013; Mehralian et al., 2012; Breen, 2008). Pharmaceutical firms that heavily depend on overseas suppliers for APIs and excipients face significant vulnerabilities, as demonstrated during

the COVID-19 pandemic when supply chain interruptions led to drug shortages worldwide (Sharma et al., 2023).

1.3 Material cost fluctuations

Changes in raw material prices—driven by tariffs, fluctuating freight costs, and economic instability—significantly impact profit margins and pricing strategies (Forghani et al., 2018; Vishwakarma et al., 2016; Jaberidoost et al., 2013, 2015; Mehralian et al., 2012). Sudden cost surges can make drug manufacturing financially unsustainable, particularly for generic drug manufacturers who operate on thin margins (Sharma et al., 2023).

1.4 Lack of appropriate technology level

A crucial yet often overlooked sub-risk, technological limitations among suppliers can cause inefficiencies, production glitches, and supply inconsistencies (Moktadir et al., 2018; Mehralian et al., 2012). Inadequate data-sharing mechanisms between suppliers and manufacturers further exacerbate this issue, leading to delays and inefficiencies in pharmaceutical production (Sharma et al., 2023).

1.5 Supplier's compliance problem

Regulatory compliance failures by suppliers—such as delays in delivery, failure to meet industry standards, or improper import documentation—pose serious risks to pharmaceutical firms (Forghani et al., 2018; Moktadir et al., 2018; Vishwakarma et al., 2016; Jaberidoost et al., 2013, 2015; Elleuch et al., 2013). These failures not only cause production delays but also erode trust among pharmaceutical firms and their global partners (Sharma et al., 2023). Non-compliant suppliers may also be subject to regulatory penalties, further impacting the reliability of their operations.

Operational risks in the pharmaceutical industry refer to threats that impact production efficiency, service quality, and overall process reliability. These risks can lead to product recalls, regulatory non-compliance, resource wastage, and financial losses. Key operational sub-risks are (Sharma et al., 2023):

2.1 Quality issues

Quality issues stem from unacceptable quality standards in pharmaceutical products, which can have direct consequences on patient safety and regulatory compliance (Silva et al., 2020; Moktadir et al., 2018; O'Connor et al., 2017; Huq et al., 2016; Vishwakarma et al., 2016; Mehralian et al., 2012). Failures in quality control, contamination risks, or formulation errors can result in adverse health effects, legal repercussions, and loss of consumer trust. Regulatory agencies, such as the FDA and EMA, impose strict guidelines to mitigate this risk (Sharma et al., 2023).

2.2 Poor service performance

Poor service performance refers to inadequate responsiveness, lack of flexibility, and inefficiencies in customer service, leading to unfulfilled drug demands and unsatisfied customers (Vishwakarma et al., 2016; Jaberidoost et al., 2013; Breen, 2008). This issue arises from delays in production cycles, slow distribution channels, and ineffective communication between stakeholders.

2.3 Improper inventory management

Inventory mismanagement includes inadequate buffer stock, expired drugs in storage, and inefficient stock monitoring, leading to resource wastage and production delays (Huq et al., 2016; Jaberidoost et al., 2013, 2015; Breen, 2008).

2.4 Operational planning issues

Poor operational planning arises from inefficient resource allocation, poor outsourcing decisions, and inadequate production scheduling, leading to delays in product manufacturing and delivery (Huq et al., 2016; Jaberidoost et al., 2013, 2015; Breen, 2008).

2.5 Operational strategy issues

Non-standard operational strategies, such as over-reliance on redundant suppliers or lack of process standardization, can contribute to quality inconsistencies and profitability losses (Jaberidoost et al., 2013, 2015; Breen, 2008). Companies that do not adhere to structured risk management protocols are more vulnerable to unexpected operational failures (Sharma et al., 2023).

Financial risks in the pharmaceutical industry can affect cash flow stability, supply chain costs, revenue generation, and investment viability. Key financial sub-risks are (Sharma et al., 2023):

3.1 Loss of customers due to partner's poor service performance

One of the significant financial risks in the pharmaceutical industry is customer loss resulting from the poor performance of partners, such as pharmacists, distributors, and retailers (Sharma et al., 2023). If these partners fail to provide reliable service, meet regulatory standards, or maintain product availability, customers may lose trust in the company, leading to revenue losses and brand reputation damage (El Mokrini et al., 2016). This risk is especially prevalent in markets where pharmaceutical firms rely heavily on third-party distribution networks (Sharma et al., 2023).

3.2 Cash flow issues

Cash flow issues arise from delayed payments, inefficiencies in money collection, and financial mismanagement, ultimately hampering the company's ability to maintain stable production schedules and supply chain operations (Jaberidoost et al., 2013, 2015).

3.3 Insecure money transfer channels

The pharmaceutical industry is increasingly vulnerable to cyber threats and financial fraud in money transfer systems (Sharma et al., 2023). The risk of cyber hacking in financial transactions can lead to losses, payment disruptions, and operational inefficiencies (Jaberidoost et al., 2015).

3.4 Increased freight charges

Logistical costs represent a major financial concern for pharmaceutical companies. Increased fuel costs, freight tariffs, and supply chain bottlenecks can directly impact profit margins and drug pricing strategies (Moktadir et al., 2018; Vishwakarma et al., 2016; Mehralian et al., 2012). Firms with global distribution networks must continuously adapt to fluctuating shipping and transportation costs to maintain profitability (Sharma et al., 2023).

3.5 Internal financial restrictions

A company's internal financial constraints—such as insufficient funds, budget misallocation, and financial mismanagement—can limit research innovation, production scalability, and market expansion (Moktadir et al., 2018; Breen, 2008). Financial restrictions can also inhibit the ability to respond to regulatory changes, technological advancements, and competitive pressures (Sharma et al., 2023).

Market risks in the pharmaceutical industry influence pricing strategies, production planning, and long-term market positioning. Key demand/customer/market sub-risks are (Sharma et al., 2023):

4.1 Forecasting error

A lack of accurate demand forecasting or errors in prediction can negatively impact inventory management, procurement strategies, and production cycles (Schuhmacher et al., 2021). Incorrect demand estimates can lead to overstocking, shortages, or inefficiencies in resource allocation, directly affecting financial performance (Torasa & Mekhum, 2020; Merkuryeva et al., 2019; Moktadir et al., 2018; Huq et al., 2016; Breen, 2008).

4.2 Demand fluctuations

Changes in consumer preferences, economic downturns, or global disruptions (e.g., COVID-19) can create significant demand volatility, making it difficult for pharmaceutical firms to adjust production and supply

chain strategies accordingly (Moktadir et al., 2018; Vishwakarma et al., 2016; Elleuch et al., 2013; Jaberidoost et al., 2013; Mehralian et al., 2012; Breen, 2008).

4.3 Bull whip effect

The bullwhip effect occurs when distorted information flows across the pharmaceutical supply chain (PSC), leading to incorrect demand signaling and inefficient inventory management (Moktadir et al., 2018). This effect results in excessive stockpiling, revenue losses from expired drugs, and inefficiencies in distribution channels (Sharma et al., 2023).

4.4 Competitive risk

Competition within the pharmaceutical industry is intense, with firms seeking to maximize market share through aggressive marketing strategies, product differentiation, and strategic pricing (Moktadir et al., 2018; Vishwakarma et al., 2016; Laínez et al., 2012).

4.5 Bad reputation of the company

A pharmaceutical company's reputation is crucial for market credibility and customer trust (Spanu, 2024). Litigations, regulatory violations, negative media coverage, or product recalls can significantly impact public perception and sales performance (Jaberidoost et al., 2013; Mehralian et al., 2012; Breen, 2008). Firms must actively engage in corporate social responsibility (CSR), transparent communication, and rigorous compliance monitoring to protect their brand image (Sharma et al., 2023).

Logistics risks in the pharmaceutical industry arise from transportation inefficiencies, supply chain disruptions, and delivery constraints. These risks can impact drug efficacy, regulatory compliance, and customer satisfaction. Key logistics sub-risks are (Sharma et al., 2023):

5.1 Absence of cold chain availability

Cold chain logistics are essential for transporting temperature-sensitive pharmaceutical products, ensuring their efficacy and safety. The absence or failure of proper cold chain systems can lead to drug degradation, regulatory non-compliance, and financial losses (Breen, 2008).

5.2 Counterfeit risk

The pharmaceutical supply chain is susceptible to counterfeit drugs, which can tarnish brand reputation, pose severe health risks to consumers, and lead to legal repercussions (Falasca et al., 2021; Saxena et al., 2020; Bagozzi & Lindmeier, 2017; Behner et al., 2017; Vishwakarma et al., 2016; Jaberidoost et al., 2013, 2015; Chaudhry & Stumpf, 2013; Enyinda et al., 2010; Breen, 2008). Companies must implement blockchain-

based track-and-trace solutions, advanced authentication technologies, and strict supplier vetting processes to combat counterfeiting (Sharma et al., 2023).

5.3 Lack of personnel

The shortage of skilled personnel in logistics operations, including loading, unloading, and transportation management, can result in delays, supply chain inefficiencies, and increased operational costs (Paul et al., 2020; Elleuch et al., 2013).

5.4 Traffic congestion

Freight delays caused by traffic congestion and inadequate transportation infrastructure can disrupt pharmaceutical supply chains, leading to customer dissatisfaction and financial losses (Paul et al., 2020; Breen, 2008).

5.5 Untimely delivery of products

Late deliveries can have critical consequences for pharmaceutical firms, as they may delay patient treatments, disrupt hospital supply chains, and erode consumer trust (Huq et al., 2016). Companies must adopt real-time tracking systems, predictive analytics for supply chain forecasting, and strategic partnerships with reliable third-party logistics providers to minimize delivery delays (Sharma et al., 2023).

Political and regulatory risks in the pharmaceutical industry stem from government policies, international relations, economic instability, and legal frameworks (Sharma et al., 2023). These risks can have significant implications for market access, supply chain efficiency, and profitability of pharma companies. Key political sub-risks are:

6.1 Inflation rate risk

Economic inflation can cause rising operational costs, financial instability, and disruptions in supply chain planning (Jaberidoost et al., 2015). Increased production costs, fluctuating exchange rates, and labor cost inflation can negatively impact profit margins and long-term investment strategies (Sharma et al., 2023).

6.2 International sanctions

Economic and political sanctions imposed for national security or legal compliance can limit access to international markets and essential raw materials (Jaberidoost et al., 2013, 2015; Mehralian et al., 2012). Sanctions may result in supply shortages, disrupted R&D activities, and increased compliance costs.

6.3 Lack of regulation transparency

Ambiguities in government policies and regulatory frameworks can lead to uninformed investment decisions, delays in drug approvals, and compliance challenges (Jaberidoost et al., 2015). The absence of clear legal guidelines creates uncertainty for pharmaceutical firms, making long-term planning and risk assessment more complex (Sharma et al., 2023).

6.4 Risk due to pricing policies

Government-imposed pricing regulations, such as price ceilings on essential drugs, can reduce profit margins and hinder market competitiveness (Silva et al., 2020; Vishwakarma et al., 2016; Jaberidoost et al., 2013, 2015). Policies aimed at making drugs more affordable may create financial constraints for pharmaceutical companies, affecting their ability to invest in innovation and production scalability (Sharma et al., 2023).

6.5 Unstable policy regulations

Frequent changes in government policies and regulatory frameworks introduce economic uncertainty and operational inefficiencies (Silva et al., 2020; Huq et al., 2016; Vishwakarma et al., 2016; Jaberidoost et al., 2013, 2015; Mehralian et al., 2012). Unpredictable shifts in regulations may lead to supply chain disruptions, increased compliance costs, and legal liabilities (Sharma et al., 2023).

Technology risks in the pharmaceutical industry emerge from digital integration challenges, cybersecurity threats, outdated infrastructure, and intellectual property vulnerabilities (Sharma et al., 2023). These risks can crucially impact supply chain efficiency and innovation capabilities of pharmaceutical firms. (Huq et al., 2016). Key technology sub-risks are (Sharma et al., 2023):

7.1 Lack of effective system integration

Inefficient information systems and digital infrastructures create data asymmetry among trading partners, leading to supply chain disruptions, poor decision-making, and unresponsive pharmaceutical supply chains (PSC) (Huq et al., 2016; Vishwakarma et al., 2016; Jaberidoost et al., 2013, 2015; Mehralian et al., 2012; Breen, 2008). Without automated, AI-driven platforms, pharmaceutical firms struggle to synchronize inventory, logistics, and market demands, resulting in delayed responses to emerging risks (Sharma et al., 2023).

7.2 Lack of visibility

Limited real-time inventory tracking and supply chain transparency prevent pharmaceutical firms from effectively managing drug availability, production cycles, and stock replenishment (Jaberidoost et al., 2013, 2015; Breen, 2008). This risk contributes to overstocking, shortages, and wasted resources (Sharma et al., 2023).

7.3 Obsolete technology

Pharmaceutical firms relying on outdated digital infrastructures and legacy IT systems face heightened risks of cyberattacks, data loss, regulatory non-compliance, and operational inefficiencies (Huq et al., 2016; Vishwakarma et al., 2016; Jaberidoost et al., 2013, 2015; Mehralian et al., 2012; Breen, 2008). Cyber vulnerabilities expose firms to data breaches, intellectual property theft, and ransomware attacks, necessitating robust cybersecurity frameworks and cloud-based digital transformations (Sharma et al., 2023).

7.4 Poor information decisions

Ineffective data collection, poor communication between supply chain entities, and inaccurate predictive modeling lead to flawed strategic decisions (Jaberidoost et al., 2013, 2015; Breen, 2008). Pharmaceutical firms must adopt AI-driven analytics, predictive forecasting, and integrated ERP (Enterprise Resource Planning) systems to improve decision accuracy and operational efficiency (Sharma et al., 2023).

7.5 Risk to intellectual property

Weak data security protocols and inadequate IP protection frameworks expose pharmaceutical firms to intellectual property theft, confidentiality breaches, and unauthorized access to proprietary research (Silva et al., 2020; Huq et al., 2016).

The pharmaceutical sector plays a crucial role in providing life-saving treatments and healthcare solutions to society (Kumar et al., 2018). However, its operations can significantly impact the environment through various channels. These include the improper disposal of medications by patients, the accumulation of expired or unused drugs, unintended pharmaceutical discharges from pharmacies, and the release of residual substances into wastewater systems when excess medications are flushed or discarded improperly (Kumar et al., 2018). The pharmaceutical sector is undergoing a profound transformation in 2025, driven by the growing urgency of environmental sustainability (Laboratorios Rubió, 2025). The impact of climate change has compelled companies to reassess their entire supply chains in a sustainable perspective, driving the urgent need for managers to adopt Green Supply Chain (GSC) initiative to address the increasingly crucial *environmental risk* (Kumar et al., 2018). As a result, major pharmaceutical corporations have drastically increased their financial commitments to sustainability, now allocating $5.2 billion annually to environmental programs, a remarkable 300% surge compared to 2020 (Laboratorios Rubió, 2025). Research laboratories worldwide are pioneering innovative approaches to drug manufacturing that significantly reduce ecological footprints (Kumar et al., 2018). Toxic solvents traditionally used in production are being substituted with environmentally friendly alternatives, while state-of-the-art water recycling systems have enabled companies to lower water consumption by 40% (Laboratorios Rubió, 2025). These advancements are reshaping pharmaceutical manufacturing, ensuring that essential medicines are produced with minimal environmental harm (Kumar et al., 2018). In addition, regulatory authorities are enforcing stricter

compliance measures, compelling companies to adhere to more rigorous environmental standards (Tetteh et al., 2023). Consumers, particularly patients, are demanding more sustainable healthcare solutions, influencing market preferences. Meanwhile, investors increasingly prioritize environmental, social, and governance (ESG) criteria, making sustainability a critical factor in financial decision-making (Tetteh et al., 2023). The industry is left with a clear directive: evolve towards greener practices or face competitive decline (Kumar et al., 2018; Tetteh et al., 2023; Laboratorios Rubió, 2025). Pharmaceutical firms that successfully integrate environmentally conscious practices into their operations experience a 15% reduction in production costs, a stronger corporate reputation, and an enhanced ability to attract top-tier professionals (Laboratorios Rubió, 2025; Tetteh et al., 2023). More importantly, they ensure the continuity of essential medical advancements while contributing to the long-term preservation of global ecosystems (Veleva et al., 2017). While the seven core risk categories previously discussed—*supplier*, *operational*, *financial*, *market*, *logistical*, *political*, and *technological* risks—remain fundamental to address for pharma companies, it is imperative to recognize *environmental risk* as a critical and increasingly pressing factor influencing the overall performance of pharmaceutical companies (Kumar et al., 2018). For the purposes of our research on risk management and long-term sustainability, environmental risk has been incorporated as the eighth critical risk category in the pharmaceutical industry. Given its far-reaching implications on operational resilience, regulatory adaptation, and corporate responsibility, the integration of environmental risk into risk assessment frameworks is essential for ensuring sustainable business practices and mitigating ecological impact (Kumar et al., 2018). In recent decades, public awareness regarding environmental sustainability has significantly increased, prompting regulatory bodies to prioritize global ecological challenges such as resource depletion, climate change, and carbon emissions (Xie & Breen, 2012; Tseng & Chiu, 2013). The pharmaceutical value chain, characterized by highly complex products and substantial investment in research and development, faces mounting global and domestic pressures to align with environmental, economic, and safety concerns (Tseng & Chiu, 2013; Kumar et al., 2018). In response, the industry has increasingly embraced GSC strategies to enhance both ecological and economic efficiency. Green Supply Chain (GSC) initiatives in the pharmaceutical sector encompass sustainable practices at every stage of the supply chain, including green sourcing, eco-conscious design, environmentally friendly manufacturing, sustainable distribution, and reverse logistics (Narayana et al., 2014; Kumar et al., 2018; Mangla, Madaan, & Chan, 2013; Dubey, Gunasekaran, & Papadopoulos, 2017). *Green sourcing*, a key component of sustainable supply chain management, plays a vital role in ensuring that the procurement of raw materials, products, and services minimizes negative environmental and social impacts (Faisal, 2016; Dubey, Gunasekaran, & Papadopoulos, 2017; Kumar et al., 2018). However, implementing GSC initiatives presents various risks that can threaten the operational stability of pharmaceutical firms (Mangla, Madaan, & Chan, 2013). These challenges include supply chain disruptions, quality control issues, increased environmental compliance costs, and potential loss of competitive advantage (Kumar et al., 2018). To enhance performance and ensure effective management of GSC initiatives, it is crucial to adopt a holistic approach to sustainability, recognizing the interconnected

risks associated with implementing green supply chain strategies (Mangla, Madaan, & Chan, 2013). By addressing these risks proactively, pharmaceutical companies can improve supply chain resilience, maintain regulatory compliance, and reinforce their commitment to sustainability while securing long-term resilience and business success (Kumar et al., 2018). The environmental risk associated with the pharmaceutical industry extends beyond general sustainability concerns, encompassing a range of specific sub-risks arise from resource-intensive production processes, pharmaceutical waste disposal, carbon emissions, supply chain vulnerabilities, and evolving regulatory landscapes (Veleva et al., 2017; Kumar et al., 2018; Tetteh et al., 2023). Key sub-risks impacting environmental sustainability in the pharmaceutical sector are:

8.1 Pharmaceutical waste management and disposal risks

One of the most critical environmental challenges faced by the pharmaceutical industry is inadequate waste management, which results in drug residues entering water systems, soil contamination, and disruptions to ecosystems (Xie & Breen, 2012). The improper disposal of pharmaceuticals, both at the consumer and industrial levels, poses severe environmental and regulatory concerns (Tetteh et al., 2023). Insufficient mechanisms for recycling pharmaceutical waste and recovering unused medications increase the volume of hazardous waste generated by the industry (Dubey, Gunasekaran, & Papadopoulos, 2017).

8.2 Carbon emissions and Greenhouse Gas (GHG) footprint

The pharmaceutical industry is an energy-intensive sector, contributing significantly to greenhouse gas (GHG) emissions due to manufacturing, global supply chains, and logistical operations (Tseng & Chiu, 2013). The carbon footprint of pharmaceutical firms represents a crucial environmental sub-risk, as highlighted by the scientific literature that analyzes the environmental impact of the pharmaceutical industry (Belkhir & Elmeligi, 2018), concluding that an immediate and striking result is that the pharmaceutical sector is far from being a green sector in terms of carbon emissions (Belkhir & Elmeligi, 2018).

8.3 Sustainable sourcing and raw material scarcity

The pharmaceutical sector is heavily dependent on raw materials, including APIs and excipients, many of which originate from finite natural resources or require environmentally damaging extraction processes (Kumar et al., 2018). Climate change-related natural disasters, droughts, and deforestation can disrupt the availability of key raw materials, increasing supply volatility and production costs (Tseng & Chiu, 2013). While pharmaceutical companies aim to source sustainable alternatives, eco-friendly materials are often more expensive, harder to procure, or incompatible with existing drug formulations (Narayana et al., 2014).

8.4 Regulatory compliance and environmental governance risks

As environmental concerns gain prominence, governments and regulatory bodies worldwide are tightening environmental standards in the pharmaceutical industry (Mangla, Madaan, & Chan, 2013). Pharmaceutical

firms must invest heavily in sustainable infrastructure, emissions tracking, and eco-friendly technologies to comply with stricter environmental laws (Xie & Breen, 2012). Companies that fail to meet environmental standards risk facing fines, product recalls, and litigation, affecting financial stability and shareholder trust (Kumar et al., 2018).

8.5 Consumer and investor expectations on ESG compliance

Beyond regulatory pressures, consumer behavior and investor priorities are shifting toward sustainability-driven decision-making (Veleva et al., 2017). The failure to meet ESG expectations introduces several risks: environmentally conscious consumers increasingly prefer pharmaceutical brands that demonstrate commitment to sustainability, influencing purchasing decisions (Tetteh et al., 2023). Institutional investors prioritize companies with strong ESG performance, meaning pharmaceutical firms that lag in sustainability may struggle to secure funding (Kumar et al., 2018). In addition, companies that fail to adopt green supply chain practices risk damaging their reputation and facing public backlash (Mangla, Madaan, & Chan, 2013).

The comprehensive review of scientific literature on risk assessment within the pharmaceutical industry has enabled us to identify and analyze the eight fundamental risk categories that define the sector's complex risk landscape. These include supplier, operational, financial, market, logistical, political, technological, and environmental risks. Each of these categories encompasses multiple sub-risks, which can independently or interdependently affect pharmaceutical firms' stability, regulatory compliance, financial performance, and long-term sustainability. Given the interdependencies among these risks, a structured, holistic approach to risk management is essential to ensure resilience, competitiveness, and adherence to evolving global regulations. The following summary table categorizes these eight crucial risks alongside their respective sub-risks, providing a clear framework for evaluating and mitigating risk in the pharmaceutical sector.

Risk category	**Sub-risks**
1. Supplier risks	1.1 - Key supplier failure
	1.2 - Raw material issues
	1.3 - Material cost fluctuations
	1.4 - Lack of appropriate technology level
	1.5 - Supplier compliance issues
2. Operational risks	2.1 - Quality issues
	2.2 - Poor service performance
	2.3 - Improper inventory management
	2.4 - Operational planning issues
	2.5 - Operational strategy weaknesses

Risk category	Sub-risks
3. Financial risks	3.1 - Loss of customers due to partner failures
	3.2 - Cash flow issues
	3.3 - Insecure money transfers
	3.4 - Increased freight charges
	3.5 - Internal financial constraints
4. Market risks	4.1 - Forecasting errors
	4.2 - Demand fluctuations
	4.3 - Bullwhip effect
	4.4 - Competitive risk
	4.5 - Reputation risk
5. Logistical risks	5.1 - Cold chain unavailability
	5.2 - Counterfeit risk
	5.3 - Personnel shortages
	5.4 - Traffic congestion
	5.5 - Late deliveries
6. Political & regulatory risks	6.1 - Inflation risk
	6.2 - International sanctions
	6.3 - Regulation transparency issues
	6.4 - Drug pricing policies
	6.5 - Unstable regulatory framework
7. Technological risks	7.1 - Lack of effective system integration
	7.2 - Limited supply chain visibility
	7.3 - Obsolete technology
	7.4 - Poor data-driven decision-making
	7.5 - Intellectual property risks
8. Environmental risks	8.1 - Pharmaceutical waste disposal risks
	8.2 - Carbon emissions & greenhouse gas footprint
	8.3 - Sustainable sourcing and raw material scarcity

	8.4 - Regulatory compliance risks
	8.5 ESG-driven consumer & investor expectations

Given the interconnected nature of these risks, a structured and proactive risk management approach is essential to ensure the industry's resilience and sustainability (Schuhmacher et al., 2021). Companies that fail to anticipate and mitigate these risks effectively may face severe consequences, including production disruptions, financial losses, reputational damage, and regulatory sanctions (Sharma et al., 2023). Having provided a detailed analysis of the most crucial risk categories and the respective sub-related risks, the next section an in-depth examination of the risk management frameworks and strategies implemented within the pharmaceutical sector.

2.2. How risk is managed in the pharmaceutical industry

Developing groundbreaking therapies while sustaining growth in the pharmaceutical sector demands the strategic utilization of research and development (R&D) resources and cutting-edge technologies to create high-value new molecular entities (NMEs) (Schuhmacher et al., 2021). However, intensifying global competition in pharmaceutical R&D, the expanding influence of generics and biosimilars, increasingly rigorous regulatory frameworks, and cost-sensitive reimbursement models are placing significant pressure on traditional business strategies of leading pharmaceutical firms (Spanu, 2024). The emergence of big data analytics and artificial intelligence (AI) has revolutionized multiple industries, and its disruptive potential is becoming increasingly evident in biopharmaceutical R&D (Schuhmacher et al., 2021). These technologies hold the promise of enhancing efficiency, accelerating drug discovery, and optimizing development pipelines, ultimately driving innovation and competitiveness in an evolving pharmaceutical landscape (Tetteh et al., 2023). In view of this, risk management has become an unprecedented discipline for pharma executives (Schuhmacher et al., 2021). Having established a classification of the most critical risks in the pharmaceutical sector along with their subcategories, this section aims to analyze the strategies that pharmaceutical companies employ to manage and mitigate these risks effectively. The pharmaceutical sector continuously encounters complex and specific risks, spanning from drug discovery and development to large-scale manufacturing and market distribution (Sharma et al., 2023). To uphold patient safety and regulatory compliance, it is essential that these risks are systematically identified, evaluated, and mitigated through structured risk management approaches (Urushihara et al., 2014). In an industry environment defined by stringent regulations, evolving market dynamics, and increasing competitive pressures, pharmaceutical companies must develop comprehensive risk assessment and mitigation strategies to safeguard not only the safety, efficacy, and quality of medicinal products but also their overall business sustainability (Tetteh et al., 2023). *Risk management* plays a pivotal role, by providing a structured framework for identifying, analyzing, and mitigating threats and risks that span the entire value chain—from early-stage research and development to regulatory compliance, financial stability, supply chain resilience, and corporate governance (SoftExpert Blog, 2024). Risk management involves the systematic identification, assessment, and prioritization of risks, followed by the implementation of preventive and corrective

measures to minimize their likelihood and impact (Hopkin, 2010). It is a comprehensive, multidisciplinary discipline aimed at anticipating potential risks, analyzing their root causes, and establishing control mechanisms to prevent failures and mitigate their recurrence (Hopkin, 2010). Each of the eight critical risks identified in the pharmaceutical industry—*supplier*, *operational*, *financial*, *market*, *logistical*, *political*, *technological*, and *environmental*—requires a specific set of management and mitigation strategies. The objective of this section is to analyze how pharmaceutical firms address each risk through targeted risk management strategies. For instance, supplier risk is managed through diversified sourcing strategies and stringent quality controls (Jaberidoost et al., 2013; Sharma et al., 2023), while operational risk requires advanced manufacturing standards and process automation to ensure regulatory compliance and product consistency (Huq et al., 2016; O'Connor et al., 2017). Financial risk mitigation involves robust investment planning and cost-containment strategies to maintain profitability amid high R&D expenditures and fluctuating market conditions (Mittal et al., 2008; Moktadir et al., 2018). Meanwhile, market risks necessitate adaptive business models, competitive positioning, and the ability to respond to shifting consumer demand and regulatory changes (Dadhich & Gurbani, 2021; Merkuryeva et al., 2019).
The following analysis will explore the precise mechanisms employed for each risk category, outlining best practices and industry standards in pharmaceutical risk management.

Supplier risks and sub-risks management

The pharmaceutical supply chain is inherently complex and increasingly vulnerable to global uncertainties, making *supplier risk* a crucial area for risk management (Wang & Jie, 2019). Supplier risk refers to the potential disruptions, quality deviations, and compliance failures that arise due to dependencies on third-party manufacturers, raw material providers, and logistics partners (Sharma et al., 2023). Given the critical nature of pharmaceutical products, any disruption in supply can have severe public health consequences, financial losses, and regulatory penalties (Jaberidoost et al., 2013; Sharma et al., 2023). The pharmaceutical supply chain is especially susceptible to external shocks, as global sourcing practices have expanded while regulatory demands have become increasingly stringent (Moktadir et al., 2018). These risks are compounded by the emergence of geopolitical instability, trade barriers, and logistical inefficiencies, which can create delays, drive up procurement costs, and limit access to essential pharmaceutical components (Truong Quang & Hara, 2019). Supplier-related risks are closely tied to uncertainty, as pharmaceutical companies must navigate unpredictable disruptions stemming from fluctuating raw material availability, changing regulatory landscapes, and supplier insolvency (Wang & Jie, 2019). The link between supply chain uncertainty and supplier risk has been extensively discussed in risk management literature, where scholars emphasize that these risks are often inseparable in practice (Simangunsong et al., 2012; Prater et al., 2001b). For instance, a 2010 McKinsey survey conducted among supply chain executives revealed that more than two-thirds reported an increase in supplier-related risks over the past three years, with a similar proportion expecting further escalation due to macroeconomic volatility and regulatory pressures (McKinsey, 2010). The

criticality of suppliers risks pushed many pharmaceutical companies to adopt structured supply chain risk management (SCRM) strategies to mitigate supplier risks effectively (Wang & Jie, 2019). Pharmaceutical companies, whether in the public or private sector, are exposed to distinct supply chain uncertainties and risks, shaped by their specific vulnerabilities and operational contexts. Given the heterogeneity and specificity of these risk factors, a standardized approach to mitigating all risks is neither feasible nor practical (Wang & Jie, 2019). However, firms can leverage their internal capabilities and resources to manage specific dimensions of supply chain uncertainty and risk effectively (Wang & Jie, 2019). Despite its global relevance, pharmaceutical supply chain risk management (SCRM) remains underdeveloped in academic research, largely because existing studies have predominantly concentrated on risk mitigation strategies within manufacturing and logistics operations, while neglecting the intricate interdependencies that characterize pharmaceutical supply networks (Wang & Jie, 2019). These networks are subject to high levels of uncertainty, driven by factors such as geopolitical instability, fluctuating raw material availability, stringent regulatory interventions, and growing concerns over counterfeit drug infiltration (Prater et al., 2001). The scarcity of research on systematic risk mitigation strategies tailored to pharmaceutical supply chains has left critical gaps in understanding how firms can develop resilient, adaptive, and compliance-driven risk management frameworks (Wang & Jie, 2019). As global pharmaceutical firms increasingly rely on outsourced manufacturing, contract development organizations (CDOs), and global raw material suppliers, the potential for supply chain disruptions, quality deviations, and regulatory non-compliance has grown significantly (Jaberidoost et al., 2013; Wang & Jie, 2019). Managing supplier-related risks in the pharmaceutical sector requires an integrated and methodical approach that addresses the various supplier sub-risks related to *key supplier failures*, *raw material shortages*, *cost fluctuations*, *technological inadequacies*, and *regulatory non-compliance* (Sharma et al., 2023). The reliance on specialized suppliers for active pharmaceutical ingredients (APIs), excipients, and packaging materials makes pharmaceutical companies highly susceptible to **key supplier failures**, that can arise from financial instability, non-compliance with Good Manufacturing Practices (GMP), natural disasters, political instability, or cyberattacks, leading to severe disruptions in drug production (Jaberidoost et al., 2013). To mitigate key supplier failures, pharmaceutical firms employ ***multi-sourcing strategies***, ensuring that critical raw materials and APIs are procured from geographically diverse suppliers to prevent over-reliance on a single entity (Forghani et al., 2018). ***Financial risk analysis models*** assess supplier creditworthiness and cash flow stability before long-term contracts are signed (Enyinda et al., 2010). Another emerging solution is the adoption of ***strategic supplier partnerships***, where firms enter into long-term, risk-sharing agreements with key vendors. These agreements include joint investments in production facilities, shared quality control responsibilities, and co-development of risk mitigation strategies (Vishwakarma et al., 2016). The second sub-risk to be managed is related to raw material shortages. **Raw material shortages** represent a significant risk in pharmaceutical supply chains due to the highly specialized nature of pharmaceutical-grade ingredients (Veleva et al., 2017). Supply chain disruptions caused by geopolitical instability, trade

restrictions, environmental regulations, and global health crises (such as the COVID-19 pandemic) have severely impacted raw material availability (Sharma et al., 2023). Additionally, quality inconsistencies, contamination risks, and increasing regulatory scrutiny over API production—particularly in offshore manufacturing hubs such as India and China—pose further threats to supply chain stability (Jaberidoost et al., 2015). To mitigate raw material shortages and quality risks, pharmaceutical firms implement ***supplier qualification programs*** that assess potential vendors based on regulatory compliance, production capacity, and risk resilience (Huq et al., 2016). ***Diversified sourcing strategies***, in which firms procure raw materials from multiple regions, reduce dependence on single-source suppliers and minimize the impact of localized supply chain disruptions (Moktadir et al., 2018). The integration of ***predictive analytics and AI-driven demand forecasting models*** enables firms to anticipate raw material shortages and adjust procurement strategies accordingly (Merkuryeva et al., 2019; Saxena et al., 2020). Additionally, ***safety stock policies*** ensure that companies maintain buffer inventories of essential raw materials, preventing production stoppages during supply chain disruptions (Kumar et al., 2018). Advances in synthetic chemistry and biomanufacturing technologies have also allowed pharmaceutical firms to develop ***alternative raw materials and biosynthetic substitutes***, reducing dependency on scarce or volatile resources (Bagozzi & Lindmeier, 2017). In many cases, pharmaceutical suppliers, particularly those operating in developing markets, **lack the necessary technological infrastructure**, automation capabilities, and digital quality control systems to meet industry standards (Schuhmacher et al., 2021). Suppliers with outdated technology may struggle with inefficient production processes, contamination risks, and substandard quality assurance protocols, increasing the likelihood of regulatory violations and product recalls (Sharma et al., 2023). To address this risk, pharmaceutical firms conduct ***rigorous supplier technology assessments***, ensuring that vendors meet minimum industry standards before entering supply agreements (Forghani et al., 2018). ***Technology transfer programs*** allow firms to co-invest in upgrading supplier capabilities, including the adoption of automated manufacturing systems and advanced quality control technologies (Mehralian et al., 2012). Leading firms are now leveraging ***blockchain-based traceability platforms*** to enhance real-time visibility into supplier production processes, ensuring full compliance with international safety and quality standards (Saxena et al., 2020). The last supplier sub-risk to be examined is related to **supplier compliance issues**. Regulatory compliance failures by suppliers—such as delays in delivery, failure to meet industry standards, or improper import documentation—pose substantial risks to pharmaceutical firms, potentially disrupting production cycles and regulatory approvals (Forghani et al., 2018; Moktadir et al., 2018; Vishwakarma et al., 2016; Jaberidoost et al., 2013, 2015; Elleuch et al., 2013). These failures not only generate operational inefficiencies but also erode trust within pharmaceutical supply chains, affecting relationships between pharmaceutical firms, contract manufacturers, and global distributors (Sharma et al., 2023). To manage supplier compliance issues, pharmaceutical companies conduct *comprehensive supplier audits*, *third-party verification inspections*, and *continuous monitoring programs* (Jaberidoost et al., 2015). Firms also implement *contractual compliance clauses*, where suppliers must maintain continuous adherence to

regulatory standards or face financial penalties and contract termination (Elleuch et al., 2013). *Compliance training programs* and *regulatory harmonization initiatives* further ensure that suppliers remain aligned with evolving safety and quality standards (Dadhich & Gurbani, 2021).

Supplier risks	**Risk management strategy**
Key supplier failure	Multi-sourcing to reduce dependency, financial risk analysis for supplier creditworthiness, and strategic partnerships for shared production responsibilities (Forghani et al., 2018; Enyinda et al., 2010; Vishwakarma et al., 2016).
Raw material shortages	Supplier qualification programs, diversified sourcing, AI-driven demand forecasting, and safety stock reserves to mitigate disruptions (Huq et al., 2016; Moktadir et al., 2018; Merkuryeva et al., 2019; Saxena et al., 2020; Kumar et al., 2018).
Material cost fluctuations	Long-term procurement contracts, hedging strategies, AI-driven cost optimization, and vertical integration to mitigate pricing volatility (Elleuch et al., 2013; Artzner et al., 1999; Merkuryeva et al., 2019; Laínez et al., 2012).
Lack of appropriate technology	Supplier technology assessments, technology transfer programs, automation adoption, and blockchain-based traceability for real-time monitoring (Forghani et al., 2018; Mehralian et al., 2012; Saxena et al., 2020).
Supplier compliance issues	Supplier audits, third-party verification, contractual enforcement, real-time performance monitoring, and regulatory harmonization initiatives (Jaberidoost et al., 2015; Elleuch et al., 2013; Dadhich & Gurbani, 2021).

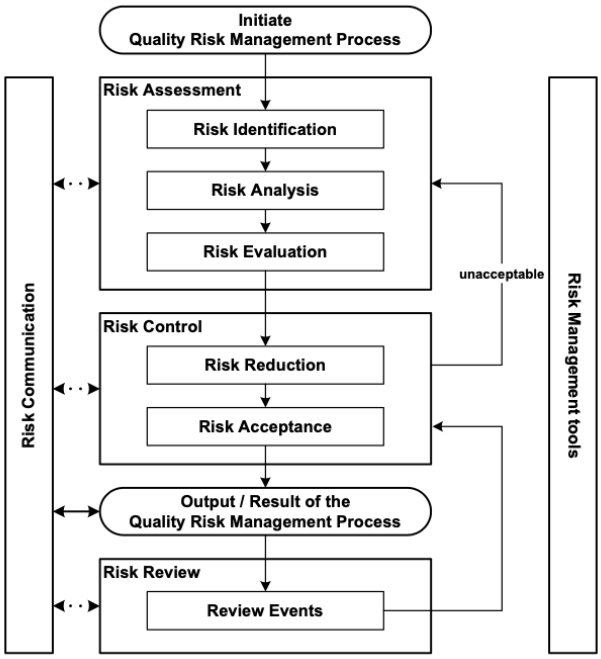
Operational risks and sub-risks management

The pharmaceutical industry operates within a highly regulated and technically demanding environment, where operational risks can compromise product quality, production efficiency, and regulatory compliance (Sharma et al., 2023). These risks stem from manufacturing inefficiencies, inadequate quality control mechanisms, inventory mismanagement, and weak strategic planning, all of which can disrupt pharmaceutical operations and hinder firms' ability to meet market demand (Sharma et al., 2023). Given the

industry's reliance on Good Manufacturing Practices (GMP) and stringent quality requirements, any deviation from established protocols can result in regulatory sanctions, production halts, and reputational damage (Jaberidoost et al., 2015). To address operational risk and its related sub-risks, pharmaceutical companies adhere to Quality Risk Management (QRM) practices established by the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (ICH, 2025). The ICH is a project that brings together regulatory authorities from Europe, Japan, and the USA along with experts from the pharmaceutical industry to harmonize the regulatory framework, ensuring the safety, efficacy, and quality of pharmaceutical products globally (ICH, 2025). In Italy, AIFA, Agenzia Italiana del Farmaco (*Italian Medicines Agency*), operates as an autonomous public body under the direction of the Ministry of Health and the supervision of the Ministry of Health and the Ministry of Economy, following the ICH 9 Quality Risk Management (QRM) guidelines to ensure that pharmaceutical companies operating in Italy comply with internationally recognized standards for risk assessment, control, and mitigation. Quality risk management is a systematic process for the assessment, control, communication, and review of risks to the quality of the medicinal product that can be applied both proactively and retrospectively (Stoppa, 2015). The quality risk management system should ensure that (ICH, 2005):

1. The evaluation of the risk to quality is based on scientific knowledge and experience with the process and ultimately links to the protection of the patient.
2. The level of effort, formality, and documentation of the quality risk management process is commensurate with the level of risk.

Overview of a typical quality risk management process



Source: *ICH, (2005). "ICH Harmonised Tripartite Guideline: QUALITY RISK MANAGEMENT Q9". Retrieved from: https://database.ich.org/sites/default/files/Q9_Guideline.pdf*

Operational risk manifests through several sub-risks, including *quality issues*, *poor service performance*, *improper inventory management*, *operational planning issues*, and *deficiencies in operational strategy*, all of which can negatively impact pharmaceutical companies by compromising operating performance but more importantly patient safety and public health (Sharma et al., 2023). Quality issues in pharmaceutical manufacturing stem from deviations in process parameters, contamination, equipment failures, or human error, all of which can compromise product integrity and patient safety (Silva et al., 2020; Moktadir et al., 2018; O'Connor et al., 2017). The ICH Q9 guidelines recommend the ***implementation of a Quality Risk Management (QRM) system*** where Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs) are continuously monitored through Process Analytical Technology (PAT) (ICH, 2005). Advanced Real-Time Release Testing (RTRT), combined with automated batch record review systems, has also been widely implemented to minimize errors and ensure compliance with Good Manufacturing Practices (GMP) (Stoppa, 2015). Additionally, Failure Mode and Effects Analysis (FMEA) is frequently utilized to identify and correct process vulnerabilities before they result in non-conforming products (ICH, 2005). Poor service performance in pharmaceutical companies is primarily linked to inefficiencies in production cycles, logistics failures, and inadequate response times in distribution channels (Vishwakarma et al., 2016; Jaberidoost et al., 2013). To manage this risk, firms deploy ***Enterprise Resource Planning (ERP) systems***, which integrate real-time supply chain tracking and optimize production scheduling (Sharma et al., 2023). ***Lean Six Sigma methodologies*** further enhance operational efficiency by eliminating waste and reducing cycle times in production (O'Connor et al., 2017). Additionally, ***automation in order processing and predictive analytics for demand forecasting*** have been widely implemented to prevent bottlenecks in service delivery (Saxena et al., 2020; Silva et al., 2020). Effective inventory management is crucial to preventing both overstocking and stockouts, particularly for time-sensitive or perishable pharmaceuticals (Jaberidoost et al., 2013). Many pharmaceutical firms now integrate ***Just-In-Time (JIT) inventory systems alongside Radio-Frequency Identification (RFID) tracking technologies*** to ensure efficient stock control (Huq et al., 2016). Furthermore, ***blockchain-enabled supply chain monitoring*** has been introduced in several major firms to enhance transparency and traceability of raw materials and finished goods (Silva et al., 2020; Saxena et al., 2020; Abdallah & Nizamuddin, 2023). The adoption of ***predictive inventory analytics*** has also significantly improved firms' ability to anticipate demand fluctuations and prevent unnecessary waste (Moktadir et al., 2018; Abdallah & Nizamuddin, 2023). Operational planning failures arise from ineffective resource allocation, poor outsourcing decisions, and lack of contingency strategies (Huq et al., 2016; Jaberidoost et al., 2013, 2015). To mitigate these risks, pharmaceutical firms rely on ***Advanced Planning and Scheduling (APS) systems***, which optimize facility capacity utilization and workforce distribution (Silva et al., 2020). Additionally, ***Scenario-Based Risk Assessment (SBRA) frameworks*** are increasingly used to model potential disruptions and develop preemptive mitigation strategies (Moktadir et al., 2018). Firms that employ ***Integrated Business Planning (IBP) strategies*** have reported improved coordination between R&D, procurement, and manufacturing divisions, reducing the likelihood of production delays (Jaberidoost et al.,

2015). Operational strategy deficiencies often result from an over-reliance on outdated methodologies, inadequate process standardization, and an inability to adapt to evolving regulatory or technological landscapes (Sharma et al., 2023). To manage operational strategy risks, pharmaceutical firms are increasingly adopting ***Total Quality Management (TQM) frameworks,*** which emphasize continuous process optimization and risk-based thinking (Silva et al., 2020). ***Investment in AI-driven process automation*** has further helped firms enhance manufacturing efficiency, while ***Digital Twin technology***—which creates virtual simulations of production processes—has enabled firms to test changes before implementation, reducing operational risk exposure (Bhatt et al., 2023).

Operational risks	**Risk management strategy**	**References**
Quality issues	Implementation of QRM systems (ICH Q9); continuous monitoring of CQAs and CPPs via PAT; adoption of RTRT and automated batch record review systems; application of FMEA to identify and correct process vulnerabilities.	ICH (2005); Stoppa (2015); Silva et al. (2020); Moktadir et al. (2018); O'Connor et al. (2017)
Poor service performance	Deployment of ERP systems for real-time supply chain tracking and optimized production scheduling; Lean Six Sigma methodologies for waste elimination; automation of order processing and predictive analytics for demand forecasting.	Vishwakarma et al. (2016); Jaberidoost et al. (2013); Sharma et al. (2023); O'Connor et al. (2017); Saxena et al. (2020); Silva et al. (2020)
Improper inventory management	Adoption of JIT inventory systems and RFID tracking; integration of blockchain-enabled supply chain monitoring for transparency; use of predictive inventory analytics to forecast demand fluctuations.	Jaberidoost et al. (2013); Huq et al. (2016); Silva et al. (2020); Saxena et al. (2020); Abdallah & Nizamuddin (2023); Moktadir et al. (2018)
Operational planning issues	Implementation of APS systems for facility capacity optimization; application of SBRA frameworks for risk scenario modeling; IBP strategies to improve coordination	Huq et al. (2016); Jaberidoost et al. (2013, 2015); Silva et al. (2020); Moktadir et al. (2018)

	between R&D, procurement, and manufacturing.	
Operational strategy weaknesses	Adoption of TQM frameworks; investment in AI-driven process automation; Digital Twin tech.	Sharma et al. (2023); Silva et al. (2020); Bhatt et al. (2023)

Financial risks and sub-risks management

The pharmaceutical industry faces numerous financial risks that can significantly impact cash flow stability, operational efficiency, and long-term investment viability (Sharma et al., 2023). These risks arise from various factors, including unreliable business partnerships, liquidity constraints, cybersecurity vulnerabilities, rising logistical costs, and internal budgetary limitations (Jaberidoost et al., 2013, 2015). Given the capital-intensive nature of the industry, effective financial risk management strategies are essential to ensure business continuity and sustainable growth (Moktadir et al., 2018). To mitigate financial risks, pharmaceutical companies implement structured risk management frameworks that integrate financial forecasting, investment diversification, and cost optimization strategies (El Mokrini et al., 2016). *Customer loss due to inefficient service from distribution partners, pharmacists, or retailers* is a significant financial risk in the pharmaceutical sector (Sharma et al., 2023). Firms that rely on third-party distribution networks are particularly vulnerable to service disruptions that can lead to reputational damage and revenue losses (El Mokrini et al., 2016). To mitigate this risk, pharmaceutical companies implement **Service Level Agreements (SLAs)** that outline performance expectations and penalties for non-compliance (Jaberidoost et al., 2013). Additionally, firms leverage **Key Performance Indicators (KPIs)** to continuously monitor the reliability of distribution partners (Moktadir et al., 2018). **Diversifying distribution networks** and integrating digital tracking systems further enhance supply chain resilience and minimize the impact of underperforming partners (Mehralian et al., 2012). *Liquidity constraints and inefficiencies in financial management* can severely impact a pharmaceutical company's ability to maintain stable production and supply chain operations (Jaberidoost et al., 2015). Late payments from customers, ineffective accounts receivable management, and unpredictable revenue streams contribute to cash flow instability (Sharma et al., 2023). To mitigate these risks, companies employ **Dynamic Cash Flow Management (DCFM) techniques**, which use predictive analytics to forecast revenue patterns and optimize financial liquidity (Moktadir et al., 2018). Additionally, pharmaceutical firms adopt **invoice factoring**, where outstanding receivables are sold to financial institutions for immediate liquidity (Mehralian et al., 2012). Implementing **Enterprise Resource Planning (ERP) systems** also streamlines financial transactions and ensures real-time cash flow visibility (Breen, 2008). The increasing digitization of financial transactions has exposed pharmaceutical firms to *cybersecurity threats and financial fraud risks* (Sharma et al., 2023; Saxena et al., 2020; Bhatt et al., 2023).

Cyberattacks targeting payment processing systems can result in monetary losses, operational disruptions, and reputational damage (Jaberidoost et al., 2015). To address this risk, companies implement **blockchain-based financial security protocols**, ensuring transaction transparency and minimizing fraud vulnerabilities (Abdallah & Nizamuddin, 2023). Moreover, adopting **multi-factor authentication (MFA) and end-to-end encryption mechanisms** significantly enhance the security of financial transfers (Saxena et al., 2020). Regular security audits and compliance with international financial security standards (e.g., ISO 27001) further strengthen financial transaction safety (Silva et al., 2020; Abdallah & Nizamuddin, 2023). Logistical costs, particularly *freight charges*, represent a substantial financial risk for pharmaceutical companies that operate global supply chains (Moktadir et al., 2018). Rising fuel prices, international tariffs, and supply chain disruptions contribute to increased transportation expenses (Sharma et al., 2023). To mitigate these risks, firms engage in **long-term freight contracts with fixed pricing structures** to shield against market volatility (Mehralian et al., 2012). Additionally, optimizing transportation routes using **AI-driven logistics planning software** enhances cost efficiency (Abdallah & Nizamuddin, 2023). Implementing green logistics initiatives, such as **fuel-efficient delivery fleets and carbon footprint reduction strategies**, can also provide cost savings and regulatory compliance benefits (Tetteh et al., 2023). *Budgetary constraints, inefficient financial planning, and poor capital allocation* can limit a pharmaceutical company's ability to invest in research and development (R&D), production scalability, and market expansion (Moktadir et al., 2018). This risk is particularly critical for firms developing new drug formulations that require significant investment before achieving market approval (Sharma et al., 2023). To mitigate financial restrictions, companies **diversify their investment portfolios by engaging in strategic partnerships, government grants, and venture capital funding** (Vishwakarma et al., 2016; Sharma et al., 2023). Additionally, implementing robust financial planning models such as Zero-Based Budgeting (ZBB) ensures that resources are allocated efficiently and aligned with business priorities (Silva et al., 2020).

Financial risks	**Risk management strategy**
Loss of customers due to partner's poor service performance	Use of SLAs, KPIs for monitoring, diversified distribution, and digital tracking for supply chain resilience (El Mokrini et al., 2016; Sharma et al., 2023).
Cash flow issues	DCFM for forecasting, invoice factoring for liquidity, and ERP systems for financial transparency (Jaberidoost et al., 2015; Sharma et al., 2023).

Insecure money transfers	Blockchain security, multi-factor authentication, encryption, and compliance with ISO 27001 (Sharma et al., 2023; Saxena et al., 2020).
High freight costs	Long-term contracts, AI-driven logistics, and green logistics for cost efficiency (Moktadir et al., 2018; Sharma et al., 2023).
Internal financial constraints	Diversified investments, ZBB budgeting, and financial planning for sustainability (Moktadir et al., 2018; Sharma et al., 2023).

Market risks and sub-risks management

The pharmaceutical sector is particularly vulnerable to market risks due to factors such as fluctuating demand, pricing pressures, evolving consumer preferences, and the increasing complexity of global supply chains (Schuhmacher et al., 2021). These risks can lead to production inefficiencies, revenue instability, and reputational damage (Moktadir et al., 2018). To mitigate market risks, pharmaceutical firms implement advanced forecasting techniques, strategic market positioning, competitive intelligence, and risk-hedging mechanisms (Sharma et al., 2023). *Errors in demand forecasting* can result in either overproduction, leading to excessive stock and wastage, or underproduction, causing supply shortages (Torasa & Mekhum, 2020). To mitigate this risk, pharmaceutical companies integrate **AI-driven predictive analytics and machine learning models** to enhance forecast accuracy (Bhatt et al., 2023). Additionally, the implementation of **demand-driven supply chain (DDSC) models** allows firms to adjust production dynamically based on real-time market data (Huq et al., 2016). The use of **Big Data analytics** has also enabled companies to refine market predictions by analyzing consumer behavior, prescription trends, and regulatory developments (Schuhmacher et al., 2021; Shafique et al., 2019). *Fluctuations in consumer demand*, driven by economic cycles, policy changes, or public health crises, require firms to adopt **agile supply chain models** that allow for rapid adjustments in production and distribution strategies (Jaberidoost et al., 2013). The adoption of **flexible manufacturing systems** and **real-time demand monitoring** has enabled pharmaceutical firms to mitigate supply-demand imbalances (Breen, 2008). Additionally, **multi-channel distribution networks and contract manufacturing partnerships** provide firms with the ability to scale production in response to demand shifts (Elleuch et al., 2013; Mehralian et al., 2012). The bullwhip effect remains a critical risk in pharmaceutical supply chains, leading to inefficiencies in inventory management and demand-supply mismatches (Moktadir et al., 2018; Sharma et al., 2023). To address this, pharmaceutical firms implement **end-to-end supply chain visibility solutions**, including **blockchain-enabled tracking systems and real-**

time inventory synchronization across suppliers and distributors (Sharma et al., 2023; Abdallah & Nizamuddin, 2023). *Competitive risk* in the pharmaceutical industry is addressed through product differentiation, competitive pricing strategies, and strategic partnerships (Laínez et al., 2012). Firms **invest heavily in R&D and patent protection** to maintain a competitive edge, while **collaborations with biotech firms and academic institutions** help accelerate drug development and market exclusivity (Moktadir et al., 2018). Moreover, **pricing analytics and reimbursement modeling** allow firms to align product pricing with market expectations and regulatory policies (Vishwakarma et al., 2016; Abdallah & Nizamuddin, 2023). *Reputation risk* is managed through proactive corporate governance, transparency, and crisis management strategies (Spanu, 2024). Firms must engage in **Corporate Social Responsibility (CSR) initiatives**, emphasizing ethical business practices and sustainability (Jaberidoost et al., 2013). Additionally, **real-time media monitoring tools** enable firms to track public sentiment and respond to reputational threats effectively (Sharma et al., 2023).

Market risks	**Risk management strategy**
Forecasting errors	AI-driven predictive analytics, machine learning models, and demand-driven supply chain (DDSC) models to enhance forecast accuracy and dynamically adjust production (Bhatt et al., 2023; Huq et al., 2016; Schuhmacher et al., 2021; Shafique et al., 2019).
Demand fluctuations	Flexible manufacturing systems, real-time demand monitoring, multi-channel distribution networks, and contract manufacturing partnerships to scale production based on demand shifts (Jaberidoost et al., 2013; Breen, 2008; Elleuch et al., 2013; Mehralian et al., 2012).
Bullwhip effect	End-to-end supply chain visibility solutions, blockchain-enabled tracking systems, and real-time inventory synchronization across suppliers and distributors (Moktadir et al., 2018; Sharma et al., 2023; Abdallah & Nizamuddin, 2023).
Competitive risk	Product differentiation, competitive pricing strategies, strategic partnerships, R&D investment, patent protection, collaborations with biotech firms, and pricing analytics (Laínez et al., 2012; Moktadir et al., 2018; Vishwakarma et al., 2016; Abdallah & Nizamuddin, 2023).

Reputation risk	Corporate governance, transparency, crisis management strategies, Corporate Social Responsibility (CSR) initiatives, ethical business practices, sustainability programs, and real-time media monitoring tools (Spanu, 2024; Jaberidoost et al., 2013; Sharma et al., 2023).

Logistical risks and sub-risks management

The pharmaceutical industry heavily relies on efficient logistics to ensure timely delivery, regulatory compliance, and product efficacy, particularly for temperature-sensitive medications (Sharma et al., 2023). Logistical risks can disrupt supply chains, cause financial losses, and compromise patient safety (Sharma et al., 2023). To mitigate these risks, pharmaceutical firms implement advanced tracking technologies, optimize supply chain routes, and enhance cold chain logistics (Breen, 2008). A lack of *cold chain availability* presents a significant risk, as improper temperature control can lead to drug degradation and non-compliance with regulatory standards (Breen, 2008; Sharma et al., 2023). To mitigate this, firms adopt **real-time temperature monitoring systems, IoT-enabled refrigeration units, and GPS-tracked cold storage vehicles** (Falasca et al., 2021; Abdallah & Nizamuddin, 2023). Blockchain-based verification systems are also used to ensure compliance with regulatory frameworks and maintain drug efficacy throughout the supply chain (Saxena et al., 2020). *Counterfeit drugs* pose another substantial risk in pharmaceutical logistics, affecting patient safety and corporate reputation (Bagozzi & Lindmeier, 2017). To combat counterfeiting, firms integrate **track-and-trace technologies, such as RFID tagging and serialization programs** (Behner et al., 2017). Blockchain-based authentication systems enhance supply chain transparency (Saxena et al., 2020), while partnerships with regulatory agencies strengthen oversight (Chaudhry & Stumpf, 2013). *Personnel shortages in logistics* operations can disrupt transportation management, leading to supply chain bottlenecks (Paul et al., 2020). Pharmaceutical companies address this issue by implementing automation in warehousing, utilizing AI-driven logistics scheduling (Bhatt et al., 2023), and investing in workforce training programs to enhance operational efficiency (Elleuch et al., 2013). *Traffic congestion* remains a persistent risk, causing delays in pharmaceutical deliveries and increasing transportation costs (Paul et al., 2020). **Strategic warehousing solutions**, such as placing distribution hubs closer to high-demand regions, reduce reliance on long-haul transport and minimize exposure to congested routes (Jaberidoost et al., 2013). Additionally, collaborations with **third-party logistics providers** (3PLs) allow pharmaceutical firms to leverage flexible transport networks, including multi-modal shipping (e.g., air, rail, and maritime transport), to bypass high-traffic areas during peak hours (Sharma et al., 2023). *Untimely delivery* of pharmaceutical products can severely impact patient care and hospital supply chains (Huq et al., 2016). To ensure timely deliveries, firms deploy **predictive analytics for demand forecasting**, establish

strategic partnerships with third-party logistics providers, and implement real-time tracking systems (Sharma et al., 2023).

Logistical risks	**Risk management strategy**
Cold chain unavailability	Real-time temperature monitoring, IoT-enabled refrigeration, GPS-tracked cold storage, and blockchain-based verification (Falasca et al., 2021; Abdallah & Nizamuddin, 2023; Saxena et al., 2020; Breen, 2008).
Counterfeit risk	Track-and-trace technologies, RFID tagging, serialization programs, blockchain-based authentication, and regulatory partnerships (Bagozzi & Lindmeier, 2017; Behner et al., 2017; Saxena et al., 2020; Chaudhry & Stumpf, 2013).
Personnel shortages	AI-driven logistics scheduling, automation in warehousing, workforce training programs, and investment in logistics staff retention (Paul et al., 2020; Bhatt et al., 2023; Elleuch et al., 2013).
Traffic congestion	AI-powered route optimization, strategic warehousing near demand centers, night-time deliveries, and multi-modal transport solutions (Paul et al., 2020; Jaberidoost et al., 2013; Sharma et al., 2023).
Late deliveries	Predictive analytics for demand forecasting, real-time tracking, and strategic third-party logistics partnerships (Huq et al., 2016; Sharma et al., 2023).

Political and regulatory risks and sub-risks management

The pharmaceutical industry operates in a highly regulated environment, where political and regulatory risks can directly impact market access, supply chain resilience, and profitability (Sharma et al., 2023). These risks stem from economic instability, international trade restrictions, regulatory inconsistencies, and government intervention in pricing strategies (Jaberidoost et al., 2015). To mitigate these risks, pharmaceutical companies adopt proactive policy monitoring, regulatory compliance frameworks, and strategic financial planning (Mehralian et al., 2012). Economic inflation remains a significant concern for pharmaceutical firms, as it leads to increased production costs, rising wages, and fluctuating currency exchange rates (Sharma et al., 2023). To mitigate *inflation risk*, companies engage in **long-term procurement contracts**, **implement cost-optimization strategies**, **and hedge against currency**

fluctuations (Jaberidoost et al., 2015). Additionally, AI-driven financial modeling enables firms to predict inflationary trends and adjust their pricing strategies accordingly (Bhatt et al., 2023). *International sanctions* can restrict access to raw materials, disrupt supply chains, and impose regulatory compliance burdens (Jaberidoost et al., 2013, 2015). To navigate these restrictions, pharmaceutical firms **diversify their supplier base, establish contingency stockpiles, and engage in trade compliance programs** (Mehralian et al., 2012**). Strategic partnerships** with local manufacturers **in sanction-free regions** help companies maintain continuity in production and distribution (Sharma et al., 2023). The *lack of transparency in regulatory frameworks* often results in delays in drug approvals, investment uncertainty, and non-compliance risks (Jaberidoost et al., 2015). To address this, companies implement **regulatory intelligence systems** that track policy changes in real time, ensuring proactive adaptation to evolving legal requirements (Sharma et al., 2023). Regulatory affairs teams engage in **continuous dialogue with policymakers** to advocate for clearer and more predictable guidelines (Silva et al., 2020). *Government-imposed pricing policies*, such as price controls on essential drugs, can limit profit margins and impact financial sustainability (Jaberidoost et al., 2013, 2015). Pharmaceutical firms mitigate this risk by **developing market-access strategies that optimize portfolio pricing**, negotiating value-based pricing agreements with regulators, and diversifying product offerings to maintain profitability across different segments (Sharma et al., 2023). Additionally, companies **invest in biosimilars** and generic drugs to offset revenue losses from price-regulated products (Vishwakarma et al., 2016). *Frequent changes in policy and regulatory frameworks* introduce uncertainty, increasing compliance costs and operational inefficiencies (Silva et al., 2020; Huq et al., 2016). To manage regulatory volatility, firms establish **compliance management systems**, **implement cross-border legal risk assessments**, and **participate in industry advocacy groups to shape policy discussions** (Sharma et al., 2023). The **adoption of digital compliance solutions** further streamlines adherence to shifting regulations, ensuring that companies remain agile in response to legislative changes (Mehralian et al., 2012).

Political and regulatory risks	**Risk management strategy**
Inflation rate risk	Long-term procurement contracts, financial hedging, AI-driven financial modeling for inflation prediction, and adaptive pricing strategies (Jaberidoost et al., 2015; Sharma et al., 2023; Bhatt et al., 2023).
International sanctions	Supplier diversification, contingency stockpiling, trade compliance programs, and partnerships with local manufacturers in sanction-free regions (Jaberidoost et al., 2013, 2015; Mehralian et al., 2012; Sharma et al., 2023).
Lack of regulation transparency	Implementation of regulatory intelligence systems, continuous policy tracking, direct engagement with

	regulators, and advocacy for clearer legal frameworks (Jaberidoost et al., 2015; Sharma et al., 2023; Silva et al., 2020).
Risk due to pricing policies	Market-access strategies, value-based pricing negotiations, diversification into biosimilars and generics, and portfolio pricing optimization (Jaberidoost et al., 2013, 2015; Vishwakarma et al., 2016; Sharma et al., 2023).
Unstable policy regulations	Compliance management systems, cross-border legal risk assessments, participation in industry advocacy groups, and adoption of digital compliance solutions (Silva et al., 2020; Huq et al., 2016; Mehralian et al., 2012; Sharma et al., 2023).

Technological risks and sub-risks management

The pharmaceutical industry faces increasing technological risks due to rapid digital advancements, cybersecurity vulnerabilities, and challenges in IT system integration (Sharma et al., 2023). These risks can lead to inefficiencies in production, regulatory non-compliance, and loss of competitive advantage (Huq et al., 2016). To mitigate these risks, pharmaceutical firms invest in digital transformation, AI-driven analytics, and robust cybersecurity frameworks (Saxena et al., 2020; Bhatt et al., 2023). A *lack of effective system integration* leads to fragmented information flows and supply chain inefficiencies, preventing firms from synchronizing inventory, logistics, and real-time market demands (Jaberidoost et al., 2013, 2015). To address this, pharmaceutical companies implement **cloud-based ERP (Enterprise Resource Planning) systems and AI-enhanced digital platforms** to streamline information sharing and automate operations (Mehralian et al., 2012; Bhatt et al., 2023). **Blockchain-enabled interoperability** further ensures transparency across stakeholders (Sharma et al., 2023; Saxena et al., 2020). *Limited supply chain visibility* results in stock shortages, overproduction, and delays in drug distribution (Wang & Jie, 2019). To mitigate this, firms adopt **IoT-based real-time tracking, predictive analytics, and end-to-end supply chain monitoring solutions** (Jaberidoost et al., 2013, 2015; Saxena et al., 2020; Bhatt et al., 2023). These technologies allow for dynamic adjustments in production and distribution networks (Sharma et al., 2023). *Reliance on obsolete technology* exposes pharmaceutical firms to cyber risks, operational inefficiencies, and regulatory non-compliance (Huq et al., 2016). Legacy IT systems lack robust security frameworks, making them vulnerable to ransomware attacks and data breaches (Bhatt et al., 2023; Silva et al., 2020). To mitigate this, companies transition to **cloud-based infrastructures** and automated compliance monitoring systems (Bhatt et al., 2023). *Poor data-driven decision-making* results in misallocation of resources, forecasting errors, and supply chain disruptions (Breen, 2008). To enhance decision-making accuracy, firms integrate **machine learning models, big data analytics,** and **AI-driven demand forecasting systems** (Sharma et al., 2023; Bhatt et al., 2023). AI-based

risk detection algorithms further support operational efficiency by identifying vulnerabilities in production and distribution networks (Bhatt et al., 2023). *Intellectual property risks* in the pharmaceutical industry stem from weak cybersecurity frameworks, inadequate IP protection policies, and data theft incidents (Huq et al., 2016). Unauthorized access to proprietary research can lead to competitive disadvantages and financial losses (Silva et al., 2020). To mitigate this, firms implement **end-to-end encryption**, **digital watermarking**, and **blockchain-secured patent management systems** (Sharma et al., 2023; Saxena et al., 2020; Bhatt et al., 2023).

Technology-related risks	**Risk management strategy**
Lack of effective system integration	Adoption of cloud-based ERP systems, AI-driven automation, and blockchain interoperability to enhance real-time data flow, improve operational synchronization, and reduce inefficiencies in supply chain management (Sharma et al., 2023; Mehralian et al., 2012; Bhatt et al., 2023; Saxena et al., 2020).
Limited supply chain visibility	Implementation of IoT-enabled real-time tracking, predictive analytics for demand fluctuations, and end-to-end supply chain monitoring solutions to improve stock management and prevent shortages (Jaberidoost et al., 2013, 2015; Wang & Jie, 2019; Sharma et al., 2023).
Obsolete technology	Migration to cloud-based infrastructures, integration of AI-powered cybersecurity frameworks, and automation of compliance monitoring systems to mitigate cyber threats and enhance regulatory adherence (Huq et al., 2016; Bhatt et al., 2023; Silva et al., 2020).
Poor data-driven decision-making	Utilization of machine learning models, big data analytics, and AI-driven predictive forecasting to optimize resource allocation, reduce forecasting errors, and enhance operational efficiency (Breen, 2008; Sharma et al., 2023; Bhatt et al., 2023).
Intellectual property risks	Implementation of blockchain-secured patent management, end-to-end encryption, and digital watermarking to safeguard proprietary research, prevent data breaches, and enhance IP protection

	(Huq et al., 2016; Silva et al., 2020; Sharma et al., 2023; Saxena et al., 2020; Bhatt et al., 2023).

Environmental risks and sub-risks management

The pharmaceutical industry plays a crucial role in public health, but its operations pose significant environmental risks, including waste disposal, carbon emissions, raw material sustainability, and evolving regulatory pressures (Kumar et al., 2018). With increasing global scrutiny on environmental impact, pharmaceutical companies are under pressure to adopt sustainable practices, mitigate ecological risks, and comply with stricter regulations (Tetteh et al., 2023). The **implementation of Green Supply Chain (GSC) principles** has become a strategic priority, helping firms reduce their environmental footprint while enhancing operational efficiency (Narayana et al., 2014; Kumar et al., 2018). *Pharmaceutical waste disposal* risks are among the most pressing environmental concerns. The improper disposal of expired or unused drugs contributes to water pollution, soil contamination, and ecosystem disruptions (Xie & Breen, 2012). Many pharmaceutical compounds are not fully biodegradable, leading to long-term accumulation in natural environments (Tetteh et al., 2023). To address these risks, companies have developed **take-back programs for unused medications**, implemented **waste treatment technologies**, and **adhered to stricter disposal regulations** (Dubey, Gunasekaran, & Papadopoulos, 2017). *Carbon emissions and the Greenhouse Gas (GHG) footprint* of pharmaceutical firms contribute significantly to global warming, particularly through energy-intensive manufacturing and complex supply chain logistics (Tseng & Chiu, 2013). Studies have shown that the pharmaceutical industry emits substantial amounts of CO_2, often surpassing other industrial sectors in terms of emissions per unit revenue (Belkhir & Elmeligi, 2018). To reduce carbon footprints, companies are investing in **green manufacturing processes**, optimizing **transportation networks**, and shifting towards **renewable energy sources** (Tseng & Chiu, 2013; Kumar et al., 2018). *Sustainable sourcing and raw material scarcity* present additional environmental risks. Many active pharmaceutical ingredients (APIs) and excipients rely on finite natural resources or require energy-intensive extraction methods, raising concerns about long-term sustainability (Kumar et al., 2018). Climate change-induced disruptions, such as droughts and natural disasters, can further exacerbate supply shortages (Tseng & Chiu, 2013). In response, pharmaceutical firms are adopting **green sourcing strategies**, **diversifying their supplier base**, and **researching biodegradable or synthetic alternatives to traditional raw materials** (Narayana et al., 2014; Sharma et al., 2023; Belkhir & Elmeligi, 2018). *Regulatory compliance and environmental governance risks* are increasing as governments impose stricter environmental laws, requiring pharmaceutical companies to align with evolving sustainability standards (Mangla, Madaan, & Chan, 2013). Failure to comply with these regulations can result in heavy fines, product recalls, and reputational damage (Xie & Breen, 2012). To mitigate this risk, firms are **investing in emissions monitoring**, **upgrading waste treatment infrastructure**, and **engaging in proactive regulatory dialogue** to stay ahead of compliance requirements (Kumar et al., 2018). *Consumer and investor expectations regarding ESG compliance* are shaping corporate

decision-making. Environmentally conscious consumers prefer brands that prioritize sustainability, while institutional investors increasingly factor ESG performance into their financial evaluations (Veleva et al., 2017). Companies failing to meet ESG expectations risk losing investor confidence, facing public criticism, and suffering long-term reputational harm (Tetteh et al., 2023). To address this, pharmaceutical firms are **enhancing transparency in sustainability reporting**, **embedding ESG principles into their strategic frameworks**, and actively engaging stakeholders to align with emerging environmental standards (Mangla, Madaan, & Chan, 2013; Kumar et al., 2018).

Environmental risks	**Risk management strategy**
Pharmaceutical waste disposal risks	Implementation of take-back programs for unused medications, development of waste treatment technologies, and stricter adherence to disposal regulations to prevent water and soil contamination (Xie & Breen, 2012; Tetteh et al., 2023; Dubey, Gunasekaran, & Papadopoulos, 2017).
Carbon emissions and Greenhouse Gas (GHG) footprint	Adoption of green manufacturing processes, investment in renewable energy, and supply chain optimization to reduce CO_2 emissions (Tseng & Chiu, 2013; Belkhir & Elmeligi, 2018; Kumar et al., 2018).
Sustainable sourcing and raw material scarcity	Diversification of supplier networks, adoption of biodegradable and synthetic alternatives to traditional raw materials, and implementation of green sourcing strategies to mitigate supply shortages (Kumar et al., 2018; Narayana et al., 2014; Sharma et al., 2023; Tseng & Chiu, 2013).
Regulatory compliance and environmental governance risks	Strengthening emissions monitoring, upgrading waste management systems, and engaging in regulatory dialogue to ensure compliance with evolving environmental laws (Mangla, Madaan, & Chan, 2013; Xie & Breen, 2012; Kumar et al., 2018).
Consumer and investor expectations on ESG compliance	Enhancing transparency in sustainability reporting, integrating ESG principles into corporate strategy, and engaging with investors and consumers to align with environmental expectations (Veleva et al.,

	2017; Tetteh et al., 2023; Mangla, Madaan, & Chan, 2013; Kumar et al., 2018).

After systematically identifying the most critical risks in the pharmaceutical sector and analyzing the prevailing risk management strategies adopted by industry best practices and standards, it is essential to provide a complete understanding of the relationship between leadership and risk management effectiveness. As established in section 1.2, leadership is strategically critical in structuring risk governance, particularly in the pharmaceutical sector, where industry-specific risks—such as regulatory compliance failures, supply chain disruptions, and cybersecurity threats—require proactive and highly skilled management (Henderson, 2023). Despite increased executive involvement, many firms still lack structured risk oversight, with 40% operating without a dedicated risk committee, limiting their ability to anticipate and mitigate threats effectively (Harvard Business Review Analytic Services, n.d.). The increasing complexity of pharmaceutical risk management, driven by regulatory tightening and operational vulnerabilities, underscores the need for leadership that integrates risk governance into corporate strategy rather than treating it as a reactive function (Henderson, 2023). A lack of structured leadership in this area weakens not only crisis response but also the long-term stability of firms operating in a highly regulated and competitive market. Having established the foundational link between leadership and risk oversight, the next section will analyze how leadership directly shapes risk management effectiveness, assessing the mechanisms through which decision-making processes, governance structures, and corporate culture influence firms' ability to manage uncertainty.

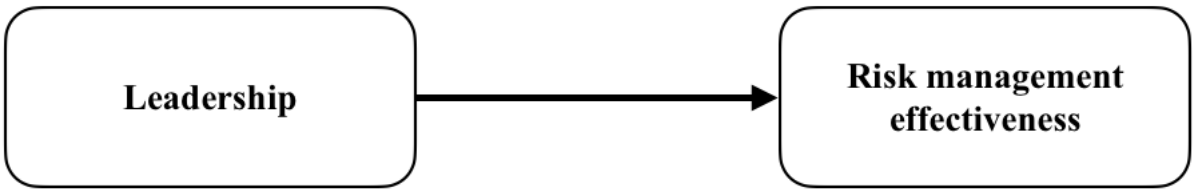
2.3. The relationship between leadership and risk management effectiveness

Every decision a leader makes involves a degree of risk (Fourie, 2022). Effective leadership requires the ability to assess, navigate, and respond to uncertainty while aligning risk management with the organization's strategic objectives (Fourie, 2022). Leaders must clearly prioritize risk management to ensure that risk-aware decision-making becomes embedded within the corporate culture (Rodríguez & Ortis, 2022). By definition, leaders are risk-takers (Rodríguez & Ortis, 2022). Leadership involves guiding an organization through change and uncertainty with no absolute guarantee of success, relying on foresight, strategic planning, and resilience to achieve favorable outcomes (Forbes, 2023). In this sense, risk and leadership are intrinsically linked: without risk, there is no leadership (Forbes, 2023). In industries with high regulatory and operational complexity, such as the pharmaceutical sector, leadership must ensure structured risk governance to prevent unmanaged exposure that could threaten the organization's long-term sustainability (Henderson, 2023). The objective of this section is to demonstrate that the effectiveness of risk management in the pharmaceutical industry is profoundly influenced by the quality of leadership overseeing it. High-intensity rivalry markets, changing consumer behaviors and preferences, impacts of climate change, disruptive technological changes, natural and man-made disasters, geopolitics turmoil (such as the war between Russia and Ukraine), and health crises such as the COVID-19 pandemic are among the critical adversities that increase the risks to be managed by companies, threatening their future well-being (Lisdiono et al., 2022). These unforeseen events have strengthened the importance placed by business executives on

the concept of developing corporate resilience (Cheema-Fox et al., 2021). Enterprises should adjust to constantly changing environmental and market conditions or definitely perish (Lisdiono et al., 2022). A resilient enterprise is one that tries to foresee proactively and repeatedly adapt to whatever uncertain changes present by incorporating risk management activities to develop resilience into the firm's overall strategies (Lisdiono et al., 2022). It is critical for enterprises to shift from a reactive strategy based on prevention measures to a proactive strategy based on a set of activities able to support everyday operational and financial needs effectively (Lisdiono et al., 2022). Enterprises must create a systematic and proactive risk management approach to achieve resilience and sustainable long-term value creation. Empirical research demonstrates that risk management plays a critical role in defining an enterprise's resilience (Lisdiono et al., 2022). Firms should make every effort to incorporate resilience into their operations in a way that benefits them in normal times as well as in the face of unpredictable threats or disruptive changes (Lisdiono et al., 2022). The 2019 health crisis of pandemic COVID-19 showed how it is essential for leadership to improve preparation and planning for major risks and disruptions, in order to be resilient to compete and stay sustainably in the business (Lisdiono et al., 2022). Despite this, many companies fail to take the necessary steps toward resilience by not integrating proactive risk management frameworks into their corporate strategy (Cheema-Fox et al., 2021). *Risk management is now more focused on managing extreme uncertainty, the risk associated with the unknown of unknown* (Lisdiono et al., 2022; Cheema-Fox et al., 2021). Leadership is the executive power that enables a company to be resilient, through the development of the most suitable and effective risk management approach. According to Lisdiono et al. (2022), top management teams are the critical component for fostering enterprise resilience and ensuring effective risk management. Leaders guide the management team in identifying the risks each organization faces, directing mitigation efforts, and seizing opportunities in challenging times by shifting risks into opportunities (Lisdiono et al., 2022). Effective leadership promotes proactive risk management to assist companies in thriving in VUCA settings and building long-term corporate resilience (Cheema-Fox et al., 2021). The relationship between leadership and risk management effectiveness is strong, especially during difficult crises times (Lisdiono et al., 2022). During unpredictable external shocks that lead to corporate crises, such as the COVID-19 pandemic, the entire organization relies on the leader to take the appropriate action that will protect them all (Lisdiono et al., 2022). A crisis is a situation that cannot be predicted, that threatens the business existence and needs urgent and unconventional risk management practices adopted by effective leadership (Fourie, 2022). One of the main responsibilities of an effective leader is being able to manage and mitigate the uncertainties and threats stemming from crises (Anwar, 2017). It is essential to recognize that crises create crucial opportunities in which a leader has the chance to reform and improve the corporate risk management strategy and long-standing policies (Anwar, 2017). For this reason, a strong leader is able to motivate the organization to effectively manage uncertain risks, enabling the company to navigate through difficult times and return to normal or better conditions (Fourie, 2022). In conclusion, there is a direct and significant relationship between leadership and risk management effectiveness, given that without effective

leadership every company would struggle in building a resilient risk management strategy, which involves the constant and systematic recognition, evaluation, control, and mitigation of risks (Anwar, 2017). While leadership plays a crucial role in risk management across all industries, its importance is even more pronounced in highly regulated and life-critical sectors such as pharmaceuticals (Henderson, 2023). The pharmaceutical industry operates in a complex risk landscape characterized by stringent regulatory requirements, expensive R&D investments, and critical ethical responsibilities (Brusco et al., 2011). Given the industry's direct impact on public health, leaders must navigate evolving and industry-specific risks, from supply chain disruptions to compliance risks, ensuring both business continuity and patient safety (Brusco et al., 2011). The COVID-19 pandemic underscored the necessity of resilient and adaptive leadership in the pharmaceutical sector, demonstrating how effective decision-making of leadership can determine the companies' ability to withstand external shocks and secure long-term sustainability (Timmis & Brüssow, 2020). A McKinsey analysis (pre-COVID) noted that many pharma companies felt ill-prepared in risk management and not sufficiently "action oriented" or far-reaching in their risk analysis (Dhankhar et al., 2018). COVID-19 proved this point: pharma companies with narrow, peacetime-focused risk management struggled to respond to the unprecedented scale of the pandemic (Dhankhar et al., 2018). Conversely, firms that embraced an enterprise risk management mindset could rapidly shift strategies (for example, some diverted R&D resources to COVID treatments or rearranged clinical trial priorities without jeopardizing their core business) (Dhankhar et al., 2018). As established in section 2.1, pharmaceutical firms are exposed to a broad spectrum of risks, including supplier risks, operational risks, financial instability, market uncertainties, logistical vulnerabilities, regulatory pressures, technological disruptions, and environmental sustainability challenges. The multifaceted and interdependent nature of these risks underscores the necessity for leadership that is not only competent in risk governance but also capable of integrating diverse leadership styles to address evolving industry-specific risks effectively. As established in section 1.4, no single leadership style can fully address the complexities of risk management in the pharmaceutical sector. Instead, effective risk management necessitates a hybrid approach that strategically combines *transformational*, *transactional*, *strategic*, *visionary*, *bureaucratic*, *collaborative*, and *situational* leadership styles (Parsity Group, 2023). Leaders exhibiting transformational qualities inspire cross-functional teams to embrace innovation, particularly in R&D and digital transformation, while embedding ethical responsibility in risk governance (Spanu, 2024). The development and deployment of COVID-19 vaccines exemplify how transformational leadership enabled pharmaceutical firms to navigate an unprecedented global crisis by aligning scientific innovation with public health priorities (Aydogdu & Asikgil, 2011). Transactional leaders reinforce a risk-averse corporate culture by ensuring strict adherence to Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), and Good Laboratory Practices (GLP), thereby minimizing regulatory violations and operational inefficiencies (Henderson, 2023). Strategic leaders enable firms to anticipate risks and implement resilient mitigation strategies (Parsity Group, 2023). For instance, during the COVID-19 pandemic, strategic leadership allowed pharmaceutical firms to swiftly adapt supply chain

operations and regulatory compliance procedures to sustain drug availability while ensuring corporate integrity (Cavaliere et al., 2021). The analysis of pharmaceutical risks in Section 2.1 reveals that leadership effectiveness is a decisive factor in determining a firm's ability to navigate uncertainty and build long-term corporate resilience. **Supplier risks**, for example, require **strategic leadership** to diversify sourcing strategies and implement financial risk models for supplier creditworthiness. **Operational risks** demand **bureaucratic and collaborative leadership** to ensure compliance with quality standards while fostering team cohesion in manufacturing and R&D operations. **Financial risks** necessitate **transactional leadership** to maintain cost discipline, while **market risks** require **visionary leadership** to anticipate consumer behavior shifts and competitive threats. Similarly, **regulatory risks** underscore the necessity of **strategic and bureaucratic leadership**, as pharmaceutical firms must proactively engage with policymakers while ensuring seamless compliance with evolving international standards. **Technological risks** demand **transformational and collaborative leadership** to drive digital transformation initiatives while mitigating cybersecurity threats and IT system inefficiencies. Finally, **environmental risks** call for **ethical and visionary leadership** to embed sustainability principles into corporate decision-making and align business strategies with Environmental, Social, and Governance (ESG) priorities. Firms that fail to cultivate leadership capable of embedding risk governance into corporate strategy will struggle to achieve long-term sustainability and resilience. By contrast, organizations that foster adaptive and diverse leadership styles will be better positioned to navigate uncertainty, secure regulatory compliance, drive innovation, and maintain public trust in an industry where risk management is not merely a corporate function but a fundamental determinant of business continuity and societal well-being. In conclusion, the effectiveness of risk management strategies largely depends on leadership's ability to foresee risks, develop adaptive responses, and foster a risk-aware culture within the organization (Fourie, 2022).



2.4. Gender-based differences on risk taking, decision-making and strategic risk management

Having identified the most critical risks in the pharmaceutical sector, examined the risk management strategies adopted by pharmaceutical companies, and established the crucial role of leadership as a determinant of risk management effectiveness, this section aims to analyze gender-based differences in risk taking, decision-making, and strategic risk management. The objective is to determine whether measurable differences exist between male and female leaders in the way they assess, respond to, and mitigate risks within the pharmaceutical industry. Research on gender is frequently incorporated within the broader field of diversity studies (Perryman et al., 2015). Diversity, in its broadest sense, can be defined as "*any meaningful distinction that differentiates one person from another*" (Kreitz, 2008). Research on gender diversity argue

that the inclusion of varied perspectives from underrepresented groups enhances decision-making quality, as these differing viewpoints encourage the consideration of less obvious alternatives (McLeod & Lobel, 1992). This cognitive variety is particularly valuable in evaluating novel and uncertain scenarios (Perryman et al., 2015). Overall, heterogeneity in decision-making and problem-solving approaches fosters superior outcomes by incorporating a wider array of viewpoints and enabling a more exhaustive and critical evaluation of strategic issues (Perryman et al., 2015). This aspect is particularly significant in light of upper echelons theory, which posits that senior executives play a fundamental role in shaping a firm's strategic direction (Hambrick, 2007). Prior studies suggest that managerial attributes significantly affect corporate decision-making and overall performance (Finkelstein & Hambrick, 1989). In this context, gender diversity—is closely linked to cognitive diversity (McLeod & Lobel, 1992). Existing literature suggests that female leaders may perceive risks differently and propose distinct solutions compared to their male counterparts (Dutton & Duncan, 1987). Consequently, increasing the representation of women in executive roles can serve as a mechanism to expand a firm's cognitive resources, improving its capacity to identify strategic opportunities, generate alternative solutions, and respond effectively to external changes (Wiersema & Bantel, 1992). The presence of top managers with varied interpretations of complex environments—both within the organization and in its external surroundings—enables more nuanced decision-making (Perryman et al., 2015). The same reality can be perceived in different yet complementary ways by leaders with diverse backgrounds, allowing them to collaborate efficiently without necessarily needing to resolve underlying interpretative ambiguities (Weick, 1995). In this regard, gender diversity may facilitate the alignment of executive teams toward shared objectives and decision-making, even when members operate with differing perspectives (Perryman et al., 2015). Although theories such as upper echelons theory and sense-making provide insight into how managerial decisions impact organizational performance, they do not directly address how risk attitudes—whether a preference for risk-taking or risk aversion—influence these decisions (Perryman et al., 2015). Risk behavior is a crucial aspect of both human psychology and economic decision-making, given that most financial and business interactions inherently involve some level of risk. One approach to theories of risk taking is to attempt to explain the differences between situations that promote risk-taking versus risk aversion (Perryman et al., 2015). Prospect theory is a behavioral theory that removes the assumption that individuals are universally rational, utility-maximizing decision makers. Instead, it emphasizes how decision-making is shaped by the way outcomes are framed (Kahneman & Tversky, 1979). According to this theory, the framing of expected performance outcomes is such that individuals are presumed more risk averse when prospects are positive and risk seeking when prospects are negative (Perryman et al., 2015). In a business context, this translates to high performance associated with risk aversion and poor performance with risk seeking, making for a *negative risk-return relationship* known as Bowman's paradox (Bowman, 1980; Perryman et al., 2015). With respect to gender diversity, there is no universal agreement on its effects in strategic and competitive environments (Perryman et al., 2015). However, a substantial body of research consistently finds gender-based differences in risk-taking behaviors

across various domains, such as participation in lotteries, consumption-related decisions, and social dilemmas (Wester et al., 2024). This empirical evidence has led to the prevailing assumption that gender influences strategic choices and consequently corporate outcomes, particularly in relation to risk preferences and attitudes (Wester et al., 2024). Specifically, research on gender differences has frequently suggested that women exhibit a greater degree of risk aversion compared to men (Charness & Gneezy, 2011; Byrnes et al., 1999). A substantial number of studies have demonstrated that women tend to exhibit more cautious and risk-averse behavior in financial decision-making (Powell & Ansic, 1997; Jianakoplos & Bernasek, 1998; Sunden & Surette, 1998). These findings suggest that women may be more conservative when making investment decisions, favoring strategies that minimize exposure to risk and uncertainty (Palvia et al., 2020). Empirical studies investigating the relationship between gender diversity in leadership and corporate risk-taking suggest that firms led by women may adopt more cautious business strategies, with a lower propensity to engage in high-risk financial activities (Palvia et al., 2020). For instance, research on banking institutions has found that female-led banks tend to exhibit greater financial stability, reflecting a more conservative approach to risk management (Palvia et al., 2020). Building on these findings, the implications of gender-based differences in risk-taking become particularly relevant when applied to the pharmaceutical industry, a sector characterized by significant financial commitments in research and development (R&D), where the probability of success is low, and the returns on investment are often realized over an extended period (Schuhmacher et al., 2021). In this environment, strategic decision-making under uncertainty is crucial, and the risk attitude and preferences of senior executives can substantially influence a company's long-term resilience and performance (Perryman et al., 2015). Given the well-documented association between female leadership and conservative financial decision-making (Palvia et al., 2020), the presence of women in executive roles within the pharmaceutical sector could lead to more measured risk-taking approaches, thereby prioritizing risk mitigation strategies that align with long-term sustainability over short-term profit maximization (Byrnes et al., 1999). The influence of leadership style on decision-making and risk management in the pharmaceutical industry cannot be examined without addressing the distinct traits associated with male and female executives. Traditional leadership models, historically shaped by masculine attributes, have long emphasized structured, transactional, and directive management approaches (Nanjundeswaraswamy et al., 2024), which align with the high-risk, high-reward nature of pharmaceutical R&D. Conversely, emerging research highlights the increasing relevance of feminine leadership attributes, which prioritize collaboration, inclusivity, and transformational leadership (Claes, 1999; Bass, 1990; Avolio et al., 1999). As analyzed in the literature on gender-based differences in leadership within section 1.5, it is possible to distinguish the specific traits that define male and female leadership styles, and these characteristics profoundly shape how decision-making and strategic risk management are approached within the pharmaceutical sector (Appelbaum et al., 2003; Henderson, 2023). Male leadership is traditionally characterized by structure, transactional relationships, autocratic decision-making, instruction-driven communication, and a business-oriented approach (Appelbaum et al., 2003). These attributes align with a

leadership style that emphasize authority, efficiency, and hierarchical control (Nanjundeswaraswamy et al., 2024). Male leaders tend to prioritize well-defined structures and clear chains of command within an organization (Appelbaum et al., 2003). This preference for rigid hierarchical frameworks is particularly relevant in pharmaceutical firms, where corporate governance and compliance with industry regulations require highly structured processes (Henderson, 2023). By emphasizing strict procedural oversight and disciplined execution, male leaders ensure operational efficiency and regulatory adherence. However, this rigid approach can sometimes limit flexibility in navigating unforeseen risks, particularly in areas such as drug development, where adaptive strategies are essential (Schuhmacher et al., 2021). A defining feature of male leadership is its transactional nature, in which leaders focus on goal-setting, performance-based rewards, and clear accountability (Bass, 1990). This results in an outcome-oriented leadership style that prioritizes measurable performance indicators (Appelbaum et al., 2003). Within the pharmaceutical industry, this approach translates into strict evaluation of R&D productivity, cost efficiency, and revenue generation. Male executives may adopt aggressive performance targets for drug development, pushing teams to meet regulatory milestones and product launch deadlines. While this strategy can enhance efficiency and ensure accountability, it may also pressure teams into prioritizing short-term gains over long-term innovation (Burke & Collins, 2001; Byrnes et al., 1999). Male leaders often exhibit a more autocratic approach to decision-making, favoring centralized control and directive leadership (Appelbaum et al., 2003). This trait is particularly relevant in high-risk industries such as pharmaceuticals, where complex regulatory environments and high-stakes investments necessitate decisive leadership. Autocratic executives may excel in crisis management, particularly when swift action is required to address regulatory scrutiny, market fluctuations, or drug safety concerns (Fener & Cevik, 2015). However, this style may hinder open dialogue and collaborative problem-solving, limiting the potential for innovative risk management strategies. Male leaders tend to engage in directive communication, providing clear instructions and expectations to subordinates (Appelbaum et al., 2003). This style ensures that strategic objectives are executed with precision and efficiency, which is essential in regulatory compliance and pharmaceutical manufacturing. However, this top-down communication model may create barriers to information sharing, reducing the likelihood that diverse perspectives—particularly from research teams, regulatory advisors, and patient advocacy groups—are fully integrated into decision-making. Male executives typically adopt a business-oriented leadership style, focusing on financial performance, market expansion, and competitive positioning (Appelbaum et al., 2003). In the pharmaceutical sector, this translates into bold investment decisions, such as large-scale acquisitions, aggressive R&D funding for novel drug development, and high-risk market entry strategies (Schuhmacher et al., 2021). While these decisions can drive significant growth, they also expose firms to greater financial volatility. In contrast to male leadership, female leadership is often defined by transformational leadership principles, participative decision-making, socio-expressive management styles, and a people-oriented approach (Appelbaum et al., 2003). These attributes foster a leadership style that emphasizes collaboration, stakeholder engagement, and sustainable growth (Claes, 1999; Avolio et al.,

1999). Female leaders tend to exhibit a higher degree of consideration for employees, stakeholders, and external partners (Spanu, 2024). This people-oriented leadership style aligns with the pharmaceutical industry's increasing emphasis on ethical business practices, patient-centric innovation, and corporate social responsibility (Tetteh et al., 2023). Female executives are more likely to integrate patient advocacy perspectives into strategic decisions, ensuring that drug pricing, accessibility, and long-term health impacts are factored into corporate strategies (Ozdenerol et al., 2023). Women in leadership roles frequently adopt transformational leadership styles, inspiring teams through vision, motivation, and personal engagement (Bass, 1990; Avolio et al., 1999; Stempel et al., 2015). This approach is particularly relevant in pharmaceutical R&D, where fostering creativity, scientific collaboration, and long-term innovation is essential (Sharma et al., 2023). Female leaders may encourage cross-functional teams to explore innovative treatment solutions while maintaining ethical considerations and sustainability (Stempel et al., 2015). Unlike transactional leaders who emphasize immediate performance targets, transformational leaders focus on creating a long-term strategic vision (Avolio et al., 1999; Khan, 2024) that balances financial returns with patient welfare and regulatory responsibility. A critical distinction between male and female leadership styles is the participative nature of decision-making (Appelbaum et al., 2003). Female executives are more likely to adopt inclusive leadership models that encourage input from diverse stakeholders, including scientists, regulatory experts, investors, and patient representatives (Hare et al., 1997). Within pharmaceutical firms, this participative approach enhances strategic risk management by ensuring that multiple perspectives inform corporate decisions. By promoting open discussions and diverse viewpoints, female leaders can mitigate blind spots in risk assessment and ensure that long-term sustainability is prioritized (Palvia et al., 2020). Socio-expressive leadership, often associated with female executives, emphasizes empathy, emotional intelligence, and ethical responsibility (Kabacoff, 1998). In the pharmaceutical industry, this trait manifests in a stronger commitment to corporate transparency, regulatory compliance, and ethical drug development. Female leaders may be more inclined to implement rigorous internal oversight mechanisms to prevent issues such as drug safety scandals, unethical marketing practices, or regulatory breaches (Blais & Weber, 2001). This emphasis on ethical governance reduces reputational risks and enhances public trust, a critical asset in the healthcare sector (Sharma et al., 2023). Female executives typically adopt a people-oriented approach that prioritizes employee well-being, corporate culture, and leadership development (Appelbaum et al., 2003). Within pharmaceutical companies, this translates into greater investment in talent retention, workforce diversity, and employee engagement initiatives. Studies suggest that firms led by female executives tend to have lower employee turnover rates and higher job satisfaction levels, which contribute to more stable organizational performance (Appelbaum et al., 2003). Additionally, this leadership style fosters sustainable growth, as it balances financial performance with long-term human capital development and social impact.

Gender-based leadership differences

	Male leadership	Female leadership
Leadership style	Transactional, goal-oriented, and performance-driven	Transformational, fostering collaboration and long-term vision
Risk-taking behavior	Higher risk tolerance, favoring bold financial and strategic moves	More risk-averse, prioritizing sustainable and stable strategies
Decision-making approach	Hierarchical, centralized decision-making with strong top-down control	Participative, inclusive decision-making with diverse stakeholder input
Communication	Directive, instruction-giving, and focused on efficiency	Open, participatory, emphasizing emotional intelligence and team cohesion
Strategic orientation	Business-oriented, prioritizing financial growth and competitive advantage	People-oriented, integrating ethical, social, and regulatory considerations
Ethical governance	Emphasizes corporate growth over ethical considerations	Prioritizes transparency, corporate responsibility, and ethical leadership
Investment strategy	Prefers high-risk, high-reward investments such as M&As and aggressive R&D funding	Favors stable, long-term investments with lower financial volatility

2.5. Female leadership as a driver of risk-adjusted decision-making and ESG-oriented strategies in pharma

Having established that gender differences influence risk-taking behaviors, decision-making styles, and strategic risk management approaches, it is now necessary to transition towards the core variable of this research: female leadership. In Section 2.4, we explored the primary differences in risk management approaches that distinguish male and female leadership. The analysis revealed that male leadership is traditionally characterized by a transactional, performance-driven approach that prioritizes high-risk, high-reward strategies, centralized decision-making, and aggressive financial expansion. Male executives tend to favor bold capital allocation strategies, including leveraged acquisitions and speculative investments, often prioritizing short-term profitability over long-term stability. Risk management within male-led organizations is therefore shaped by hierarchical structures, where decision-making authority is concentrated at the executive level, limiting stakeholder input and alternative perspectives. While this approach can accelerate corporate growth, it also heightens exposure to financial volatility and reputational risks. Conversely, female

leadership is associated with transformational traits, emphasizing collaborative decision-making, ethical accountability, and stakeholder inclusivity. Female executives display greater risk awareness, adopting measured investment strategies that balance corporate expansion with financial prudence. Their leadership style is inherently participatory, integrating diverse perspectives into risk governance frameworks, which fosters adaptability in uncertain environments. Furthermore, female-led firms exhibit stronger regulatory compliance, lower financial volatility, and enhanced corporate transparency, demonstrating a more sustainable and resilient approach to strategic risk management. These characteristics are particularly relevant in industries where regulatory oversight, long investment cycles, and ethical considerations dictate corporate strategy, as is the case in the pharmaceutical sector. Building upon these findings, the objective of this section is to demonstrate the strategic necessity of increasing female representation in leadership roles, particularly as a mechanism for enhancing the implementation of ESG-driven corporate strategies in the pharmaceutical industry. The implementation of a sustainability strategy and the transformation of business models through an ESG-oriented approach have become strategic imperatives across all industries. As environmental risk reaches unprecedented levels, it is no longer a peripheral concern but a fundamental factor shaping corporate governance, investment strategies, and long-term viability. The pharmaceutical sector is characterized by heightened environmental risk, as outlined in Section 2.1. The industry's reliance on resource-intensive production processes, chemical waste disposal, and global supply chain dependencies amplifies its ecological footprint, making environmental sustainability a critical component of corporate risk management. Regulatory bodies, institutional investors, and civil society increasingly demand greater accountability and proactive measures to mitigate environmental damage, reinforcing the necessity of ESG integration at every stage of pharmaceutical operations. Within this context, the objective of this research is to highlight the unique contributions of female leadership in advancing risk-adjusted decision-making and the development of ESG-driven strategies. Gender socialization theory suggests that women are more concerned with the welfare of stakeholders, making them more likely to take action to preempt environmental risks that can harm communities (Carlson, 1972; Adams et al., 2007; Gilligan, 2024; Liu, 2018). According to diversity theory, female directors bring different perspectives and offer a wider range of eco-friendly solutions, which improves board decision-making on environmental risks (Erhardt et al., 2003; Westphal and Bednar, 2005; Cumming et al., 2015; Liu, 2018). Finally, academic studies show that women executives and directors are less overconfident and more likely to seek expert advice than their male counterparts (Huang and Kisgen, 2012; Levi et al., 2012; Liu, 2018); both traits are expected to reduce firms' exposure to environmental risks. According to Albitar et al. (2023), better commitment to climate change is realized when a firm implements new practices to prevent or reduce environmental damage. As the firm's primary governance body, corporate boards are responsible for formulating strategies that mitigate stakeholders' concerns, including climate actions (Hill and Jones, 1992). The diversity of the board of directors is an important influence on the firm's decision-making (Prado-Lorenzo and Garcia-Sanchez, 2010), as it brings different knowledge spheres, perspectives, and experiences, leading to robust

deliberations before reaching decisions (Post et al., 2011; Liao et al., 2015). More importantly, existing literature indicates that women directors are more compassionate about environmental matters, and firms with gender-diverse boards put more stress on corporate social responsibility (CSR) (Shaukat et al., 2016; Liu, 2018). Moreover, environmental sociologists have found that women directors are more likely to adopt pro-environmental behavior and tackle environmental issues to enhance ecological protection (McCright and Xiao, 2014). These actions of female leaders demonstrate their social responsiveness by answering stakeholders' calls regarding greater climate actions (Nuber and Velte, 2021). To understand why women directors are more likely to implement ESG policies within pharmaceutical companies' risk management strategies, gender social role theory (Dawson, 1997) underlines the extent to which men and women are behaviorally different: women are inclined to hold different points of view and behave differently when facing dilemma situations. Indeed, psychology and behavioral economics studies reveal that women are not as overconfident and experience higher levels of risk aversion while having an increased likelihood of conforming to regulations and rules (Borghans et al., 2009; Ittonen et al., 2013). Furthermore, women are expected to focus on communal traits while men mainly concentrate on agentic traits (Eagly and Sczesny, 2009). Specifically, women tend to be more careful, submissive, compassionate, and attentive to the well-being of others (Cook and Glass, 2016). Women focus on social welfare, while men focus on personal achievement, status, and power (Carlson, 1972; Eagly & Johnson, 1990; Eagly & Carly, 2007). A growing body of behavioral, psychological, and social studies shows substantial gender differences in attitudes toward risky situations, ethics, and values (Beutel and Marini, 1995; Lund, 2007; Zeni et al., 2016). Women are considered to play a preemptive role in pro-social decision-making, especially regarding environmental policies (Nielsen and Huse, 2010). Business management literature concurs that women leaders are more dedicated to ethical and socially responsible behavior (Bear et al., 2010) and are more likely to take measures to decrease risks that firms face (Schubert et al., 1999; Carter et al., 2003; Adams & Ferreira, 2009). More importantly, women directors are likely to be more concerned regarding the environmental impact of business operations (Bear et al., 2010; Nekhili et al., 2017), which results in fewer environmental lawsuits (Liu, 2018). Boulouta (2013) supports the ethical behavior and caring nature of women directors by documenting that women directors are inclined to decrease environmentally harmful business practices. Owing to their psychological and behavioral differences, women directors bring qualities to boards that substantially influence boards' decisions and policies (Gul et al., 2013; Cook and Glass, 2016). Some studies document that women directors are vital in constraining opaque decisions and managerial opportunism (Cumming et al., 2015; Lara et al., 2017; Srinidhi et al., 2011), thereby protecting stakeholders' interests, and prioritizing ESG performance. For instance, Adams and Ferreira (2009) suggest that female directors positively impact firm performance, especially when governance is weak. Based on the reviewed literature, we expect that women directors are more likely to scrutinize non-transparent environmental practices and engage in more effective ethical corporate initiatives, demonstrating firms' strong commitment to climate actions with the implementation of an ESG-driven risk management strategy. Indeed, prior research suggests

that women directors have a lower tolerance of unethical practices than their male counterparts (Galbreath, 2016; Abebe and Dadanlar, 2021) and are more sensitive to ethical aspects in corporate settings (Cohen et al., 1998). Adam and Funk (2011) argue that women's decisions are generally more stakeholder-oriented. As such, based on their ethical behaviors, women board members could discourage systematic environmental violations and engage in ESG practices that make a real difference in climate change in line with stakeholders' demands (Galbreath, 2016). This, in turn, suggests that women directors are more likely to focus on risk management strategies that increase firms' commitment to ESG performance to reduce the negative impact of business operations on the environment and society at large (Liu, 2018). The findings discussed in this section provide substantial evidence that female directors may exhibit a stronger propensity for ESG-driven risk management strategies compared to their male counterparts. Their emphasis on ethical corporate governance, regulatory compliance, and long-term sustainability aligns closely with the increasing prioritization of environmental, social, and governance (ESG) factors in the pharmaceutical industry. Given the sector's inherent exposure to regulatory risks, operational hazards, and reputational vulnerabilities, these risk-sensitive characteristics associated with female leadership could represent a strategic advantage for pharmaceutical companies seeking to enhance their ESG performance and mitigate firm-level uncertainties. While the existing literature strongly supports the argument that ethical orientation, risk awareness and transformational female leadership enhances ESG-driven risk management strategies, there is still a critical lack of its empirical validation within the pharmaceutical industry. In the next chapter, the main objective of the research is to determine in an empirical setting to what extent a higher representation of women in executive positions within Italian pharmaceutical companies can be associated with an improvement of risk management strategies and ESG performance. Specifically, Chapter 3 will explore whether and how it is possible to find a positive and reliable relationship between female leadership and risk management effectiveness within Italian pharmaceutical companies, with the aim of assessing whether companies with a higher proportion of female executives exhibit stronger risk mitigation capabilities, improved regulatory compliance, and greater corporate sustainability.

Chapter 3 – Empirical analysis: the impact of female leadership on risk management of Italian pharma companies

3.1. Research framework and hypotheses development

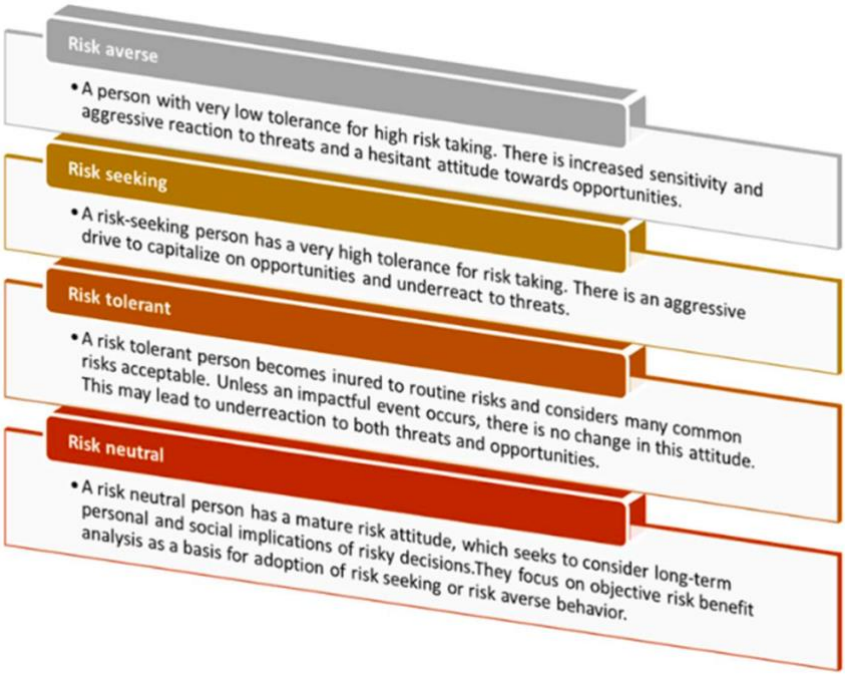
This empirical analysis seeks to investigate the relationship between female leadership and risk management within the Italian pharmaceutical industry. Building on the theoretical analysis from previous chapters, this section establishes the research framework that guides the empirical investigation. While the connection between gender diversity in leadership and corporate risk management has been explored in other highly regulated sectors, no prior studies have empirically examined this relationship within the pharmaceutical industry. For instance, existing literature has demonstrated that banks led by female executives tend to adopt more conservative financial policies, exhibit lower risk exposure, and achieve greater financial stability over

the long term (Palvia et al., 2020). Given the highly regulated nature of the pharmaceutical industry and its exposure to financial and operational risks, it is reasonable to hypothesize that similar dynamics may exist in this sector. Building upon the theoretical findings of Chapter 1 and 2, a significant number of empirical studies support the idea that female executives are associated with transformational leadership traits, while male executives typically adopt a transactional leadership style (Carli & Eagly, 2016). According to Bass (1990), on a macro level, the leadership style can either be transformational or transactional (Moon, 2020). The **transformational leader** is more inspirational, empathetic, motivating, adaptive and fits into the *affiliative*, *visionary*, *democratic*, *pacesetting* and *coaching leadership styles* described by Goleman (2000). The *commanding* or *coercive* leadership style on the other hand, is a bipolar **transactional style** which promises rewards for good behavior and punishment for poor performance (Goleman, 2000; Carli & Eagly, 2016). In addition, consistent literature on gender-based differences about ESG risk perceptions and attitude towards sustainability demonstrates that women executives are more likely to implement ESG considerations in their strategic decision-making, thereby prioritizing sustainable risk management over profit-seeking business-oriented risk management (Palvia et al., 2020; Byrnes et al., 1999; Abebe and Dadanlar, 2021). On the contrary, transactional leadership style of men executives prioritizes autocratic performance-driven decision-making and a business-oriented profit-seeking strategic orientation over ESG risk management priorities (Appelbaum et al., 2003). Building on these theoretical considerations, the main objective of this research is to empirically assess to what extent in the Italian pharmaceutical sector:

1. Female leaders adopt a transformational leadership style and are more likely to focus on risk management strategies that increase firms' commitment to ESG performance to reduce the negative impact of pharmaceutical business operations on the environment and society at large;
2. Male leaders adopt a transactional leadership style and are more likely to focus on profit-seeking business-oriented risk management strategies and less focused on ESG priorities.

Risk management in the pharmaceutical industry is increasingly contingent upon the extent to which companies successfully integrate ESG considerations into their core business activities. Given the heightened regulatory scrutiny, stakeholder expectations, and environmental and social implications inherent in pharmaceutical companies' operations, ESG-oriented risk management has become pivotal for firms striving to achieve sustainable growth and maintain competitive advantage. Building upon the risk categorization established by the literature review in Chapter 2—encompassing supplier, operational, financial, demand, logistical, political, and technology-related risks—this study explicitly defines risk management in the pharmaceutical industry as a dependent variable along two distinct but complementary dimensions: ESG-oriented risk management and business-oriented risk management. Each of the eight fundamental risk categories is systematically evaluated according to both dimensions based on their primary strategic implications for pharmaceutical companies. Each risk category is recognized as containing subcomponents that may be addressed through both ESG-oriented and business-oriented risk management approaches. ESG-oriented risk management is defined as the strategic commitment to mitigating risks

through long-term sustainability, ethical responsibility, regulatory compliance, and stakeholder engagement. Conversely, business-oriented risk management refers to strategies that prioritize short-term operational efficiency, profit maximization, market responsiveness, and technological competitiveness. By examining how leaders respond to each risk category from both ESG and business standpoints, the analysis allows for a more comprehensive understanding of how gender-based differences in leadership style influence the integration—or tension—between sustainability objectives and performance-driven imperatives in risk management practices. In order to explain how gender-based leadership differences can shape a risk management approach that is more focused on ESG impact of business operations rather than the maximization of the profit and the market share, the present research investigated the existing literature to assess the explanatory variables that can link leadership styles and risk management effectiveness. Research by Moon (2020) investigates the effects and the differences of transformational and transactional leadership styles on risk intelligent decision-making and risk management using two main explanatory variables: emotional intelligence (EI) and risk attitude. Risk attitude is defined as a person or an organization's approach to assess, and eventually pursue, retain, take, or turn away from risk (Moon, 2020). A detailed description of risk attitudes is defined in the following diagram provided by (Moon, 2020):



Empirical findings by Moon (2020) demonstrate that:

1. Transformational leaders have a less perceived bias in critical decision-making than transactional leaders
2. Transformational leaders have mature risk averse or risk neutral attitudes as compared to transactional leaders
3. Transactional leaders are perceived to take risk seeking and less fact/data driven decisions (on a 'hunch') than transformational leaders

Based on these empirical findings, the research framework of this study aims to contribute to Moon (2020) analysis by using the *risk attitude* of pharmaceutical companies as mediating variable of the relationship

between leadership and risk management outcomes. The underlying premise for this choice is that risk attitude, personal preferences, and values of individual top executives and directors strongly influence corporate decisions and outcomes (Palvia et al., 2020). This hypothesis is supported by the upper echelons theory of Hambrick and Mason (1984) and a large body of empirical studies on the impact of individual CEOs, CFOs and board chairs on the business strategies, financial policies, and governance structures of their firms (Hambrick, 2007; Palvia et al., 2020). Many studies show that firms with female executives make more conservative and risk averse financing and investment decisions with respect to the aggressive and risk-seeking approach of male executives (Powell & Ansic, 1997; Jianakoplos & Bernasek, 1998; Sunden & Surette, 1998; Palvia et al., 2020). Hence, the existing empirical evidence suggests that gender-based differences in risk tolerance persist in professional settings among leaders and are strongly reflected in corporate-level outcomes, because the risk attitude of executives is reflected in strategic decision-making, that influences the risk attitude of the organization as a whole and it consequently determines risk management outcomes (Palvia et al., 2020). Since the above-mentioned existing literature supports the hypothesis that women leaders are more likely to adopt a transformational leadership style and also to implement ethical, risk averse and socially responsible corporate risk management strategies with respect to men leaders, that on the other hand are more likely to adopt a transactional leadership style focused on aggressive risk-seeking and profit-oriented risk management strategies, the present research is going to empirically verify whether these findings hold within Italian pharmaceutical companies. The research framework contributes to Moon (2020) empirical findings through the development of the following hypotheses:

- *Hypothesis 1: Female leaders of Italian pharmaceutical companies are more likely to adopt a transformational leadership style that has a positive direct effect on the implementation of ESG-oriented risk management strategies through a risk averse attitude of the organization.*

- *Hypothesis 2: Male leaders of Italian pharmaceutical companies are more likely to adopt a transactional leadership style that has a positive direct effect on the implementation of business-oriented profit-seeking risk management strategies through a risk seeking attitude of the organization.*

The research framework has been adapted from Alrowwad et al. (2020) work on the effect of transformational and transactional leadership styles on organizational performance with innovation and intellectual capital as mediating variables. However, the present research framework is built with the aim of assessing whether there is an existent positive relationship between female transformational leadership (*independent variable*) and the implementation of ESG-oriented risk management strategies (*dependent variable*) through risk averse or risk neutral attitude of pharmaceutical companies (*mediating variable*), as well as the existence of a positive relationship between male transactional leadership (*independent variable*)

and profit-seeking business-oriented risk management strategies (*dependent variable*) through risk seeking or risk tolerant attitude of pharmaceutical companies (*mediating variable*).

3.2. Definition and measurement of variables and research methodology

As outlined by the research framework, the objective of this empirical analysis is to test whether there is a positive and significant relationship between transactional and transformational leadership styles adopted by female and male executives (*independent variable*) of Italian pharmaceutical companies and the implementation of either a business-oriented or ESG-oriented risk management strategies (*dependent variable*), through either a risk averse or risk seeking attitude of pharmaceutical companies (*mediating variable*). In order to test the hypotheses previously stated, it is essential to define the research methodology that will be employed to gather data that will be used in the statistical analysis, as well as how the variables under analysis will be quantified. Following the design of the research framework, the research methodology of the present study aims to carry out a quantitative analysis through the realization of a *Qualtrics survey* (see Appendix for further information) targeting employees of Italian pharmaceutical companies with specific questions aimed at assessing:

1. To what extent the leadership style of their supervisor can be classified as transactional or transformational in relation to his/her gender (*independent variable*)
2. Which is the perceived risk attitude of their supervisor and to which extent it influences the perceived risk attitude of the company (*mediating variable*)

3. Which is the risk management orientation of their supervisor and to what extent it can be classified as business-oriented or ESG-oriented (*dependent variable*)

The survey is designed to collect perceptions and attitudes of employees currently working in pharmaceutical companies operating in Italy regarding three key variables: the leadership style of the supervisor (*independent variable*), the risk attitude promoted within the organization (risk averse vs. risk seeking) (*mediating variable*), and the predominant approach to risk management adopted by the supervisor (business-oriented vs. ESG-oriented) (*dependent variable*). Firstly, a series of control questions about gender, educational level, job position and job tenure will be collected to provide a description of the sample under analysis. Then, a main conditional question about the gender of the supervisor will be submitted to understand and compare the differences between leadership styles (transactional vs. transformational) adopted respectively by men and female supervisors, as well as the differences related to their risk attitude and risk management orientation.

Independent variable: Leadership style based on gender

To quantify the extent to which leadership style adopted by supervisors of Italian pharmaceutical companies can be defined either transactional or transformational, this study will employ a survey-based methodology using a 5-point Likert scale (ranging from 1 = strongly disagree to 5 = strongly agree), following the framework developed by Alrowwad et al. (2020). Given the need to adapt leadership measurement to the specific risk environment of the Italian pharmaceutical sector, survey questions will be tailored to capture the transformational and transactional dimensions of leadership as they manifest in the industry. Prior to assessing employees' perceptions of their supervisor's leadership behaviors, the survey presents a conditional question aimed at identifying the gender of the supervisor. This allows the analysis to explore gender-based differences in the adoption of transformational and transactional leadership styles, with the aim of understanding whether existing findings from the literature—according to which women are more likely to exhibit transformational behaviors and men are more likely to adopt transactional approaches (Eagly & Johannesen-Schmidt, 2001; Carli & Eagly, 2016)—hold true within the Italian pharmaceutical sector. After asking about the gender of the supervisor, the first section of survey focuses on assessing the leadership style of the respondent's direct supervisor. To this end, participants are asked to indicate their level of agreement with a series of statements describing observable leadership behaviors. Specifically, transformational leadership style will be measured through employees' agreement with statements that reflect the extent to which their supervisor:

- Encourages team members to embrace challenges and take initiative when facing operational or strategic decisions;
- Stimulates creative thinking and a problem-solving approach that goes beyond routine task execution;
- Demonstrates confidence, resilience, and a forward-looking vision in managing work and people;

- Supports the continuous development of employees' competencies, with particular focus on coaching and mentoring;
- Actively invests time in transmitting know-how, offering feedback, and strengthening team capabilities.

Conversely, transactional leadership style will be measured through employees' agreement with statements that reflect the extent to which their supervisor:

- Places a strong emphasis on the monitoring of employee performance and adherence to clearly defined procedures and protocols, especially in relation to compliance, quality control, and production standards;
- Provides recognition or rewards in direct response to goal achievement, task execution, or measurable results, often in relation to short-term productivity targets or regulatory milestones;
- Applies corrective actions or sanctions in response to errors, non-compliance, or failure to meet expected standards, with a focus on maintaining discipline and procedural rigor;
- Establishes a structured and hierarchical relationship with subordinates, where communication is primarily directive and centered on task fulfillment rather than strategic alignment or personal development.

Each supervisor, independently of the gender chosen by the respondent, will be evaluated in terms of both transformational and transactional leadership traits, so that it is possible to understand whether it is true that women supervisors score higher in transformational leadership traits and men supervisors score higher in transactional leadership traits.

Mediating variable: Risk attitude

The mediating variable selected for this study is risk attitude, which captures the perceived orientation of the supervisor—and by extension the organization—toward risk-related decisions and strategies. This variable plays a central role in the research framework, as it is hypothesized to act as a channel through which the leadership style (transformational vs. transactional) influences the company's risk management approach (business-oriented vs. ESG-oriented). Besides exploring whether there is a positive direct relationship between leadership style and risk management orientation, the research aims to assess also the indirect effect of leadership style on risk management orientation through the risk attitude promoted within the organization, that according to Moon (2020) can range from risk averse to risk seeking. To quantify this variable, the survey includes a dedicated section in which participants are asked to express their level of agreement with a set of five statements describing observable leadership behaviors that reflect the supervisor's general attitude toward risk, as well as the influence over the risk attitude of the company. These questions are designed to evaluate the extent to which the respondent perceives their supervisor—and consequently the firm—as being:

- Risk averse, defined by a cautious, compliance-driven, and conservative approach to decision-making, often prioritizing regulatory alignment, operational safety, and long-term sustainability over short-term performance;
- Risk seeking, defined by a willingness to pursue opportunities despite uncertainty, with a focus on innovation, speed, and aggressive growth strategies even under conditions of limited information or elevated exposure.

Specifically, the statements included in the questionnaire focus on evaluating whether the supervisor:

- Displays a tolerance for ambiguity and incomplete information when making strategic decisions;
- Tends to favor rapid execution and seizing short-term opportunities over slow, deliberative processes anchored in compliance or safety;
- Minimizes regulatory and reputational constraints when assessing risky strategic alternatives that may lead to competitive advantage;
- Actively encourages employees to challenge internal control systems and risk protocols when proposing new initiatives;
- Promotes a corporate risk culture that frames risk-seeking as a driver of innovation and long-term competitiveness, even at the cost of increased volatility or short-term disruption.

These five items are designed to jointly capture the extent to which the supervisor adopts a risk-seeking or risk-averse orientation, as well as the extent to which the leader influence the overall risk attitude of the organization. Respondents indicate their level of agreement on a 5-point Likert scale, where 1 corresponds to strong agreement with risk-averse attitudes and 5 to strong agreement with risk-seeking attitudes. The final risk attitude index is calculated as the average of the five item scores. Higher average values indicate a more risk-seeking attitude promoted by the supervisor and perceived within the organization, whereas lower values indicate a more risk-averse orientation. This method allows for an integrated evaluation of how leadership style—through its influence on the internal risk culture—can shape the orientation of pharmaceutical companies toward either business-oriented strategies, which tend to tolerate and even encourage higher levels of risk exposure, or ESG-oriented strategies, which are rooted in precautionary, stakeholder-aligned, and compliance-driven risk averse behaviors.

Dependent variable: Risk management

The dependent variable of this study is the risk management orientation promoted by the supervisor—and, by extension, the organization—within Italian pharmaceutical companies. This variable captures the strategic prioritization between two competing yet complementary approaches to corporate risk management: ESG-oriented risk management and business-oriented risk management. Building upon the theoretical framework discussed in Chapters 1 and 2 and following the categorization of risk domains outlined by Sharma et al. (2023), this variable is quantified through the evaluation of eight critical pharmaceutical risk categories: supplier, operational, financial, market/demand, logistical, political/regulatory, technological, and

environmental risks. To measure the extent to which each of these eight risk domains is addressed with a focus on sustainability and stakeholder accountability versus profit-driven and performance-oriented logic, the survey includes a dedicated section composed of sixteen items. For each of the eight risk categories, two complementary statements are presented. One statement reflects an ESG-oriented risk management approach, emphasizing regulatory compliance, ethical responsibility, environmental sustainability, and long-term stakeholder interests. The other reflects a business-oriented approach, highlighting cost efficiency, speed, market expansion, innovation, and short-term profitability. Respondents are asked to rate their level of agreement with each statement using a 5-point Likert scale (ranging from 1 = strongly disagree to 5 = strongly agree), based on their perception of their supervisor's typical behaviors and strategic priorities in relation to each risk category. This dual-structure design allows for a systematic comparison of the perceived strategic direction taken by the supervisor in each specific risk domain. More specifically, the ESG-oriented risk management items focus on the following dimensions:

- Supplier risks: prioritization of partnerships based on sustainability certifications and ethical practices;
- Operational risks: implementation of procedures and training aimed at exceeding compliance thresholds and fostering safe, socially responsible operations;
- Financial risks: promotion of long-term sustainable financial strategies aligned with ESG principles and prudence;
- Market and demand risks: support for ethical pricing, access equity, and value-driven product strategies;
- Logistical risks: integration of green logistics and eco-efficient transport models;
- Political and regulatory risks: proactive adaptation to changing regulations and investment in public health-oriented policy engagement;
- Technological risks: use of technology for ethical monitoring, data security, and supply chain transparency;
- Environmental risks: commitment to pollution prevention, carbon emission reduction, and green supply chain practices.

Conversely, the business-oriented risk management items assess the following dimensions:

- Supplier risks: focus on price-based selection, delivery optimization, and flexibility in switching partners;
- Operational risks: emphasis on lean production models, speed, and output maximization;
- Financial risks: pursuit of high-return investments and performance indicators such as EBITDA and profit margin;
- Market and demand risks: aggressive competition, pricing strategies, and rapid market penetration;
- Logistical risks: prioritization of delivery speed and cost efficiency, including outsourcing;

- Political and regulatory risks: tactical adaptation aimed at minimizing compliance costs and maximizing profitability;
- Technological risks: fast adoption of innovation with little concern for sustainability impact;
- Environmental risks: minimization of environmental costs in favor of operational performance and competitive positioning.

For each respondent, two composite indices are computed:

- An ESG-oriented risk management index, calculated as the average of the eight ESG-focused item scores;
- A business-oriented risk management index, calculated as the average of the eight business-focused item scores.

To determine the supervisor's dominant risk management orientation, a binary variable is then created based on the comparative evaluation of the two indices. This dummy variable takes the value of 0 if the ESG-oriented risk management index exceeds the business-oriented risk management index (i.e., ESG > Business), and 1 if the opposite is true (i.e., Business > ESG). This binary classification allows the study to analyze how gender-based leadership styles and associated risk attitudes influence the probability that a supervisor—and thus the organization—adopts a primarily ESG-oriented versus business-oriented risk management approach across the full spectrum of pharmaceutical risks.

3.3. Data collection

Following the design of the research framework, the process of data collection was implemented through a Qualtrics survey administered to employees currently working in pharmaceutical companies operating in Italy. Given the targeted nature of the sample, the survey was distributed through a snowball sampling approach, starting from a set of personal contacts working in the pharmaceutical sector in Italy. These initial participants were then encouraged to share the survey within their professional network, ensuring that responses were collected exclusively from individuals employed in the Italian pharmaceutical industry. While the sampling method does not follow a probabilistic logic, it was deemed appropriate for the exploratory objectives of the study and allowed for the collection of context-specific data relevant to the research framework. The survey was designed to assess the relationship between the gender of the supervisor, the leadership style adopted, the risk attitude promoted within the organization, and the predominant risk management orientation. Specifically, the questionnaire was structured to measure the three core variables of the study—leadership style (independent variable), risk attitude (mediating variable), and risk management orientation (dependent variable)—through a total of 31 closed-ended items, each evaluated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The first part of the survey consisted of control questions to describe the sample, followed by a conditional question regarding the gender of the respondent's direct supervisor. This conditional item enables the comparative analysis of leadership styles in relation to the supervisor gender, allowing the understanding of whether female supervisor score higher or lower in transformational leadership than transactional leadership, and vice versa

in the case of a male supervisor. The main body of the survey was divided into three sections, one for each core variable under investigation:

1. Leadership style:

Respondents were presented with 10 items aimed at assessing the extent to which their direct supervisor exhibits transformational or transactional leadership traits, as defined in the theoretical framework. Five items were designed to capture transformational leadership behaviors, including vision, empowerment, mentoring, and support for innovation. The other five items assessed transactional leadership behaviors, such as rule enforcement, compliance monitoring, reward-based recognition, and task-centered feedback.

2. Risk attitude:

The second section measured the risk attitude promoted by the supervisor, capturing the extent to which risk-averse or risk-seeking behavior was perceived to dominate the organization's strategic approach. This section included 5 statements that evaluated observable tendencies toward ambiguity tolerance, speed-over-safety logic, disregard for reputational constraints, encouragement to bypass internal controls, and the normalization of bold risk-taking as a cultural trait. Each item was measured using a 5-point Likert scale, where respondents expressed their level of agreement (from 1 = strongly disagree to 5 = strongly agree). The items were explicitly designed such that higher levels of agreement indicate a stronger risk-seeking attitude of the supervisor and the organization, while lower levels of agreement indicate a stronger risk-averse attitude. Therefore, the composite risk attitude index derived from the average of these items for each respondent ranges from 1 (strongly risk-averse) to 5 (strongly risk-seeking), with higher values reflecting greater organizational tolerance for strategic risk exposure.

3. Risk management orientation:

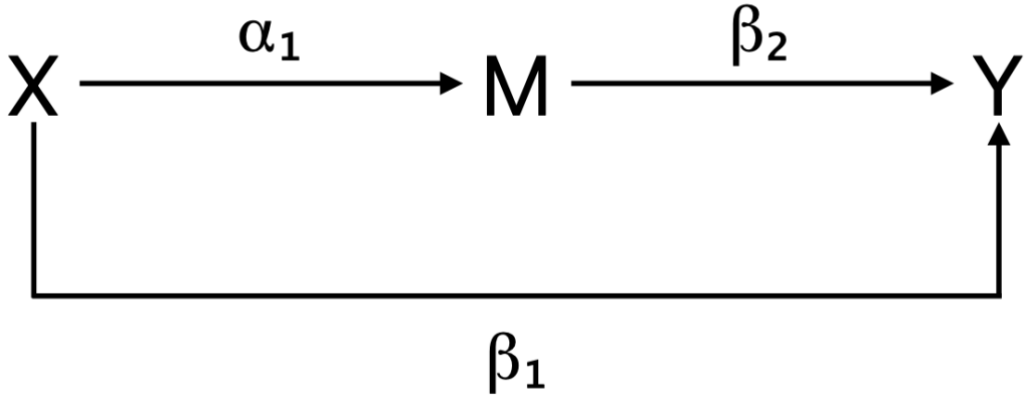
The final section focused on the dependent variable and included 16 items, structured as paired statements—one for ESG-oriented risk management and one for business-oriented risk management—for each of the eight key risk categories identified in Chapter 2 (supplier, operational, financial, market/demand, logistical, political/regulatory, technological, and environmental). This dual-item structure allowed the analysis to capture the respondent's perception of whether their supervisor emphasized sustainability, compliance, and stakeholder interests (ESG-oriented) or cost-efficiency, growth, and performance-driven strategies (business-oriented) in managing each risk category.

This survey design enables the empirical comparison between transformational and transactional leadership styles across male and female supervisors, the mediating role of the risk attitude in shaping organizational behavior, and the prevailing risk management orientation promoted within the firm. For each respondent, three composite indices were calculated:

- A transformational leadership score and a transactional leadership score, based on the average of their respective item sets;
- A risk attitude index, with higher scores reflecting a stronger risk-seeking orientation and lower scores reflecting a risk averse orientation;
- Two risk management indices—ESG-oriented and business-oriented—derived from the average of the eight items aligned with each strategic orientation. A binary variable was then constructed to identify whether a supervisor was perceived to prioritize ESG-oriented (value = 0) or business-oriented (value = 1) risk management, based on which index scored higher.

3.4. Research model

To empirically investigate the direct and indirect effects of gender-based leadership styles on corporate risk management practices, the present study relies on a mediation analysis model developed by Hayes (2012). Specifically, the statistical analysis was carried out by implementing PROCESS, an observed variable OLS and logistic regression path analysis modeling tool widely used through the social, business, and health sciences for estimating direct and indirect effects in single and multiple mediator models (parallel and serial), two and three way interactions in moderation models along with simple slopes and regions of significance for probing interactions, and conditional indirect effects in moderated mediation models with a single or multiple mediators or moderators (Hayes, 2012). This empirical analysis employes Hayes (2012) *PROCESS Model 4: Mediation analysis with multiple mediators* to test whether the relationship between leadership style (**independent variable**, ***X***) and risk management orientation (**dependent variable**, ***Y***) is mediated by the risk attitude promoted within the organization (**mediating variable**, ***M***). Given that the research objective is to analyze the impact of transformational and transactional leadership styles on risk management orientation (ESG-oriented vs. business-oriented), the model will be estimated in two separate versions on Python, in order to clearly isolate the role played by each leadership style. Prior to testing the mediation model, the analysis will first examine the average score of transformational and transactional leadership styles across male and female leaders, based on the conditional question that identifies the gender of the respondent's direct supervisor. This preliminary step will allow us to verify whether female supervisors are more associated with a transformational leadership style and whether male supervisors tend to display higher levels of transactional leadership, in line with existing theoretical assumptions. Following this preliminary test, the mediation analysis will be conducted in two distinct specifications: the first model will consider the transactional leadership style as the independent variable X, while the second will take the transformational leadership style as X. This approach allows the analysis to identify whether and to what extent each leadership style independently contributes to shaping the organization's risk management orientation Y, both directly and indirectly through the mediating effect of the risk attitude M.



Given the above-mentioned measurement framework adopted to quantify each variable, it is essential to provide a specification of the statistical model to better understand how to analyze and interpret results. Formally, the model is expressed through the following pair of regression equations:

Mediation equation:

$$M_i = \alpha_0 + \alpha_1 X_i + \varepsilon_{Mi}$$

Where:

M_i = risk attitude of the company

X_i = leadership style

α_1 = direct effect of leadership style on risk attitude

ε_{Mi} = error term

Since risk attitude is measured on a scale ranging from 1 = strongly risk averse and 5 = strongly risk seeking, the coefficient α_1 is interpreted as follows:

$\alpha_1 > 0$: Leadership style increases risk-seeking behavior

$\alpha_1 < 0$: Leadership style increases risk-averse behavior

Outcome equation:

$$Y_i = \beta_0 + \beta_1 X_i + \beta_2 M_i + \varepsilon_{Yi}$$

Where:

Y_i = risk management orientation (1 = business-oriented; 0 = ESG-oriented)

β_1 = direct effect of leadership style on risk management orientation

β_2 = direct effect of risk attitude on risk management orientation

ε_{Yi} = error term

Since risk management orientation (Y_i) is a binary variable coded as 1 when business-oriented risk management is perceived as dominant and 0 when ESG-oriented risk management is dominant, the regression coefficients are interpreted as directional effects on the likelihood of adopting either a business-

oriented risk management approach or an ESG-oriented risk management approach. In this context, the two main predictors under analysis are the leadership style (X_i) and risk attitude (M_i). A positive coefficient (either β_1 for leadership style or β_2 for risk attitude) indicates that an increase in the predictor is associated with a higher probability that the supervisor adopts a business-oriented risk management approach (i.e., that Y_i = 1). In contrast, a negative coefficient implies that an increase in the predictor is associated with a higher probability of observing an ESG-oriented approach (i.e., that Y_i = 0). For instance, if $\beta_2 > 0$, then a more risk-seeking attitude is associated with a higher likelihood of business-oriented risk management. If $\beta_2 < 0$, then a more risk-averse attitude increases the likelihood of ESG-oriented risk management. Similarly, if $\beta_1 < 0$, the leadership style under examination is directly linked to a higher probability of ESG-oriented risk management; if $\beta_1 > 0$, it instead increases the likelihood of business-oriented risk management. To provide further clarity, the regression coefficients are interpreted as follows:

$\beta_1 > 0$: leadership style directly increases the likelihood of business-oriented risk management

$\beta_1 < 0$: leadership style directly increases the likelihood of ESG-oriented risk management

$\beta_2 > 0$: a more risk-seeking attitude increases the likelihood of business-oriented risk management

$\beta_2 < 0$: a more risk averse attitude increases the likelihood of ESG-oriented risk management

In the end, the *indirect effect* of leadership style on risk management orientation through either a risk averse or risk seeking attitude is calculated as:

$$Indirect\ effect = \alpha_1 \cdot \beta_2$$

Where:
$\alpha_1 =$ indicates how leadership style influences the risk attitude of the supervisor and the organization
and if:
$\alpha_1 > 0$: Leadership style increases risk-seeking behavior
$\alpha_1 < 0$: Leadership style increases risk-averse behavior

$\beta_2 =$ captures how risk attitude influences the risk management orientation

- If the indirect effect is positive, the leadership style encourages risk-seeking attitude of the organization, and this increased risk appetite makes it more likely that the risk management orientation is business-oriented.

- If the indirect effect is negative, the leadership style promotes risk aversion within the organization, which in turn increases the probability of an ESG-oriented risk management approach.

3.5. Explanation of results and limitations of the study

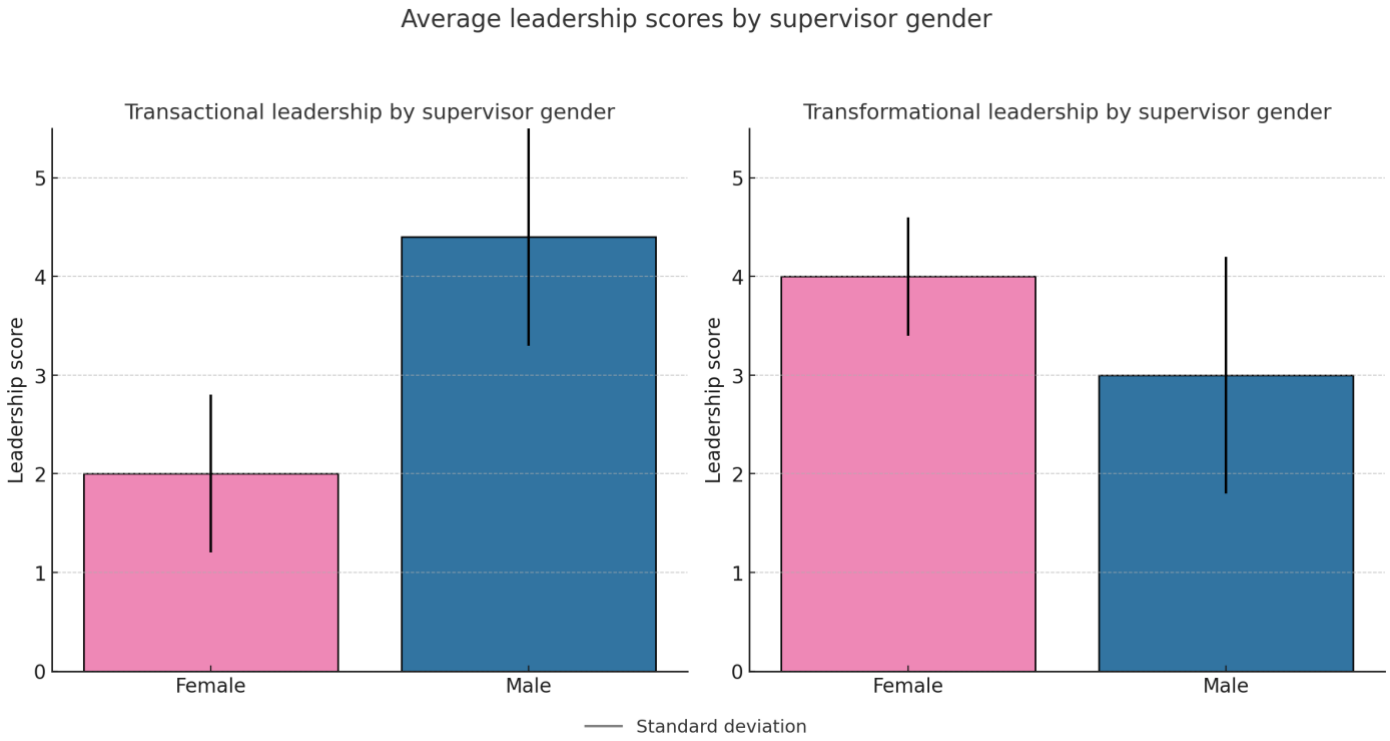
This final section provides a detailed interpretation of the empirical results obtained through the application of the statistical mediation model *PROCESS 4* of Hayes (2012) and discusses the main limitations that may affect the generalizability and robustness of the findings. The analysis is based on a final dataset composed of 157 responses obtained through the Qualtrics survey from employees currently working in pharmaceutical companies operating in Italy. The respondents evaluated the leadership style, risk attitude, and risk management orientation of a total of 79 male and 78 female supervisors. This balanced gender distribution allowed for a comparative assessment of the leadership styles under analysis and for the empirical testing of the two central hypotheses derived from the theoretical framework. Descriptive statistic is provided below as a first preliminary analytical step to understand the characteristics of the sample under analysis:

Descriptive Statistics

Gender	**Percentage**	**Number**
Male	55%	87
Female	39%	61
Non-binary/third gender	2%	3
Prefer not to say	4%	6
Educational level	**Percentage**	**Number**
High school or below	1%	1
Bachelor's degree	36%	57
Master's degree	54%	85
Doctorate degree	9%	14
Job tenure	**Percentage**	**Number**
Less than 1 year	1%	2
1–3 years	53%	83
4–6 years	40%	63
7–10 years	6%	9
Job position	**Percentage**	**Number**
Entry-level/Junior	48%	75
Mid-level/Supervisor	45%	70
Senior-level/Manager	8%	12
Please, indicate the gender of your direct supervisor	**Percentage**	**Number**
Male	50%	79
Female	50%	78

The first objective of this analysis is to empirically understand the extent to which female and male supervisors within Italian pharmaceutical companies adopt either a transactional or transformational leadership style. In order to empirically determine whether distinct patterns exist between supervisors' gender and their prevalent leadership orientation, each respondent rated their supervisor in terms of transformational and transactional leadership styles using a 5-point Likert scale. Subsequently, average scores for both leadership styles were calculated separately for male and female supervisors to measure their

predominant leadership orientation, with the aim of providing empirical support to the two core hypotheses established in this study. Specifically, these hypotheses posit that female supervisors tend to exhibit a predominantly transformational leadership style, characterized by traits such as visionary thinking, motivational support, mentoring, and encouragement of creativity, while male supervisors tend to demonstrate a transactional style, characterized by structured oversight, task-centered rewards, rule enforcement, and emphasis on short-term goals (Carli & Eagly, 2016). To provide empirical support for these assumptions, the following bar chart illustrates the average scores of transactional and transformational leadership styles, separated according to the gender of the supervisor as reported by the 157 survey respondents:



The left panel of the figure shows the average transactional leadership score for male and female supervisors, while the right panel reports the average transformational leadership score for the same two groups. The average leadership scores range from 1 to 5, since they are derived from respondents' agreements with statements built with a 5-point Likert scale, as defined in the research methodology section. Error bars indicate standard deviations, providing insight into the dispersion of the individual responses around the mean. The empirical evidence drawn from this chart demonstrates a clear and statistically meaningful divergence in leadership style based on gender:

- Male supervisors scored significantly higher on the transactional leadership dimension, with an average score equal to 4.5. This confirms the prevalence of behaviors such as close procedural oversight, reward-based recognition, rule enforcement, and short-term performance orientation among male executives.

- In contrast, female supervisors recorded a markedly lower average transactional leadership score equal to 2, which aligns with the theoretical considerations that women are less inclined to adopt coercive or hierarchical leadership strategies.

Conversely, the pattern is reversed when examining average transformational leadership scores:

- Female supervisors obtained a higher average score of 4 on transformational leadership traits, indicating widespread adoption of visionary, inspirational, and empowering leadership practices. This supports the notion that women in executive roles are more likely to mentor subordinates, stimulate innovation, and promote long-term development.
- Male supervisors, while still exhibiting important transformational characteristics, scored closer to an average of 3, suggesting a relative underutilization of these behaviors compared to their female counterparts.

These findings are strongly consistent with the gender-based leadership considerations advanced by Carli & Eagly (2016), who argue that women are more predisposed toward transformational leadership, while men are more likely to exhibit transactional leadership traits. This initial result provides the first empirical confirmation within the context of Italian pharmaceutical companies that such theoretical predictions hold in practice, and also sets the necessary foundation to empirically test the two core research hypotheses previously formulated. Specifically, the subsequent statistical analysis will implement on Python the mediation model of Hayes (2012) *PROCESS 4* to test in two different model specifications whether and how the relationship between leadership style (*independent variable*, *X*) and risk management orientation (*dependent variable*, *Y*) is mediated by the risk attitude promoted by leaders within the organization (*mediating variable*, *M*). In the context of this study, the independent variable is the leadership style adopted by supervisors—either transformational or transactional depending on the model specification. The dependent variable is the risk management orientation promoted by the supervisor within the pharmaceutical firm, measured as a binary outcome that takes the value of 1 when the risk management strategy is perceived as predominantly business-oriented, and 0 when it is ESG-oriented. The mediating variable represents the risk attitude promoted by the supervisor and internalized by the organization, captured on scale ranging from 1 (strongly risk-averse) to 5 (strongly risk-seeking).

Hypotheses testing

- *Hypothesis 1: Female leaders of Italian pharmaceutical companies are more likely to adopt a transformational leadership style that has a positive direct effect on the implementation of ESG-oriented risk management strategies through a risk averse attitude of the organization.*

```
Process successfully initialized.
Based on the Process Macro by Andrew F. Hayes, Ph.D. (www.afhayes.com)

************************** SPECIFICATION **************************

Model = 4
Variables:
  Cons = Cons
  x = Transformational leadership style
  y = Risk management
  m1 = Risk attitude

Sample size:
  157

Bootstrapping information for indirect effects:
  Final number of bootstrap samples: 5000
  Number of samples discarded due to convergence issues: 0

************************** OUTCOME MODELS **************************

Outcome = Risk management
OLS Regression Summary

R²      Adj. R² MSE     F        df1   df2   p-value
0.8830  0.8807  0.0298  580.9268   2    154    0.0000

Coefficients
                         coeff   se      t        p       LLCI    ULCI
Cons                    0.6728  0.0870   7.7286   0.0000  0.8434  0.5021
Transformational style -0.0459  0.0124  -3.7176   0.0003 -0.0701 -0.0217
Risk attitude           0.3998  0.0164  24.3838   0.0000  0.3677  0.4319

----------------------------------------------------------------------

Outcome = Risk attitude
OLS Regression Summary

R²      Adj. R² MSE     F         df1   df2   p-value
0.3802  0.3721  0.7158  95.0623     1    155    0.0000

Coefficients
                         coeff   se      t        p       LLCI    ULCI
Cons                    4.8600  0.1716  28.3188   0.0000  4.5236  5.1963
Transformational style -0.4645  0.0476  -9.7500   0.0000 -0.5579 -0.3711

********************** DIRECT AND INDIRECT EFFECTS **********************

Direct effect of Transformational leadership style on Risk management:

Effect    SE      t        p       LLCI     ULCI
-0.0459   0.0124  -3.7176  0.0003  -0.0701  -0.0217

Indirect effect of Transformational leadership style on Risk management:

               Effect   Boot SE  BootLLCI  BootULCI
Risk attitude  -0.1857   0.0456   -0.2558   -0.0797
```

Direct effect of transformational leadership style on risk management orientation

The first outcome of the model is the regression of the binary variable indicating risk management orientation on both transformational leadership style and risk attitude. The coefficient associated with transformational leadership style is β_1 = -0.0459, with a standard error of 0.0124, and is statistically significant at the 1% level (p = 0.0003). This coefficient measures the direct effect of transformational leadership style on risk management orientation. A negative sign of the coefficient implies that, holding risk attitude constant, an increase in transformational leadership is associated with a decreased likelihood of business-oriented risk management (i.e., that Y_i = 1), and thus a higher likelihood of ESG-oriented risk management practices (i.e., that Y_i = 0). This finding confirms that transformational leaders, who emphasize long-term sustainability, team development, and ethical decision-making, are more inclined to prioritize risk management practices that align with ESG principles rather than profit-seeking objectives. Moreover, the statistical significance of this coefficient is further confirmed by its confidence interval, which ranges from -0.0701 to -0.0217, excluding zero and indicating a reliable effect direction.

Direct effect of transformational leadership style on risk attitude (mediator)

The second outcome of the model is the regression of the risk attitude promoted and perceived within the organization on the transformational leadership style adopted by the supervisor. The estimated coefficient is α_1 = -0.4645, with a standard error of 0.0476 and a t-value of -9.7500, which is significant at the 0.1% level (p < 0.0001). This coefficient measures the direct effect of transformational leadership style on risk attitude. As risk attitude is a variable quantified such that lower values indicate a risk-averse attitude whereas higher values indicate a risk-seeking attitude adopted by the supervisor and promoted within the organization, a negative and highly significant α_1 suggests that supervisors with higher transformational leadership scores are perceived to promote a more risk-averse organizational climate. This is consistent with the empirical findings of Moon (2020), according to which transformational leaders are more prudent, compliance-oriented, and strategically cautious in their decision-making. The confidence interval for α_1 is again strictly negative, ranging from -0.5579 to -0.3711, further reinforcing the robustness of the result.

Mediation path: indirect effect of transformational leadership style on risk management orientation through risk attitude promoted and perceived within the organization

The indirect effect of transformational leadership on risk management orientation through the mediating variable of risk attitude is calculated as the product of α_1 and β_2:

$$Indirect\ effect = \alpha_1 \cdot \beta_2 = -0.4645 \cdot 0.3998 = -0.1857$$

This indirect effect is statistically significant, with a bootstrap standard error of 0.0456 and a 95% confidence interval ranging from -0.2558 to -0.0797, which clearly excludes zero. This indicates that

transformational leadership style indirectly contributes to ESG-oriented risk management by fostering a risk-averse organizational culture. Together, these results provide compelling evidence in support of Hypothesis 1. The total effect of transformational leadership on risk management orientation is not only significant in its direct path, but also in its indirect mechanism, mediated by risk attitude. This finding suggests that transformational leadership exerts a dual influence: it directly promotes ESG risk management priorities through its normative values and ethical stance, and indirectly reinforces ESG orientation by shaping a conservative risk culture that is averse to aggressive, short-term, profit-maximizing behaviors. The fact that both the direct and indirect effects are negative and statistically significant implies that the overall effect of transformational leadership consistently pushes organizations away from business-oriented and toward ESG-oriented risk management practices. This confirms the central theoretical claim that female supervisors, to the extent that they embody transformational traits, are more likely to integrate sustainability, ethical responsibility, and stakeholder welfare into corporate risk strategies.

- *Hypothesis 2: Male leaders of Italian pharmaceutical companies are more likely to adopt a transactional leadership style that has a positive direct effect on the implementation of business-oriented profit-seeking risk management strategies through a risk seeking attitude of the organization.*

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Process successfully initialized.
Based on the Process Macro by Andrew F. Hayes, Ph.D. (www.afhayes.com)

************************** SPECIFICATION **************************

Model = 4
Variables:
  Cons = Cons
  x = Transactional leadership style
  y = Risk management
  m1 = Risk attitude

Sample size:
  157

Bootstrapping information for indirect effects:
  Final number of bootstrap samples: 5000
  Number of samples discarded due to convergence issues: 0

************************** OUTCOME MODELS **************************

Outcome = Risk management
OLS Regression Summary

R²      Adj. R² MSE     F        df1   df2   p-value
0.9129  0.9112  0.0222  807.1441   2    154    0.0000

Coefficients
                         coeff   se      t        p       LLCI    ULCI
Cons                    0.9833  0.0391  25.1767   0.0000  1.0598  0.9068
Transactional style     0.1704  0.0201   8.4571   0.0000  0.1309  0.2098
Risk attitude           0.2817  0.0215  13.0980   0.0000  0.2396  0.3239

---------------------------------------------------------------------------

Outcome = Risk attitude
OLS Regression Summary

R²      Adj. R² MSE     F         df1   df2   p-value
0.7320  0.7285  0.3095  423.3648     1    155    0.0000

Coefficients
                         coeff   se      t        p       LLCI    ULCI
Cons                    0.7320  0.1335   5.4850   0.0000  0.4704  0.9936
Transactional style     0.8012  0.0389  20.5758   0.0000  0.7249  0.8775

********************** DIRECT AND INDIRECT EFFECTS **********************

Direct effect of Transactional leadership style on Risk management:

Effect    SE      t        p       LLCI     ULCI
 0.1704   0.0201   8.4571  0.0000   0.1309   0.2098

Indirect effect of Transactional leadership style on Risk management:

                Effect   Boot SE  BootLLCI  BootULCI
Risk attitude   0.2257   0.0262    0.1783    0.2794
```

Direct effect of transactional leadership style on risk management orientation

The first outcome of the model investigates the direct relationship between transactional leadership style and risk management orientation, controlling for the mediating variable risk attitude. The estimated coefficient for transactional leadership style is β_1 = 0.1704, with a standard error of 0.0201 and a t-value of 8.4571, statistically significant at the 0.1% level ($p < 0.0001$). Since the dependent variable in this regression is a binary indicator coded as 1 if the risk management strategy is business-oriented and 0 if ESG-oriented, a positive β_1 coefficient implies that higher levels of transactional leadership are associated with a greater likelihood of business-oriented risk management (i.e., that Y_i = 1). In other words, leaders who exhibit transactional characteristics—emphasizing structure, discipline, task efficiency, and results-based performance—tend to implement risk management strategies that prioritize short-term performance, operational responsiveness, and profit maximization, consistent with business-oriented goals. The statistical robustness of this finding is further confirmed by the confidence interval, which ranges from 0.1309 to 0.2098, excluding zero and thus validating the significance and direction of the effect.

Direct effect of transactional leadership style on risk attitude (mediator)

The second regression models the direct effect of transactional leadership style on the organization's risk attitude (*outcome variable*). The estimated coefficient is α_1= 0.8012, with a standard error of 0.0389 and a t-statistic of 20.5758, significant at the 0.1% level ($p < 0.0001$). Since risk attitude is measured on a 5-point Likert scale where higher values indicate a more risk-seeking orientation, this positive and highly significant coefficient indicates that supervisors perceived as highly transactional are also associated with promoting a risk-seeking corporate culture. This finding is aligned with the empirical results of Moon (2020), who highlights that transactional leaders often prioritize aggressive growth, speed, and performance even under conditions of uncertainty or limited information. The confidence interval for α_1 ranges from 0.7249 to 0.8775, further confirming the statistical significance and providing a strong empirical basis for the inclusion of risk attitude as a credible mediator in this model.

Mediation path: indirect effect of transactional leadership style on risk management orientation through risk attitude

The indirect effect of transactional leadership on risk management orientation, as mediated by risk attitude, is calculated as the product of the α_1 and β_2 coefficients:

$$Indirect\ effect = \alpha_1 \cdot \beta_2 = 0.8012 \cdot 0.2817 = 0.2257$$

This indirect effect is statistically significant, with a bootstrap standard error of 0.0262 and a confidence interval ranging from 0.1783 to 0.2794, clearly excluding zero. These results indicate that transactional leadership not only has a positive direct effect on the implementation of business-oriented risk management

practices, but also an indirect effect, through its influence on the risk attitude promoted within the organization. Specifically, transactional leaders cultivate a risk-seeking attitude that further increases the probability of adopting profit-driven, performance-centered risk management strategies. This indirect pathway reinforces and supports Hypothesis 2, according to which male supervisors, through their adoption of transactional leadership styles, contribute to a risk-seeking culture that values assertiveness, efficiency, and profit maximization, by prioritizing business-oriented risk management strategies at the expense of sustainability and stakeholder inclusivity.

Limitations of the study and suggestions for future research

Taken together with the results from Hypothesis 1, the empirical evidence of this statistical analysis supports the theoretical expectation that gender-based leadership differences significantly shape risk attitude and strategic orientation of risk management in the Italian pharmaceutical industry. However, this research is not free of limitations. A first important limitation concerns the representativeness of the sample. The survey was distributed to employees of pharmaceutical companies operating in Italy through a snowball sampling approach. While this method enabled the collection of industry-specific data, it did not allow for identification of the specific firms in which respondents are employed. As a result, it is not possible to determine whether participants are evenly distributed across different companies or concentrated within a few organizations. This introduces the possibility of intra-firm clustering or organizational culture bias, which may distort the generalizability of the findings. A second relevant limitation relates to the methodology adopted to quantify the core variables of the study: leadership style, risk attitude, and risk management orientation. These variables were measured through a structured questionnaire based on employee perceptions. Although this method is widely used in academic research on leadership studies and organizational performance (Alrowwad et al., 2020), it introduces several subjective biases. The absence of objective firm-level data on actual ESG practices and business performance strategies makes it difficult to verify whether the perceived leadership behaviors are effectively reflected in the risk management decisions and outcomes of the company. As such, the results provide insight into the employees' perception of corporate risk management outcomes but cannot conclusively demonstrate its alignment with observable corporate performance metrics or objective and well-defined strategic outcomes. To address the first limitation, future research could improve the design of the questionnaire by including additional control variables that help identify the organizational context of each respondent, such as the size of the company, its geographical location, or the department in which the employee works. Without compromising anonymity, this information would make it possible to better understand the diversity of firms represented in the sample and control for potential subjective biases related to internal organizational culture. As for the second limitation, future studies could strengthen the analysis by combining survey responses with firm-level data from external sources. For example, actual ESG performance metrics obtained from recognized databases such as Bloomberg or Refinitiv could be used to validate whether the perceived leadership style and risk

orientation are reflected in real corporate strategies. This would make it possible to go beyond employee perceptions and test more objectively the relationship between leadership traits and the actual implementation of ESG-oriented or business-driven risk management strategies.

Appendix

Research questionnaire

Introduction:

This survey is part of an academic research project aimed at investigating the relationship between leadership styles, risk attitudes, and corporate risk management strategies within pharmaceutical companies operating in Italy. Specifically, the study seeks to assess whether gender-based differences in leadership styles influence the way risks are perceived and managed in the pharmaceutical sector, with a particular focus on the balance between ESG-oriented and business-oriented approaches. Participation in this survey is completely anonymous and voluntary. All responses will be treated with strict confidentiality and used exclusively for academic purposes in aggregated form. The estimated time for completion is approximately 8–10 minutes. Your contribution is valuable for advancing the understanding of how leadership can shape sustainable and responsible risk management practices in the Italian pharmaceutical industry. Thank you for your participation.

Q1. Gender

- ○ Male
- ○ Female
- ○ Non-binary/third gender
- ○ Prefer not to say

Q2. Educational level

- ○ High school or below
- ○ Bachelor's degree
- ○ Master's degree
- ○ Doctorate degree

Q3. Job tenure

- ○ Less than 1 year
- ○ 1–3 years
- ○ 4–6 years
- ○ 7–10 years

Q4. Job position

- ○ Entry-level/Junior
- ○ Mid-level/Supervisor
- ○ Senior-level/Manager

Q5. Please, indicate the gender of your direct supervisor

- ○ Male
- ○ Female

Leadership style

Q6. To what extent do you agree with these statements about your direct supervisor?

	Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
My supervisor encourages me to question conventional approaches and explore improvements in how we work.					
My supervisor supports me when I propose new ideas or solutions related to our team's responsibilities.					
My supervisor expresses confidence and determination when managing team objectives.					
My supervisor helps me develop my professional abilities through feedback and guidance.					
My supervisor dedicates time to mentoring or coaching me, beyond routine task assignments.					
My supervisor reacts firmly when I fail to meet task or process expectations.					
My supervisor closely monitors compliance with internal procedures and protocols.					
My supervisor makes it clear that good performance is rewarded and poor performance is sanctioned.					
My supervisor bases recognition primarily on task completion and results achieved.					

My supervisor expects strict adherence to predefined goals and provides limited flexibility in how tasks are executed.					

Risk attitude

Q7. To what extent do you agree with these statements?

	Strongly disagree	**Somewhat disagree**	**Neither agree or disagree**	**Somewhat agree**	**Strongly agree**
My supervisor is willing to proceed with strategic decisions even when important information is incomplete or uncertain.					
My supervisor tends to prioritize speed and opportunity over caution and procedural rigidity when making decisions under pressure.					
My supervisor tends to minimize the role of regulatory or reputational constraints when evaluating high-risk opportunities that could offer significant competitive or financial advantage.					
The organizational environment promoted by my supervisor rewards initiative even when proposed actions challenge established internal risk controls or compliance standards.					
The organizational environment promoted by my supervisor actively promotes a risk-seeking culture where taking bold and aggressive risks is perceived as necessary to drive long-term growth and innovation, even at the cost of short-term stability.					

Risk management

Q8. To what extent do you agree with these statements?

	Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
My supervisor promotes the selection of suppliers based on their environmental certifications and social responsibility standards, even when this entails higher costs.					
My supervisor is willing to switch suppliers rapidly to reduce lead times or gain cost advantages, regardless of their sustainability profile.					
My supervisor emphasizes the implementation of operational procedures that go beyond compliance to ensure environmental safety and social responsibility.					
My supervisor is focused on maximizing throughput and minimizing downtime, even when it increases stress on human and technical resources.					
My supervisor supports investment decisions that prioritize ESG and long-term financial sustainability by minimizing speculative or high-volatility financial practices.					
My supervisor evaluates investment decisions based on short-term financial performance indicators such as EBITDA or profit margin.					
My supervisor promotes product strategies that align with societal and environmental values, even when market demand is uncertain.					
My supervisor focuses on aggressive marketing and competitive pricing to maximize market share and outpace rivals.					

My supervisor supports the implementation of green logistics initiatives (e.g., eco-efficient transport, reverse logistics), even if they increase costs and operational complexity.					
My supervisor prioritizes logistics strategies that optimize delivery speed and cost, even at the expense of environmental considerations.					
My supervisor supports policy engagement initiatives aimed at promoting fair access to medicines and public health advocacy.					
My supervisor focuses on minimizing compliance costs and avoiding regulatory penalties, rather than embracing long-term reforms.					
My supervisor supports the adoption of new digital solutions that enhance environmental monitoring, patient safety, or ethical oversight.					
My supervisor prioritizes the implementation of emerging technologies (e.g., Al, blockchain) to boost innovation and reduce costs, regardless of their environmental or ethical implications.					
My supervisor supports initiatives to minimize the environmental footprint of pharmaceutical production, such as green chemistry or energy efficiency.					
My supervisor focuses on regulatory compliance for environmental standards but resists voluntary adoption of stricter ESG measures.					

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