TITLE: AGILE TRANSFORMATION IN PHARMACEUTICAL COMPANIES: INDEPTH ANALYSIS OF THE ROLE OF LEADERSHIP AND CHANGE MANAGEMENT DURING THE IMPLEMENTATION OF AGILE METHODOLOGIES

RESEARCH THESIS

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Title of Thesis: AGILE TRANSFORMATION IN PHARMACEUTICAL COMPANIES: INDEPTH ANALYSIS OF THE ROLE OF LEADERSHIP AND CHANGE MANAGEMENT DURING THE IMPLEMENTAITON OF AGILE METHODOLOGIES

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APPENDIX

IMPORTANT TERMS AND DEFINITIONS

1. Agile Transformation: The process of integrating agile techniques and concepts throughout an organisation to improve operational effectiveness and responsiveness to market demands is known as agile transformation.
2. Lean and Agile: By fusing the flexibility of agile with the efficiency of lean, software development strategies that combine both approaches strive to improve both flexibility and economic efficiency.
3. Change Management in Agile: Agile change management is a methodology that focuses on assisting individuals, groups, and organisations in putting agile techniques and practices for organisational change into practice.

LIST OF FIGURES

QUESTIONS ASKED TO PARTICIPANTS

1. How does the adoption of Agile methodologies impact the productivity of R&D teams in pharmaceutical companies?

2. How can Agile methodologies be adapted within the stringent regulatory environment of the pharmaceutical industry to enhance compliance while maintaining flexibility?

3. How does Agile transformation influence the innovation capabilities of pharmaceutical companies, particularly in the ideation and development of new drugs?

4. How does the Agile transformation affect cross-functional collabouration between scientific, regulatory, and marketing teams in pharmaceutical companies?

5. How does the shift to agile methodologies impact the well-being and job satisfaction of employees in pharmaceutical R&D?

6. How does the adoption of agile practices influence the time to market for new drugs?

7. How does agile transformation enable more customer-centric innovation in the pharmaceutical industry?

8. How would you address the challenges of implementing Agile in a pharmaceutical R&D team that is accustomed to traditional project management?

9. In your experience, what Agile practices have you found to be most beneficial for innovation in pharmaceutical R&D?

10. Can you give an example of a project where you utilized cross-functional teams to accelerate the development process in a pharmaceutical environment? How did Agile methodologies contribute to the project's success?

11. Reflecting on your experience, what are the most common misconceptions about applying Agile in pharmaceutical R&D, and how do you address them?

12. What strategies do you use to foster collabouration between R&D and other departments, such as regulatory affairs or marketing, in an Agile transformation context?

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Abstract:

The pharmaceutical industry is highly regulated and traditionally known for its hierarchical and process-driven approach. However, in recent years, there has been a growing trend towards adopting agile practices and principles to enhance flexibility, innovation, and responsiveness. This research proposal explores the challenges, benefits, and outcomes of agile transformation in pharmaceutical companies and its effect on innovation, efficiency and R&D process. Through a comprehensive literature review and case studies, this research will provide valuable insights into implementing agile methodologies in the pharmaceutical context. The findings will contribute to a deeper understanding of how agile transformation can drive organisational change and improve competitiveness in the pharmaceutical industry.

CHAPTER 1: INTRODUCTION

1.1 BACKGROUND

PHARMACUETICAL INDUSTRY

Even with the pharmaceutical industry's explosive expansion, industrialised nations continue to be the dominant producers and consumers, which leads to an unequal distribution of pharmaceuticals. Pharmaceutical companies spend a lot of money on research; yet poor product development can result in low earnings and dubious product introductions. (Rao, Anita 2020).

Therapeutic chemicals are produced and distributed by the pharmaceutical business, which is an essential part of healthcare. The sector is going through a lot of changes despite its conventional hierarchical structure. These changes are due to the industry's complex and dynamic environment, strict rules, fierce rivalry, and quickly advancing scientific discoveries. As a result, a move towards agile techniques is required. (Danzon, P.M., 2014).

In contrast to the pharmaceutical industry's worldwide spending of over 244 billion dollars on research and development in 2022, which includes product development, clinical trials, and medicine discovery, the pharmaceutical industry spent $83 billion on R&D in 2019. After accounting for inflation, this sum is ten times greater than it was in the 1980s. Pharmaceutical businesses now spend over 25% of their sales on research and development (R&D), which is an increase from the industry's 5% share in 2000. Compared to other knowledge-based businesses like semiconductors, technological hardware, and software, this revenue share is higher (Congressional Budget Office, April 2021)

The pharmaceutical industry's lengthy development cycles, inflexible silos, and strict protocols make it difficult for them to comprehend the demands of patients. The waterfall method of software development has been replaced by agile, a style that focuses on business results and has been embraced by a number of industries,

including software, financial services, consumer packaged goods, and the public sector. (Vaidyanathan, S. et al. (2021).

RESEARCH AND DEVELOPMENT IN PHARMA INDUSTRY

The pharmaceutical sector is involved in various business operations such as sales and marketing, regulatory submission, R&D, and investment collection. To maintain sustainable growth, businesses must increase revenue by releasing new products and optimize expenses by increasing productivity. This concept is unique to the pharmaceutical industry, unlike other sectors that can benefit from it (Teramae, F., *et al,* 2020).

The COVID-19 pandemic has significantly impacted global innovation systems, causing production and innovation capacity issues. Despite financial constraints, R&D investment is crucial for long-term economic growth, climate emergencies, Sustainable Development Goals, digital transition, and inclusive societies, despite financial constraints. (Tudor, C., & Sova, R., 2022).

Global pharmaceutical corporations are modifying their business practices to take advantage of fresh chances for innovation and investment as well as growing consumer demand. But creating novel pharmaceuticals is expensive, time-consuming, risky, and improbable. This research offers a theoretical foundation for comprehending the difficulties and prospects in this subject by concentrating on scientific publications, discoveries, and investments in the pharmaceutical business. (Nagy, S., & Asmyatullin, R. 2023).

Research and development (R&D) activities are crucial for a firm's productivity, growth, and competitiveness, encompassing basic, applied, and support activities like technology intelligence, technology scouting, and market analysis. Measurement of R&D performance enhances firms' performance, but uncontrollable factors make it challenging. Literature on measuring R&D performance is unclear, with different levels of importance assigned to different perspectives and measures. Understanding these differences can help R&D managers formulate effective strategies for improved performance (Salimi, N. and Rezaei, J., 2018).

ROLE OF MANAGERS IN R&D

Innovation in R&D operations is driven by global competitiveness, necessitating the use of specialised managerial strategies. Because they operate in less competitive environments, public institutions are less inventive. Concerned about a unified platform for public and commercial R&D sectors are policy makers and practitioners. Collabourations can be facilitated by a managerial approach that takes R&D performance into account (Mikulskienė, B., 2010).

Not just for R&D, but for efficient organisational functioning as well, technical communication is essential. Product innovation has an impact on the link between R&D and company success, but management innovation is frequently underestimated. (Heij, C., *et al.,* 2020).

AGILE TRANFORMATION

Agile transformations, initially designed for software development projects, are now being adopted on an enterprise scale by companies. These transformations impact various levels of the organisation, including teams, programs, portfolios, finance, sales, and human resources, despite their potential to improve agility and responsiveness. (Stettina et al. 2021).

Because of its focus on cross-functional teams, continuous code development, and a client-centric approach, agile is a customer-centric technique that works well for software development firms as well as other sectors. (Pavlovic & Beric, 2018).

1.2 PROBLEM STATEMENT

Pharmaceutical corporations work with NGOs and governments to manage rights and adjust to changes brought about by the digital revolution in order to remain competitive. They strike a balance between protecting intellectual property rights and providing inexpensive drugs in poor nations. (Amalia-Amelia, Mukhlas., *et al* 2022). (H., C., Bindusha., H, L, Tare. 2022)

The pharmaceutical industry has limited use of agile approaches because of risk-averse attitudes, lengthy development cycles, and regulatory compliance. Comprehending these obstacles is essential to organisational transformation and competitiveness.. In A Vision of Medical Affairs (2025), Matthias (2019) writes that medical affairs in pharmaceutical firms must adopt agile ways of working, such as being more business-savvy and nimble in order to connect dynamically with patients stakeholders and quickly adjust to a situation that is changing.

Agile implementation in large-scale healthcare is challenging due to reluctance to change, integration difficulties, and the need for team unity (Dikert, K., Paasivaara, M., & Lassenius, C., 2016). The pharmaceutical sector faces additional challenges due to strict regulatory requirements and product quality and safety. Agile approaches can improve patient-centreedness and provide fair access to healthcare through digital technologies. However, adoption of agile cultures in the healthcare industry, particularly the pharmaceutical sector, has been slow (Kokol, P., Vošner, H., Kokol, M., & Završnik, J., 2022). To address these challenges, agile methodologies designed specifically for the pharmaceutical sector are needed. For example, method ae is tailored to meet the specific needs of developing software for pharmaceuticals, ensuring adherence to EU GMP Annex 11. This customised strategy helps manage industry-specific documentation needs and associated risks (Hajou, A., Batenburg, R., & Jansen, S., 2015).

The pharmaceutical industry must effectively implement digital transformation programs and align IT strategy with digital initiatives to enhance innovation and productivity in drug development and commercial operations.

1.3 SCOPE OF THE STUDY

This study explores agile transformation in pharmaceutical companies, focusing on innovation and efficiency in R&D. It highlights the transformative potential of agile methodologies and outlines challenges and strategies for effective implementation.

- **Assessment of current r&d practices:** The study evaluates traditional R&D practices in pharmaceutical companies, identifying inefficiencies and rigidities that

may hinder innovation and speed, thereby assessing the potential impact of agile transformation (Algorri et al., 2021).

- **Agile transformation strategies:** This section discusses strategies for agile transformation in pharmaceutical companies, including leadership engagement, culture change, and team restructuring, and integrating agile practices into workflows (Schuhmacher et al., 2013).

- **Challenges and solutions:** The study aims to address challenges in implementing agile methodologies in the pharmaceutical industry, including regulatory compliance, organisational resistance, and ensuring quality and safety (Hajou, Batenburg, & Jansen, 2014).

- **Impact on innovation and efficiency:** The study examines the impact of agile transformation on pharmaceutical R&D, focusing on improvements in drug development timelines, productivity, and success rates, as well as fostering innovation and collabouration (Algorri et al., 2021)

- **Case studies and best practices:** The article presents case studies from pharmaceutical companies implementing agile methodologies, outlining best practices, lessons learned, and recommendations for other companies considering agile transformation.

- **Future directions:** The study will explore future directions of agile transformation in pharmaceutical R&D, focusing on digital technologies, continuous learning, and innovation ecosystems to support safe, effective, and innovative treatments.

1.4 RESEARCH OBJECTIVES

The pharmaceutical sector is changing quickly to satisfy patient demands, particularly in the area of specialised, small-batch drugs. Though flexible, putting agile manufacturing technology into practice is difficult because of international regulatory issues. There must be cooperation between regulators and manufacturers. The 21st-century manufacturing paradigm, known as "agile manufacturing," is essential for companies looking to boost productivity and take the lead in the market as customer

expectations change quickly. It allows for fast modification without sacrificing quality. Because of decreased efficiency, the pharmaceutical sector is bringing outside ideas into its R&D teams and encouraging openness through agile approaches that support the adaption of products and services. (Algorri, M., *et al* 2021).

The primary objective of this research proposal is to explore tzxhe agile transformation process in pharmaceutical companies and examine its implications on organisational performance. The specific research objectives are as follows:

- Identify the key drivers for agile transformation in the pharmaceutical industry.

- Investigate the challenges faced by pharmaceutical companies during the implementation of agile methodologies.

- Assess the benefits and outcomes of agile transformation in terms of innovation, product development, and organisational culture.

- Understand the role of leadership and change management in facilitating successful agile transformations.

- Provide recommendations and guidelines for pharmaceutical companies embarking on an agile transformation journey.

1.5 RESEARCH QUESTIONS

To achieve the stated research objectives, this study will seek answers to the following research questions:

1. What are the primary drivers for agile transformation in pharmaceutical companies?

2. What are the main challenges faced by pharmaceutical companies in implementing agile methodologies?

3. What are the benefits and outcomes of agile transformation in pharmaceutical companies?

4. How does leadership and change management influence the success of agile transformation in the pharmaceutical context?

5. What recommendations can be provided for pharmaceutical companies seeking to undergo an agile transformation?

1.6 SIGNIFICANCE OF THE STUDY

This research is important for a number of reasons, all of which highlight how agile approaches may revolutionise an industry where speed, creativity, and compliance with regulations are critical.

- **Accelerating drug development:** By encouraging flexibility, rapid iteration, and continuous feedback loops, agile transformation speeds up the development of new drugs by cutting time-to-market and facilitating quicker reactions to patient requirements and medical crises (Grebić, Ćirić Lalić, & Savković, 2023).

- **Increasing r&d productivity:** Agile approaches in pharmaceutical R&D increase productivity by encouraging efficient resource allocation, fostering cross-functional collabouration, and emphasising continuous improvement. They also tackle industry-wide productivity problems and concentrate on waste reduction (Mancin, 2016).

- **Encouraging innovation:** Agile transformation encourages creativity in research and development by enabling teams to grow from their mistakes and adjust, which might result in important breakthroughs in the pharmaceutical sector (Trier & Treffers, 2021).

- **Enhancing adaptability to regulatory and market changes:** Agile techniques lower project failure rates, ensure compliance and competitiveness, and help enterprises in the pharmaceutical industry swiftly adjust to changes in the market and regulatory requirements (Nascimento et al., 2023).

- **Encouraging collabouration and knowledge sharing:** Agile transformation encourages collabouration across disciplines and information sharing, especially

in pharmaceutical research and development (R&D), where combining a variety of skills is critical to innovation (Tshabalala & Marnewick, 2021).

- **Risk management and quality improvement:** Agile development methodologies incorporate quality improvement and risk management, allowing pharmaceutical companies to detect and address issues early on and guarantee the safety and effectiveness of new pharmaceutical products.

- **Influence on the economy and society:** Agile change in pharmaceutical companies improves public health, speeds up drug discovery, lowers healthcare costs, and improves health outcomes—all of which are good for the economy and society.

This study examines the advantages and difficulties of agile transformation in the pharmaceutical industry, highlighting the critical roles that strong leadership and efficient change management play in smooth transitions.

1.7 RESEARCH METHODOLOGY

To achieve the research objectives, a qualitative method will be used. The study will include a comprehensive literature review to establish a theoretical foundation and identify key concepts and trends related to agile transformation in the pharmaceutical industry. Additionally, multiple case studies will be conducted to gather qualitative data and gain in-depth insights into real-world agile transformation initiatives. Interviews with key stakeholders, such as executives, project managers, and agile coaches, will be conducted to collect primary data. The collected data will be analysed using thematic analysis and triangulated with the existing literature to draw meaningful conclusions, this is still under consideration as not many companies have adopted this method and the people working at manager and above level are from a scientific background which makes it harder to find people with the same experience and knowledge. The study will be more focused on case study and literature with a compilation of data generated from interviews and qualitative data.

CHAPTER 2: LITERATURE REVIEW

2.1 BACKGROUND

The history of agile transformation shows a dramatic change in how project management and product development are approached, especially in the context of software development and larger organisational settings. Adoption of agile methods intended to improve adaptability, reactivity, and teamwork characterises this shift. I've outlined the most important discoveries from the literature on this subject below.

The concepts of agile thinking, which have their origins in the 1970s, include flexibility, customer interaction, and putting functional software ahead of copious documentation (Dikert, Paasivaara, & Lassenius, 2016). Large-scale agile transformations in critical environments require stakeholder commitment, quick deployment, and requirements alignment. Implementing agile techniques across multiple teams and departments is a major obstacle. However, management backing, modifying agile models, and encouraging an agile mindset are critical success factors. The rise of agile software development has shifted focus towards flexibility, teamwork, and customer satisfaction (Russo, 2021).

The early 1990s saw the fast evolution of the software development sector, which is the backdrop against which the history of Agile Transformation began. The sequential and linear nature of traditional project management systems meant that they frequently fell short of the dynamic requirements of software projects (Kuhrmann et al., 2021). These methods, like the Waterfall model, were showing signs of growing inflexibility and a sluggish reaction to change. Agile approaches emerged as a response to the demand for a more responsive and adaptable approach.

The transition from conventional to Agile approaches in software development and project management is known as Agile Transformation. The Agile Manifesto, which was written in 2001 by a group of seventeen software professionals, is the foundation of this change. According to Beck et al. (2001), these people understood the importance of "individuals and interactions over processes and tools," "working software over comprehensive documentation," "customer collabouration over contract negotiation,"

and "responding to change over following a plan". This credo, which placed a strong emphasis on adaptation to change, flexibility, continuous delivery, and customer satisfaction, set the foundation for Agile techniques (Dikert, Paasivaara, & Lassenius, 2016).

The shift from conventional, inflexible project management frameworks to Agile approaches like Extreme Programming (XP), Scrum, and Kanban was noteworthy. For example, Scrum popularised the idea of iterative development, in which projects are broken up into sprints to enable ongoing input and modifications. Kanban prioritised just-in-time production and workflow visualisation, enabling more effective job management and throughput (Mergel, Ganapati, & Whitford, 2020). The goal of Extreme Programming (XP) was to increase software quality and adaptability to changing customer needs by utilising techniques like pair programming and test-driven development (TDD).

Agile Transformation enhances efficiency in software development by optimizing project outcomes and fostering team cooperation. However, challenges like organisational culture shift persist. Future success depends on adapting to new technologies.

2.2 AGILE PRINCIPLES AND METHODOLOGIES

In recent years, there has been an increase in interest in scaling Agile processes to bigger companies. Agile principles and methodologies commonly employed in the software development industry, such as Scrum, Kanban, and Lean, offer a viable way to improve responsiveness in both IT and product development (Sommer, A.F., 2019). Agile organisations have developed to prosper in an environment that is uncertain and changing quickly. They are both dependable and flexible, putting the consumer first and incorporating customer centricity into all they do. The key principles of agility include iterative development, collabouration, adaptive planning, and continuous improvement. (De Smet, A., *et al.*, 2018).

Agile principles, originally designed for software development, have been applied to various industries, including pharmaceuticals, to enhance project management and

operational effectiveness through flexibility, rapid iteration, and collabouration. The Agile Manifesto ideals are as follows: persons, workable solutions, collabouration, and adaptability to change are prioritized above old inflexible procedures. The manifesto was developed by Beck et al. (2001). These qualities are:

- **People and interactions over procedures and systems:** Stressing the value of stakeholder and team communication and cooperation above strict adherence to processes and tools.

- Prioritising the delivery of functioning goods above thorough documentation, while nevertheless ensuring that all relevant documentation is completed, is known as working software over comprehensive documentation.

- **Collabouration with customers rather than contract negotiations:** Promoting ongoing communication with clients to make sure the product fulfils their requirements and expectations.

- **Adapting to change rather than sticking to a plan:** placing more value on adaptability and flexibility than rigid adherence to original ideas. Agile companies are driven by a "north star" to create value with and for stakeholders, while also being customer-focused.

- **Agile businesses use quick decision-making and learning cycles**: breaking work down into manageable pieces, and adapting to monitored objectives and measurements.

- Agile firms place people at the centre of culture and leadership, enabling them to quickly generate value.

- Agile businesses use next-generation technology to support rapid iterations, better deployment velocity, and flexibility.

Leadership is crucial for agile businesses, impacting performance and well-being. Agile Manifesto's eleven principles emphasize continuous delivery, customer happiness, adaptability, and team empowerment (Beck et al., 2001).

These principles help to further define the agile methodology. Prominent tenets consist of:

1. Customer satisfaction requires timely and consistent delivery of worthwhile items.

2. Accept change: To improve customer advantage, be receptive to needs modifications, even at the end of development.

3. Regular delivery: Deliver functional things on a weekly or monthly basis at most.

4. Cooperation: Maintain continuous communication with business stakeholders throughout the project.

5. Friendly environment: Assemble teams of driven individuals, provide them the assistance they require, and have faith in their ability to complete the task at hand.

6. Face-to-Face conversation: Promote direct communication to facilitate efficient sharing of information.

7. Working product: Delivering functional products is a good way to gauge progress.

8. Sustainable development: Keep users, stakeholders, and developers moving forward at a steady rate forever.

9. Excellence via simplicity: To maximise work not done, simplify activities and concentrate on technical excellence and good design.

10. Teams that are empowered to self-organise produce superior architectures, specifications, and designs.

11. Frequent reflection: Consider ways to improve effectiveness on a frequent basis, then tweak and modify behavior accordingly.

TYPICAL AGILE TECHNIQUES

- **Scrum:** A methodology that, via fixed-length iterations known as Sprints, encourages collaboration on challenging projects (Schwaber & Beedle, 2002).

Scrums, or daily stand-up meetings, and positions like Product Owner and Scrum Master improve teamwork and productivity.

- **Kanban:** A visual workflow management technique based on Toyota's production system, Kanban emphasises work-in-progress constraints and just-in-time delivery (Anderson, 2010). It encourages ongoing cooperation and development.

- **Extreme Programming (XP):** XP emphasises customer satisfaction and technical quality. It promotes frequent releases within brief development cycles to boost output and provide checkpoints where needs from customers may be implemented (Beck, 1999).

- **Lean Development:** This technique, which takes its cues from lean manufacturing, seeks to maximise productivity through waste reduction, improved product flow, and customer value delivery (Poppendieck & Poppendieck, 2003).

- **Feature-Driven Development (FDD):** This paradigm emphasises feature-driven development within an incremental and iterative framework, integrating industry-recognized best practices into a coherent whole (Palmer & Felsing, 2002).

Agile techniques are adaptable, flexible, and efficient, making them ideal for product development and project management in industries like manufacturing, healthcare, and pharmaceuticals, enhancing customer value delivery and efficiency.

2.3 AGILE TRANSFORMATION

The concept of agile transformation is the process of transitioning from traditional hierarchical structures and practices to an agile mindset and approach. The Agile methodology is a project management methodology where tasks and assignments are completed in sprints or iterations. Iterations or sprints are brief periods of time, often lasting two weeks, during which a team meets and discusses the life cycle of a project. The success of a project is greatly influenced by teamwork and communication between the customer, managers and the employees (Bhargava, P., 2017).

The Lehigh Report, funded by the U.S. Department of Defence, was a report published by the Iacocca Institute at Lehigh University in Pennsylvania in the 1990s. Senior executives from significant U.S. companies participated in the initiative, which focused on appropriate management practices and the circumstances that businesses will face in the future. Agile manufacturing was seen as the essential ingredient for success, and researchers in the domains of production and supply chain management, industrial economics, software development, and information technology embraced the phrase. (Dühring, L. and Zerfass, A., 2021).

Agile transformation, which is the process of switching from traditional to agile approaches, is becoming more and more acknowledged as being essential to success in a number of fields, including as digital transformation, large-scale software development, and e-government initiatives. It is important to underscore the complex and diverse aspects of this endeavour, encompassing not just the implementation of agile methodology but also the management of organisational culture, leadership, and digital transformation tactics.

The following summarizes the main findings of current research:

Digital transformation and agile business analysis: By fostering ongoing feedback, learning, integration, and improvement, and by optimising value to stakeholders, the integration of agile perspectives with business analysis methodologies greatly boosts the success of digital transformation initiatives (Kose, 2021).. For digital transformation, agile approaches like Scrum and XP—which are bolstered by Jira and Agilo—are indispensable. These techniques provide advantages including incremental development, flexible requirements, and improved client interaction (Alruwaili et al., 2019).

Large-scale agile transformations: Systematic literature evaluations identify success elements like management support and tailoring the agile model to the organisation's needs, as well as hurdles like integrating agile at scale and combining it with other organisational functions.

Agile leadership and organisational dynamics: Agile leadership is crucial for empowering teams during digital transformation, promoting experimentation, failure-based learning, and continuous improvement. This leadership style promotes workforce transformation, strategic flexibility, and dynamic capability, ensuring smooth and successful digital transitions while maintaining company goals. (Delioglu & Uysal, 2023).

2.4 AGILE IN PHARMACEUTICAL INDUSTRY

Agile is gaining popularity in the pharmaceutical sector due to its advantages over Waterfall, including time, money, methodologies, and scope flexibility. It enhances documentation and helps pharmaceutical businesses gain a competitive advantage in R&D. (Bhargava, P., 2017).

All transitions are challenging, but those in research and development have an added complexity:

- **A business that depends on science** - Pharma is a business that relies on science and is research-intensive, with high investment levels, protracted development timetables, and high failure rates due to elements outside of the company's control.

- **Aversion to taking risks** - R&D workers tend to be specialised and used to rigid, sequential ways of working, making it difficult to transition to an agile approach.

- **Intense rivalry** - Transitions must be managed to prevent distractions that could delay crucial initiatives in quickly developing fields like oncology, as rival assets may only be separated by a few months.

- **Stakeholder engagement** - The complexity of transformation planning can be increased by external stakeholders, such as regulators, payers, providers, and patients.

(Berggren, R., *et al.*, 2018)

Agile software development techniques, known for their adaptability and effectiveness, pose challenges in the pharmaceutical industry due to conflicts with regulatory environments and industry needs. However, a customised agile approach called Method ae has been developed to address these issues, emphasizing risk-oriented decision-making and adhering to EU GMP Annex 11 regulations. This approach can be carefully customised and applied to the pharmaceutical industry. The industry's reluctance to adopt agile approaches despite their potential benefits may lead to projects going over budget and schedule due to their inherent lack of flexibility and adaptation. (Hajou, Batenburg, & Jansen, 2014)..

Agile manufacturing techniques enhance competitiveness in the pharmaceutical sector by improving supply chain resilience and responsiveness to market demands through flexible production facilities and customer-supplier cooperation. (Gunasekaran, 1999). Agile supply chain in the pharmaceutical industry is crucial for responding to market changes and customer needs. It focuses on rapid, cost-effective delivery of novel products, offering a competitive advantage. Agile manufacturing methods can improve patient access to medications worldwide. However, regulatory constraints pose a challenge for successful implementation, necessitating collabouration between regulators and manufacturers. (Algorri et al., 2021).

Agile manufacturing principles can improve efficiency and innovation in the pharmaceutical sector, despite challenges due to regulatory issues. Effective communication and cooperation between regulatory organisations and the industry are crucial.

2.5 BENEFITS AND CHALLENGES OF AGILE TRANSFORMATION

The possible advantages of agile transformation for pharmaceutical organisations will be discussed in this section. These advantages might include of organisations that switch to agile approaches face a variety of advantages and difficulties. This synopsis offers insights into both areas based on current studies:

- **Improved performance and efficiency:** Agile approaches improve performance by encouraging adaptability, quick development, and the capacity to handle

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change, which satisfies the software industry's growing need for on-time delivery (Kulkarni et al., 2017).

- **Increased stakeholder satisfaction:** Agile tends to improve stakeholder satisfaction and more successfully match consumer demands because of its emphasis on customer participation and its iterative development approach, which delivers functioning products often.

- **Enhanced collaboration and communication:** Agile methodologies cultivate an environment of transparent communication and cooperation among development teams and stakeholders, resulting in enhanced project results and congruence with corporate goals (Srivastava, Mehrotra, Kapur, & Aggarwal, 2020).

- **Flexibility in dealing with changes:** Agile frameworks are especially good at handling requirements changes that arise throughout the development process, making sure the finished product stays relevant to the needs of stakeholders and market circumstances (Fernández-Sánchez et al., 2014).

On the other hand, the **challenges and potential obstacles** faced during the agile transformation process will be discussed, such as

- **Scaling agile practices:** Maintaining the agility and coherence of processes presents special problems when implementing agile principles at scale in big organisations since it requires coordinating operations across numerous teams and interacting with other organisational units (Dikert, Paasivaara, & Lassenius, 2016).

- **Management and cultural shifts:** Making the shift to agile necessitates profound adjustments to organisational culture and management procedures, including adopting a continuous improvement, customer-centric, and flexible mentality. In order to support and propel this transition, managers and leaders are essential, and doing so frequently calls for a change in conventional leadership philosophies and methods (Boehm & Turner, 2005).

- **Training and skill development:** For an agile transition to be effective, team members must get in-depth coaching and training in order to completely comprehend and implement agile practices. This entails learning new abilities and modifying current ones so they perform inside an agile framework.

- **Integration with existing processes:** It can be difficult to integrate agile approaches with current traditional development processes and business practices; customised solutions are frequently needed to guarantee smooth operation and alignment with corporate goals.

- **Resistance to change:** Agile transformation may encounter strong opposition from management and staff. This opposition is frequently the result of a lack of knowledge about the advantages of agile methods, anxiety about losing control or job security, and discomfort with the enhanced responsibility and openness that these methods bring.

2.6 PHARMA LEADERSHIP IN AGILE TRANSFORMATION

The leadership role in agile transformation in pharmaceutical firms involves integrating agile approaches that prioritize adaptability, quick iteration, and cross-functional cooperation. Organisational culture, structural changes, and leadership philosophies are crucial for enabling this transformation. Research suggests certain leadership philosophies are appropriate for agile transformation.

ROLE OF LEADERSHIP IN AGILE TRANSFORMATION

The efficacy and success of the Agile transformation inside organisations are greatly influenced by leadership, which is a crucial component of the process. Numerous important facets and effects of leadership in agile contexts have been found via research:

- **Effective leadership in agile development:** Agile software development involves dynamically sharing leadership responsibilities among team members, fostering a sense of community and balancing conflicting organisational cultures. Effective agile leadership requires a sense of belonging, willingness to take on

responsibility, and awareness of cultural differences among team members. (Gren & Ralph, 2022).

- **Agile leadership and digital transformation:** The effective and seamless integration of digital transformation into organisational structures and functions is greatly influenced by agile leadership. It cultivates the three essential elements of digital transformation: dynamic capacity, strategic flexibility, and workforce change. Incorporating these elements into the organisational environment requires leadership agility (DeliŇoglu & Uysal, 2023).

- **Leadership approaches in agile project management:** The choice of the right leadership style in agile project management settings is crucial for each unique scenario, as agile methods must be flexible enough to adapt to the volatile, unpredictable, complex, and ambiguous (VUCA) corporate environment, requiring the use of both agile and conventional project management techniques. (Fischer, 2021).

- **Leadership roles in agile teams must evolve:** Moving from a Scrum Master to a More Distributed Model within the Development Team is One Way to Change Leadership in Agile Teams. A supportive environment within the team and the belief that team members may assume new leadership responsibilities enable this shift, encouraging self-organisation and empowerment (Spiegler, Heinecke, & Wagner, 2021).

- The significance of "affective leaders" in high-agility teams cannot be overstated, particularly in times of crisis. These leaders help their staff have pleasant emotional experiences, which facilitates effective adversity reactions. This emphasises how crucial it is for Agile managers to comprehend, deal with, and actively manage emotions (Renault & Tarakci, 2023).

CHALLENGES FACED BY LEADERS WHILE IMPLEMENTING AGILE TRANSFORMATION STRATEGIES

The effective implementation of agile approaches inside organisations can be hampered by a range of problems that leaders facing agile transformation journeys frequently face. A survey of the literature reveals that the difficulties fall into a few major categories:

- **Agile methodologies implementation at scale:** Overcoming opposition to change, integrating agile methods with other functions, and putting them into large-scale contexts are all tough tasks. It's critical to strike the correct balance between the structure required in large organisations and the flexibility of agile approaches (Dikert, Paasivaara, & Lassenius, 2016).

- **Management challenges:** Conventional development organisations encounter challenges when adopting agile processes, such as incompatibilities between agile and current business procedures, challenges in modifying organisational culture, and problems with collabouration and people management (Boehm & Turner, 2005).

- **Organisational culture and mentality:** A major cultural transformation inside the organisation is necessary to facilitate the adoption of an agile mentality. The three pillars of agile approaches—rapid iteration, adaptability, and collabouration—are sometimes difficult for leaders to promote (Reginaldo & Santos, 2020).

- **Adapting to agile practices:** It might be difficult to choose the right agile framework and to tailor agile practices to the organisational setting. According to Conboy and Carroll (2019), leaders are responsible for guaranteeing that agile methods are seamlessly incorporated into the organisation's workflow and in line with its aims and objectives.

- **Training and skills development:** It might be difficult to make sure team members are equipped with the right knowledge and skills regarding agile processes. Agile approaches must be implemented successfully, which requires sufficient training and continuing assistance (Paasivaara & Lassenius, 2016).

- Agile approaches place a strong emphasis on the value of communication and cooperation inside teams as well as between the team and stakeholders. It can be difficult to break down barriers to communication and guarantee productive teamwork, particularly in remote teams (Denning, 2016).

2.7 CURRENT TRENDS FOR AGILE TRASNFORMATION IN PHARMACEUTICAL COMPANIES

Agile transformation is gaining popularity in the pharmaceutical industry for its adaptability, efficiency, and quick change reactions, aligning with global trends towards dynamic corporate methods and fostering creativity in response to changing regulatory environments.

- **Agile production for products focused on patients:** popularity due to its decentralisation, flexibility, and quick patient response. Digital technologies can enhance supply chain robustness, ensuring timely drug access. (Miriam Sarkis et al., 2021).

- **Agile software product line engineering in big businesses:** Agile methodologies manage software complexity in large enterprises, preserving efficacy and adaptability. Integrating agile approaches with risk management is crucial for rapid digital transformation. (V. Muntés-Mulero et al., 2019).

- **Organisational development based on agile transformation:** The portfolio management model effectively balances agile transformation and traditional development, promoting creativity, efficiency, and adaptability, particularly in pharmaceutical businesses, fostering innovation and sustainable growth. (J. Palfreyman & J. Morton, 2022).

- **Agile as an innovation enabler**: Agile concepts, involving collabouration, continuous improvement, and flexibility, are crucial for facilitating organisational transitions and fostering an innovative culture within businesses, navigating challenges posed by globalization and digitalization. (Mothepane M. Tshabalala & C. Marnewick, 2021).

- **Digital twins in pharmaceutical manufacturing:** Digital twins revolutionize the pharmaceutical industry by simulating manufacturing processes in a virtual environment, enabling faster innovation, predictive maintenance, and process optimization. (Yingjie Chen et al., 2020).

2.8 CONCLUSION

Agile transformation has transformed project management and software development by replacing conventional techniques with adaptable, iterative strategies. The Agile Manifesto emphasizes people, interactions, and customer collabouration. Agile approaches like Scrum, Kanban, and Extreme Programming (XP) have improved stakeholder satisfaction, efficiency, and adaptability in various industries. These methodologies are increasingly used in the pharmaceutical industry to manage the complexity of medication development and production, demonstrating their adaptability and efficacy in advancing project management.

Agile transformation is a strategy used in the pharmaceutical industry to address issues like risk aversion, regulatory compliance, and innovation demand. It involves integrating Agile methodologies with pharmaceutical development specifications and promoting effective leadership. However, it has drawbacks like managing cultural changes and integrating Agile with current procedures. Contemporary developments, such as digital transformation and agile manufacturing, demonstrate the continued application of agile approaches in meeting industry demands. Case studies highlight the importance of adaptability, stakeholder involvement, and digital technology in improving operational efficiency and service delivery.

CHAPTER 3: RESEARCH QUESTIONS

This study looks at the implementation of agile transformation and its effects in the pharmaceutical sector, emphasising how these approaches improve stakeholder participation, efficiency, and flexibility. It draws attention to how changing healthcare needs, legal regulations, and technology developments impact medication development and market response.

This study examines the impact of leadership and change management on agile transformations in pharmaceutical businesses. It aims to understand how these factors influence the success of agile approaches, focusing on how effective leadership and communication can foster efficiency and innovation in this competitive and regulated sector. The study emphasizes the importance of understanding these core issues for successful agile adoption.

RESEARCH QUESTION

1. What are the primary drivers for agile transformation in pharmaceutical companies?
2. What are the main challenges faced by pharmaceutical companies in implementing agile methodologies?
3. How do leadership and change management influence the success of agile transformation in the pharmaceutical context?

RESEARCH SUB - QUESTION

1. How can the application of agile principles enhance departmental cooperation across R&D, marketing, and sales domains?
2. How does better communication help to expedite the development of new drugs?
3. How can the time it takes to bring a medicine to market go shorter with agile transformation?
4. What effect does a quicker time to market have on profitability and competitive advantage in the pharmaceutical sector?

5. How can executives in the pharmaceutical industry promote and embody agile principles?

6. How can project managers oversee the shift from conventional to agile approaches without interfering with existing work?

A fuller knowledge of how agile approaches affect the operations, culture, and results in pharmaceutical businesses may be gained by investigating these sub-questions.

CHAPTER 4: CASE STUDIES

This section outlines selection criteria for case studies, focusing on pharmaceutical companies undergoing agile transformation, considering diversity in size, location, and subsector. Existing case studies will be used as control.

Criteria for inclusion as follows,

- Relevance, Similarity and novelty

- Accessible Data, Data Availability, Data Reliability

- Feasibility, Time and Resources, Ethical Considerations

Criteria for exclusion as re follows,

- Enhancing validity and generalizability

- Research objectives and study design

- Avoiding discrimination and bias

- Potential for unintended consequences

1. **Article title - "Moving faster than the covid-19 pandemic: the rapid digital transformation of a public health system" (Sullivan et al., 2021).**

The Queensland, Australia, case study demonstrates the state's use of digital technology to manage the COVID-19 pandemic. Outdated technologies were replaced by a digital system called the Digital Coronavirus Application (DCOVA), which made it easier to monitor data in real time and make decisions about containment. By integrating data from many authorities, this integrated system ensures a coordinated approach and real-time surveillance of persons under quarantine.

A flexible, iterative strategy was used to quickly deploy the DCOVA development process, allowing for real-time user feedback and continual modifications to operational and regulatory requirements. This tactic greatly enhanced data management and aided Queensland's successful COVID-19 response. In times of crisis, the case study

emphasises the need of having a clear objective and flexible digital transformation strategies, especially for pharmaceutical companies.

2. Article title - "Catalyzing healthcare transformation with digital health: performance indicators and lessons learned from a digital health innovation group" (Tseng et al., 2017).

A methodical strategy to advancing distributed computing (DH) breakthroughs has been created by the Brigham and Women's Hospital Digital Health Innovation Group. Between July 2014 and December 2016, the group reviewed 54 different DH solutions, provided a pre-pilot needs checklist, and facilitated links throughout the whole organisation. This systematic approach provides a blueprint for accelerating DH advances that other health systems might apply. Using the DH ecosystem, developing best practices for innovation processes, and developing post-pilot procedures should be the main areas of future study. Pharmaceutical companies may find the case study helpful in learning how to implement agile methods and digital technology in the healthcare industry.

3. Article title - "Improving the quality of services in medical clinics: a case study based on digital transformation" (Alzamanan, Ayidh Ali, *et al.,* 2022)

The research explores the potential benefits of digital transformation in Saudi Arabia's healthcare system. It highlights the challenges in implementing new digital strategies, such as ineffective administrative procedures, poor communication, and data management issues. The study suggests that clinics can improve patient care by utilizing Electronic Health Records (EHRs), telemedicine, patient portals, remote monitoring technology, data analytics, and workflow automation. EHRs offer a secure and comprehensive management of patient data, while patient portals allow for better involvement and communication. Telemedicine technologies increase healthcare access, especially in disadvantaged countries. EHRs also provide safe and comprehensive administration of patient data, enhancing patient involvement and

communication. Data analytics and insights can optimize resources, make decisions, and improve quality. Automation of administrative processes and workflow automation can enhance operational efficiency. However, strategic planning, patient-centreed care, and stakeholder participation are required for successful implementation.

4. **Article title - "Agile transformation: impact on employee satisfaction and reputation of pharmaceutical corporations in thailand" (Aramaphon Torchot, 2022)**

Aramaphon Torchot's study examines the impact of agile transformation in Thailand's pharmaceutical sector, focusing on its impact on reputation and employee happiness. Agile transformation involves shifting operations and attitude towards flexibility, and is proposed as a solution for quick innovation and new medicines in the pharmaceutical industry.

The study uses an online questionnaire to gather data from Thai pharmaceutical company workers about agile transformation. It reveals that it enhances cooperation, flexibility, and self-organisation, leading to increased employee satisfaction and a positive company reputation. However, widespread knowledge can cause confusion. The report recommends ongoing staff education and strategic planning for effective digital transformation in the pharmaceutical industry.

5. **Article title - "From pyramid to communities: how a pharma company reinvented themselves using scrum," (Lilja, S., Kailanto, J. and Saanila-Sotamaa, M., 2021)**

Gives a thorough explanation of how Scrum, an Agile paradigm, was effectively incorporated into operations at Roche Pharma Finland. The goal of this change was to overcome the difficulties presented by the pharmaceutical industry's protracted development cycles and stringent regulatory regulations.

As part of a global drive to increase healthcare solutions' adaptability, customer centricity, and inventiveness, Roche embraced Scrum in 2018. Roche transitioned from conventional hierarchical organisations to dynamic, team-based communities in

collabouration with the Finnish consulting firm Reaktor Innovations. Eliminating supervisory posts and forming independent teams for designated disease regions were the primary modifications.

Initially, Roche's Scrum deployment faced challenges, including a lack of stakeholder participation in Sprint Reviews. To combat work overload, changes were made, including real Sprint Reviews and backlog management. Despite these challenges, Roche's Scrum deployment improved clarity, increased team autonomy, and quicker response to changing needs during the COVID-19 pandemic.

This case study is an invaluable resource for other pharmaceutical companies and other businesses, demonstrating that Agile methodologies like Scrum can be successfully implemented in environments that don't initially seem to be ideal for them— all with the right amount of dedication, adaptability, and strategic modifications.

CHAPTER 5: RESEARCH METHODOLOGY

5.1 INTRODUCTION TO THE METHODOLOGY

A methodological technique called qualitative research aims to comprehend human behaviour, perspectives, motives, and the ways in which people interpret and make sense of the world. Qualitative research emphasises depth over breadth, seeking deep, nuanced insights into specific situations or occurrences, in contrast to quantitative research, which is more concerned with statistics and statistical analysis.

- One of the most popular qualitative techniques is the interview, which can be conducted in an unstructured, semi-structured, or organised manner. They entail direct, one-on-one communication during which the participant is asked targeted questions by the researcher in order to elicit detailed information about their experiences, attitudes, and beliefs.
- **Case Studies:** To examine and comprehend complicated topics in real-life situations, case study research entails an in-depth, contextual investigation of a particular event, scenario, or individual. It can offer thorough insights on elements including procedure, expertise, and the success of interventions.

THEMATIC ANALYSIS

Thematic analysis (TA) is a popular and adaptable method for analyzing qualitative data, revealing theme patterns from data sets. It is a crucial tool for researchers, as it allows for the interpretation of various aspects of the research issue and provides a sophisticated framework for delving into extensive text corpora. (Braun & Clarke, 2006).

Thematic analysis provides flexibility in terms of methodological and epistemological approaches, in contrast to many qualitative analysis techniques that are restricted to certain theoretical frameworks. This makes it possible to use it in a variety of theoretical contexts, from constructivist to positivist paradigms (Clarke & Braun, 2017).

Procedure for Thematic Analysis:

- **Data familiarisation:** researchers immerse themselves in the data, making notes on preliminary concepts.

- **Generating initial codes:** data segments are coded systematically.

- **Looking for themes:** possible themes are compiled from the codes.

- **Examining themes:** to make sure the themes make sense together, they are compared to the dataset.

- **Identifying and labelling themes:** every theme is clarified and given a thorough examination.

- **Making the report:** the analysis is compiled in the final report in a way that persuasively narrates the story of the facts in connection to the research question.

(Lochmiller, 2021)

Conclusion: The versatility of thematic analysis to diverse data sources and research topics is demonstrated by its application in a wide range of sectors, including psychology, healthcare, and education. Its broad usefulness has been demonstrated by the use of it, for instance, in understanding experiences in health interventions and perceptions in educational contexts

5.2 QUALITATIVE RESEARCH METHOD

The primary motivation behind using the qualitative research approach for conducting interviews is to get knowledge of intricate social phenomena, people's perceptions, experiences, and the meanings they ascribe to them. In a manner that quantitative approaches cannot, qualitative interviews enable in-depth investigation and provide insights into participants' perspectives.

The main reason for selection of qualitative research methods are as follows:

- **Flexibility and Depth:** Qualitative interviews are a versatile and in-depth method for studying human experiences and perceptions. They are especially useful for investigating complicated subjects because they allow for probing and follow-up

questions depending on participant replies, which can offer deeper insights and subtleties (Lois W. Sayrs, 1996; P. Burnard, 1991).

- **Contextual knowledge:** This strategy enables researchers to collect data within the context of participants' experiences, resulting in a deep and thorough knowledge of the phenomenon under investigation. It recognises the role of environment in affecting experiences and perceptions (Dicco-Bloom & Crabtree, 2006).

- **Participant-Centreed:** The voice of the participant is given priority in qualitative research, which provides a forum for them to express their viewpoints, experiences, and stories in their own words. According to C. McGrath, Per J. Palmgren, and Matilda Liljedahl (2018), the study findings are firmly rooted in the lived experiences of the participants thanks to this participant-centreed method.

- **Rich, Detailed Data:** Qualitative interview narrative data are rich and detailed, providing insights that may not be obtained using quantitative data gathering techniques. The development of theories and an understanding of the intricacy of social phenomena depend on this richness (Sandy Q. Qu & John Dumay, 2011).

- **Adaptability:** Qualitative interviews are a flexible method that may be used by researchers in a range of study contexts and populations. In exploratory investigations, where the study topics and focus may change over time, this flexibility is essential (H. Minhat, 2015).

- **Sensitive topics:** Because the qualitative interview approach may provide a secure environment for participants to divulge private and potentially sensitive information, it is especially well-suited for investigating sensitive topics. Deeper understandings of subjects that might be challenging to investigate using other techniques can be found using this approach (M. D. Myers & M. Newman, 2007).

In summary, the use of qualitative research methodologies for conducting interviews is supported by the variety, flexibility, and depth of the data they offer, allowing for a thorough comprehension of the experiences and viewpoints of participants. This method is very helpful in examining intricate and subtle social phenomena since it provides insights that are not possible with just quantitative tools.

5.3 RESEARCH DESIGN AND STRATEGY

In the domains of pharmaceutical, systematic investigations need careful consideration of research design and strategy. Progress requires a strategic framework with agreed-upon research methods and overarching objectives. This framework makes it easier to create prescriptive classifications and descriptive research profiles since it is founded on ideas that improve national prosperity and quality of life. This strategy promotes responsive and industry-relevant design research. Design science research in information systems may be approached in two main ways: either by creating IT meta-artefacts as general solution concepts or by addressing particular issues in particular contexts and then distilling prescriptive knowledge. The environment, outcomes, methodology, and resource requirements of these techniques vary. (J. Iivari, 2015)

Variable-centreed research designs emphasise the interactions between variables, whereas case-centreed research approaches prioritise the in-depth analysis of particular cases. According to Oddbjørn Bukve (2019), these methodologies may be employed for a range of research objectives, including hypothesis testing, development, and intervention. They also result in distinct data creation and analysis methods. The decisions made about the objectives, reach, and competitive strategies of businesses or divisions are examined by strategy content research. It examines the connections between strategic choices, performance goals, and environmental factors. Future study should examine these links more thoroughly, according to this line of inquiry, in order to better understand strategic decision-making and how it affects the performance of businesses.

A research project's study design and strategy, which direct the investigation from inception to conclusion, have a significant impact on its success. These factors influence the validity and applicability of the study's results by dictating the procedures for gathering, analysing, and interpreting data. Research methodology and design are always changing in tandem with advances in technology, processes, and philosophical viewpoints. Their guidance affects the validity, consistency, and generalizability of study findings, extending from the formulation of research questions to the distribution of findings.

5.4 DATA COLLECTION METHODS

Planning a research to interview representatives of the pharmaceutical sector necessitates giving significant thought to data collecting techniques, such as participant selection criteria and sample strategy. This guarantees the accuracy and legitimacy of the information gathered.

Objective of the Study: The study aims to explore the application and implications of agile transformation in pharma R&D, focusing on problem-related questions and participant selection, allowing for understanding of personal experiences and ground-level approaches.

Primary Method: Semi-Structured Interviews

Semi-structured interviews are a reliable method for gathering qualitative information from pharmaceutical industry authorities. Digital recording ensures accuracy, multiple devices are used, consent forms are submitted, and an interview guide with open-ended questions is prepared. Participants are provided with a brief and introduction to agile.

The interview started from 20th of March to 20th of April, Before and during this time the participants were contacted and asked for a particular time for conducting an interview, for the interviews MS teams was used, before the start of the interview the participants were briefed about the topic a general introduction about the interviewee, also some rules regarding the interview, and the interview will be recorded. The interviews generally lasted between 25-40 minutes depending on the time frame, knowledge base about the topic of the participant, and if they had any additional points to add. All the participants were asked 15 questions based on the main questions to be asked linking them to the final outcome. The questions were designed to indirectly provide the answers to the primary questions listed on chapter one.

5.5 SAMPLE SELECTION

The interview process's critical stage of sample selection has an impact on the reliability and validity of the study's conclusions. It need to be guided by clearly stated study objectives as well as research questions and goals. For thesis interviews, purposeful

selection—which entails reaching out to people with comparable experience, industry, and skill set—is frequently employed. With this approach, participants are chosen from a larger pool of people, including former coworkers, CEOs, business owners, and those connected on LinkedIn. Participants should be selected according to characteristics pertinent to the study topic, and the purpose of the study should be clearly stated.

5.6 DATA ANALYSIS TECHNIQUES

Examining, purifying, transforming, and modelling data in order to find relevant information, draw conclusions, and aid in decision-making is the process known as data analysis. There are many distinct aspects and methods to data analysis, which include many methodologies under various titles in the corporate, scientific, and social science areas.

Thematic analysis (TA) is a popular and adaptable qualitative research technique that helps researchers organise and characterize their data set by identifying and evaluating patterns within the collected data. This method is widely used in psychology and can be adapted to different types of qualitative data and research objectives. Thematic analysis emphasizes rigor and a systematic approach to ensure the credibility of the analysis, involving a step-by-step process from data familiarization to theme definition and reporting. Kiger and Varpio (2020) provide detailed guidance on conducting thematic analysis, highlighting its advantages in various fields, including medical education. Thematic analysis's flexibility allows researchers to apply it in diverse ways according to their research needs and epistemological stances. Clarke and Braun (2017) emphasize the thematic analysis's applicability, emphasizing its robustness in providing a robust method for qualitative analysis that is adaptable to the researcher's specific needs.

5.7 ETHICAL CONSIDERATION

The dynamic nature of the research process necessitates that participants comprehend the purpose and expectations of the study. This entails anticipating interview questions, safeguarding participant privacy, and maintaining participant anonymity. In order to manage discomfort and provide assistance when required,

researchers must strike a balance between the therapeutic advantages of the interview and its emotional impact. There might be moral conundrums when people divulge more than they meant to (Pascoe Leahy, 2021). In situations when permission is a continuous process, continuous consent is advised. Respect and decency should be shown to participants in all aspects, including time, privacy, and emotional burden. Informed permission, confidentiality, minimising damage, being ready for unanticipated obstacles, and respecting participants are some of the ethical factors to be taken into account when conducting dissertation interviews. In order to safeguard participant welfare and study integrity, researchers should regularly assess and modify their ethical procedures (Allmark et al., 2009).

Researchers should adapt techniques to vulnerable groups, embracing reciprocity ethics for meaningful participation. Maintaining communication after interviews, debriefing sessions, and being open about objectives, data usage, and results is crucial for ethical research. Responding to participants and academic institutions is essential. (Mohd Arifin, 2018).

CHAPTER 6: DATA ANALYSIS AND FINDINGS

6.1 INTRODUCTION

Thematic analsis is a qualitative research technique used to identify and present patterns in data, providing a comprehensive summary. It is commonly used in social sciences, psychology, and health fields to evaluate data sets like survey responses and interview transcripts. The process involves reading and interacting with data, creating preliminary codes, grouping information into possible themes, evaluating and improving themes, and characterizing each topic.

6.2 GENERATED DATA

The study aimed to understand research questions related to R&D processes in the pharmaceutical industry. 20 professional were contacted through different channels and 10 professionals were selected using various recruitment methods, including LinkedIn, personal connections, and referrals. All participants had at least five years of experience in R&D roles. Data collection involved online interviews, allowing remote communication and rich qualitative data. Open-ended and closed-ended questions were used, allowing participants to share their experiences and insights. The interviews were linked to the research question and subquestions, eliciting valuable perspectives and data. The methodologies used, including targeted recruitment, structured interview formats, and thorough transcription, provided a solid foundation for analysis and research outcomes.

PARTICIPANT	A	B	C	D
INDUSTRY	PHARMACEUTICAL	BIO PHARMACEUTICAL	BIO PHARMACEUTICAL	PHARMACEUTICAL
SUB CATEGORY	R&D MANUFACTURING	R&D RESEARCH	RESEARCH	MEDICAL DEVCES
JOB TITLE	R&D SCIENTIST	R&D SCIENTIST	RESEARCH ASSOCIATE	CEO&OWNER
COMPANY SIZE	22000+	6000+	2000+	100+
VALUATION	US $300 MILLION	US $12 BILLION	US $50 MILLION	US $10 MILLION
TEAM SIZE	12	9	3	5
INTERVIEW DATE	6TH APRIL	9TH APRIL	15TH APRIL	18TH APRIL

PARTICIPANT	E	F	G	H
INDUSTRY	PHARMACEUTICAL	PHARMACEUTICAL	PHARMACEUTICAL	FINANCE
SUB CATEGORY	MEDICAL DEVICES	SUPPLY CHAIN OPERATIONS	HEALTHCARE	PHARMA INVESTMENT AND FINANCE
JOB TITLE	CO-OWNER	SR. SPECIALIST SUPPLIER OPERATIONS	R&D SCIENTIST	ENGAGEMENT MANAGER
COMPANY SIZE	100+	72000+	36000+	45000+
VALUATION	US $10 MILLION	US $60 BILLION	US $42 BILLION	US $245 MILLION
TEAM SIZE	5	48	15	5
INTERVIEW DATE	18TH APRIL	18TH APRIL	8TH APRIL	14TH APRIL

Figure 1: Details of participants

IDENTIFIED THEMES AND CODES

Determined themes and symbols

1. **Challenges of agile transformation:**

- Codes: Difficulties include long development cycles, risk aversion, and regulatory compliance.

- Colour Red: Stands for difficulties and barriers.

2. **Role of leadership in agile transformation:**

- Codes: Facilitating Agile Adoption, Change Management, and Leadership.

- Colour blue denotes power and leadership.

3. **The management of change:**

- Codes: Innovation, efficiency in R&D, tolerance to change.

- Green: Indicates adaptability and resistance in a certain organisation.

4. **Effect on culture of the organisation:**

- Codes: Modifications to company culture, cooperation, and employee participation.

- Colour Purple: This hue symbolises innovation and metamorphosis.

The study proposal's discussion of many facets of agile transformation in the pharmaceutical business will be made easier to see with the use of this theme colour

coding. To make the information simpler to comprehend and debate, each topic has been given a colour that represents it.

THEMATIC ANALYSIS OF PARTICIPANTS				
PARTICIPANTS	A	B	C	D
Familiarity with agile	NO	NO	NO	YES
Challenges of Agile Transformation	Unfamiliar	Cautious	Conservative	progressive
Role of Leadership in Agile Transformation	Visionary	Traditional	Unmotivated	Collaborative
The management of change	Erratic	Steady	traditional	Effective
Effect on Culture of the Organisation	Collaborative	Competitive	Teamwork	Uncertain
PARTICIPANTS	E	F	G	H
Familiarity with agile	YES	YES	no	YES
Challenges of Agile Transformation	Comprehensive	Challenged	mixed	Mixed
Role of Leadership in Agile Transformation	strategic	Enabler	Balanced	Open
The management of change	Agile	Patience	Phased	Inclusive
Effect on Culture of the Organisation	Supportive	Efficient	Transparent	Inclusive

Figure 2: Thematic analysis of participants

6.3 CHALLENGES OF AGILE TRANSFORMATION:

The difficulties in understanding and executing agile transformation in a business are covered in this section. Interviews showed that while D, E, F, and H were aware of the idea and its ramifications, participants A, B, C, and G were not.

A biopharma company's process development scientist, Participant A, shares insights on the unique challenges faced by the pharmaceutical industry when implementing Agile methodology. Despite not being familiar with Agile, his expertise helps clarify its advantages and obstacles.

Findings - "When it comes to industry, things are very stringent because of the regulatory aspect"

"First of all, if we compare it with the IT industry, this industry here, I think I'm using the right term that is return of investment, ROI, is delayed."

Analysis - Agile technique faces challenges in healthcare and pharmaceutical industries due to strict regulatory compliance, requiring careful navigating to ensure patient safety and operational effectiveness (Ahmad & Wasim, 2023). Making R&D a lengthy and stringent process with many hurdles which can be overcome anf with the

addition or delayed ROI and also trying to mitigate risk as well the odd are always stacked against thme. (Beerbaum, 2019).

There was a similar trend observed between the answers provided by participant B and C, they both were also associated with Pharmaceutical companies working in the R&D department.

Findings - Participant C - "R&D is companies is a slow and pain staking process for the companies, and they just focus on making some small changes or try to play it safe",

Participant B - "And it is also, we need to keep this in mind that the person who is owning the company or who is the entrepreneur, he is also from our own society, he is not there for charity."

Analysis - Nord and Ossella-Durbal's (2011) study indicates that higher R&D spending in the pharmaceutical industry leads to higher market value, highlighting its importance for growth and profitability. Munos and Chin (2011) contend that pharmaceutical corporations frequently opt for "safe" incremental innovation over high-risk discovery research, mostly in order to sustain profitability. This bolsters Participant C's assertion regarding companies who play it safe.

Participant H, a pharmaceutical company veteran with R&D and management experience, expressed mixed reactions to agile deployment in the company's change management process.

Findings - "The adoption of agile methodologies has sometimes disrupted the productivity of R&D teams. The frequent meetings and iterative processes can detract from deep, focused research time, which is crucial in pharmaceuticals."

Analysis - Agile approaches enhance responsiveness and expedite processes, but may cause frequent disruptions and shift away from in-depth research in the pharmaceutical industry, potentially affecting R&D teams' productivity (Paul et al., 2010)

Participants D, E, F, and H expressed positive attitudes towards agile implementation in the pharmaceutical industry, citing their experience in transitioning

from traditional R&D methodologies to agile, and their entrepreneurial background in product development and company establishment.

Findings - Participant E "Other than employees, I have to take care of all those aspects, whether they are on time, whether they are working or not, whether their objectives are identified. So all those methodologies come under the picture."

Participant D "there are a few private companies that comes into the picture and they use this kind of technologies to fasten the process, faster your documentation cycle."

Analysis - The 2015 study by Jesse W. Campbell examines how organisational identity functions in performance management, with an emphasis on structured framework-based methods for monitoring employee performance. Using a neural-fuzzy network technique, Caryl Charlene Escolar-Jimenez (2019) presents a data-driven, objective way for assessing employee performance.

Participant F has been an early applicant of agile in the field of process development, research and manufacturing for more than 10 years.

Findings - Participant F "The biggest hurdle we've faced with Agile is definitely the cultural aspect. People are used to doing things a certain way and changing that mindset takes a lot of time and effort" and "Scaling Agile across multiple teams has been a nightmare. Each team has its nuances, and finding a one-size-fits-all approach is nearly impossible"

Participant H "To address challenges in implementing Agile in teams accustomed to traditional project management, it is crucial to emphasize training and change management"

Analysis - Dikert, Paasivaara, and Lassenius (2016) emphasised the necessity for a customised strategy by underlining the difficulties associated with scaling Agile across varied teams and cultural resistance to change. Kalenda, Hyna, and Rossi (2018) emphasised the significance of change management and training in overcoming resistance and executing Agile in big organisations.
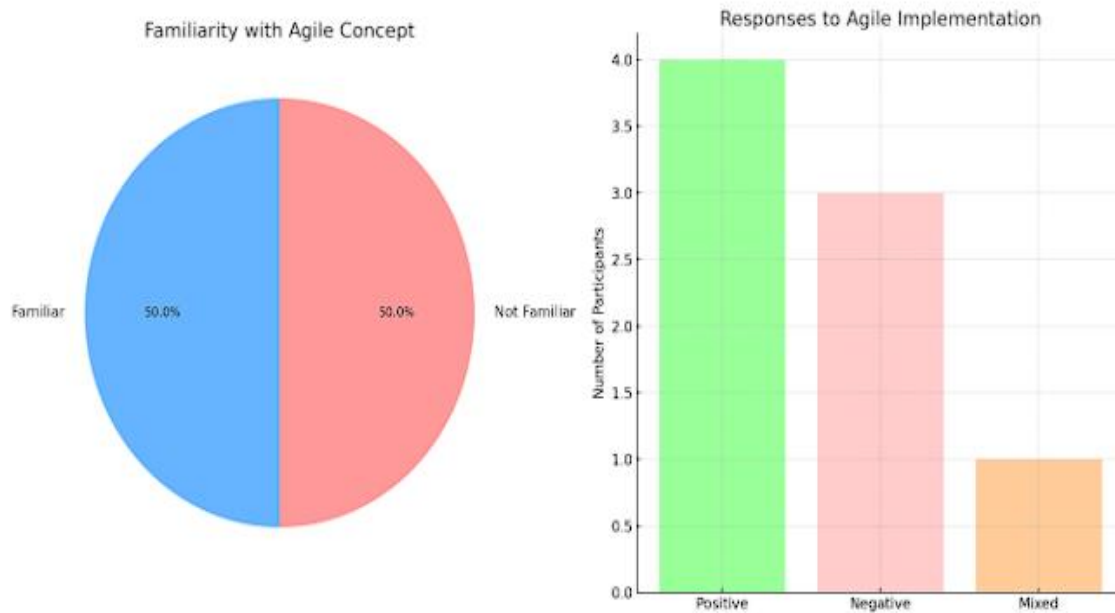
Figure 3: Pie chart shows the familiarity with the topic and Figure 3 responses to agile implementation:

It's amazing to observe how evenly participants' acquaintance with Agile approach splits—exactly 50% are familiar, while the other 50% are not. This distribution, which is exactly even, shows that there are a variety of viewpoints and experiences with Agile principles within the community.

CONCLUSION – The report compares Agile approaches to traditional pharmaceutical practices, revealing challenges in adopting Agile transformation. Barriers include cultural resistance, large investments, and risk aversion. A survey shows a knowledge gap, with over 50% not familiar with Agile techniques. Operational interruptions, risk aversion, and regulatory compliance issues also hinder Agile adoption. The varied opinions on Agile implementation in the pharmaceutical industry highlight the complex and polarizing nature of integrating Agile. Positive outcome - Agile methodologies offer enhanced flexibility and speed, facilitating quicker decision-making and project turnover, and improving management practices due to their emphasis on continuous improvement and responsiveness, according to positive experiences.

6.4 ROLE OF LEADERSHIP IN AGILE TRANSFORMATION:

The study on "Leadership in Agile Transformation" emphasizes the importance of strong leadership in fostering agility in teams. Approximately 50% of participants were familiar with leadership concepts, but found significant improvements in R&D when leaders were given additional tasks and a focused approach.

Participant A emphasizes the significance of leadership in agile transformation, highlighting the advantages and challenges faced by executives in regulated, slow-to-change sectors like the pharmaceutical industry.

Findings - "Yes, if I have enough literature support, and if I am confident that this transformation or changing the portfolio to some other product might help us create a breakthrough at industry level in India, I would be very willing to do that."

"Our transition to agile wouldn't have been possible without strong leadership. The top management was not only involved in the decision-making but also took active steps to be part of the agile rituals."

Analysis - In highly regulated environments such as the pharmaceutical industry, leadership is especially important in promoting an agile attitude and incorporating teamwork, start-up culture, and matrix management (Salvetti & Bertagni, 2020)

Participant B and C gave negative responses where they said that there was no major focus on leadership and the company was content with their traditional approach.

Findings - Participant B "There was no or any emphasis on leadership, there was always some kind of surveillance on all activities and they were dependant on old ideas and were resistant to change."

Participant C quoted that "there was a lack of motivation or persuasion for development"

Analysis - Fakhriyeh Hamidianpour, Majid Esmaeilpour, and R. Zarei (2016) found that the cultural intelligence of managers and their transformational leadership style can significantly impact employees' resistance to change. This suggests that poor leadership can exacerbate resistance to organisational change (Hamidianpour, Esmaeilpour, & Zarei, 2016).

Participant G had a different approach, they were familiar with eh concept of agile and had a different approach towards leadership, they have a dynamic mindset he was more focused on productivity and team mentality during R&D he quoted

Findings - "it necessary to understand the mindset of the team members, as a leader it is my responsibility to push my team when it is required and to also not piush them too hard so that they break"

Analysis - The substantial effects of agile team management on productivity are emphasised by Melo et al. (2013), who also stress the significance of comprehending team dynamics, team design, member turnover, and inter-team cooperation.

Participant D and E had a very positive outlook towards leadership and being at the top of their respective firms, they focused highly on development of the team together and not as an individual for this they quoted that

Findings – "We have this question probably a couple of days ago, we had this recent discussion. Even though we are a team of five people, and we want to move to five to seven people, we consider before for these two people, how their time will be utilized."

Analysis - Schaubroeck, Lam, and Peng (2011) found that trust in leaders significantly influences team performance, emphasizing the importance of inspiring cognitive and affective trust.

Participant F and H viewed leadership as more than just giving instructions; it involves fostering a culture of flexibility, transparency, and iterative learning for agile processes.

Findings - Participant F "A leader in an agile transformation must be a facilitator and an enabler rather than just a traditional manager, Leadership commitment is essential. Without the active support and involvement from top management, agile practices are just superficial changes".

Participant H "Effective leaders in an agile setting are those who understand the importance of collabouration and are open to feedback and continuous improvement"

Analysis - Agile transitions need leaders to shift from traditional management positions to those of enablers and facilitators, creating a culture where employees use creativity to define the direction of the organisation and talent drives strategy. (Denning, 2018).
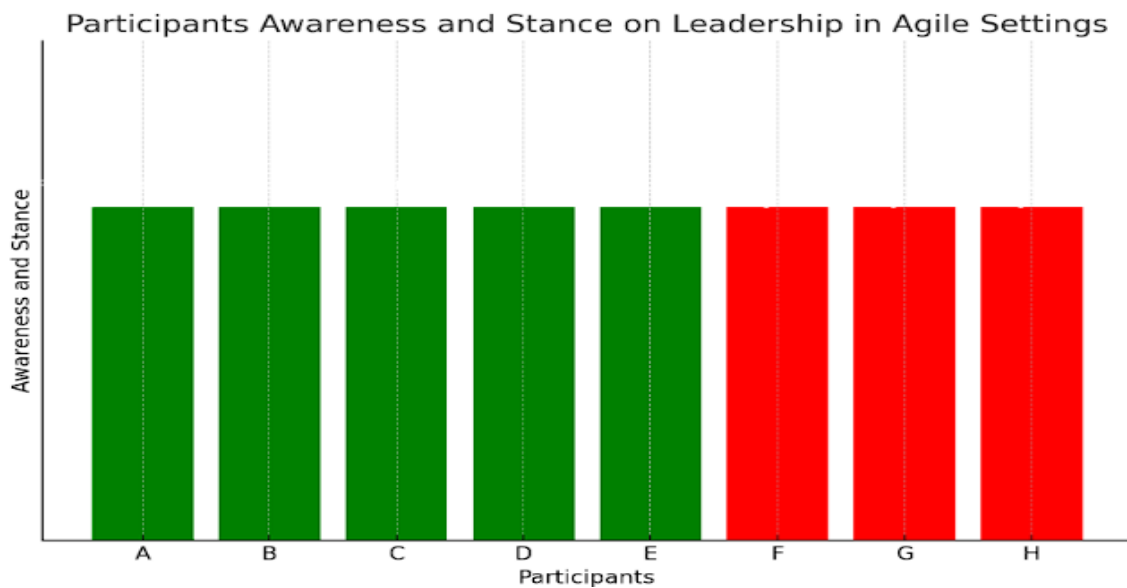

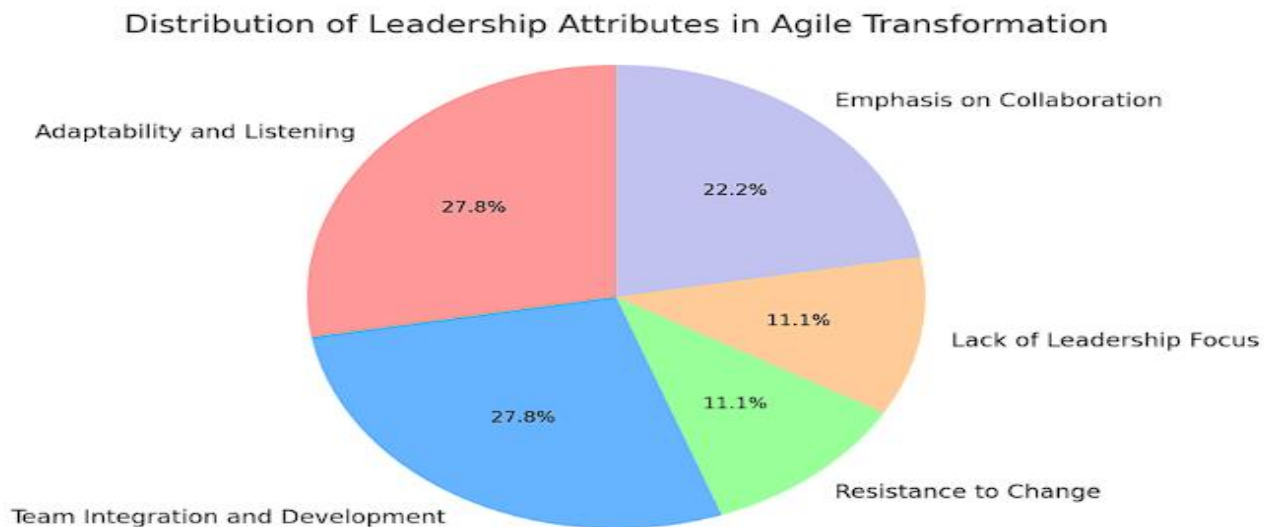*Figure 4: Participant awareness and stance on leadership in agile settings*

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Figure 5: Distribution of leadership attributes in agile trasnformation

CONCLUSION - Leadership is crucial for agile transformation, especially in resistant environments. Effective leaders encourage open communication, iterative learning, and

collaboration, enhancing agility and competitiveness. A study in the pharmaceutical industry highlighted the importance of strong leadership in fostering adaptability, openness, and iterative learning. However, some businesses lack leadership focus, leading to resistance to change.

6.5 THE MANAGEMENT OF CHANGE:

The theme "The Management of Change" examines organisational change tactics, difficulties, and effects, emphasising the effects on people and the group as a whole. These include stakeholder participation, communication, pace, scale, and support systems.

Participant A suggested that change was not managed properly, it was erratic and without any guidance they quoted that,

Findings - "Change was constant, but communication was erratic. It felt like we were supposed to adapt overnight without much guidance or support."

Analysis - A well-thought-out communication approach can greatly increase staff acceptance of new arrangements and reduce their apprehension about change. (Torppa & Smith, 2011).

Participant B and C on the other had no exposure to any kind of change in their respective companies, they quoted

Findings - "Work here is redundant, mostly focusing on R&D in the traditional way and not focusing on the results, other places are in the rat race but we prefer the slow and steady approach."

Analysis - In their discussion of the impact of redundant systems on individual performance, Contte and Jacobs (1997) point out how these systems can both strengthen and obfuscate accountability, potentially having an impact on the volume and quality of work produced.

Participant G had seen and experienced these transitions themselves and had a very positive outlook towards the results that can be obtained if change management is carried out properly.

Findings - "I saw firsthand how clear and frequent updates made a difference in how staff accepted the new changes"

Analysis - The study shows that employees' psychological health and job happiness can be greatly impacted by communication and how they perceive changes in their work environment (Verhaeghe et al., 2006).

Participant D and E were highly optimistic about the agile implementation and while the change was challenging in their experience they were able to tackle it with proper management and training.

Findings - "Adapting to new technologies was challenging, yet vital for our growth. Training and patience from management during this phase were crucial"

Analysis - The 2005 study by Boehm and Turner explores the management barriers that traditional development organisations face while implementing agile methods, emphasising the tensions that exist between development, business, and people.

Findings - Participant F "Initially, the change was overwhelming because it wasn't just a small tweak; it was a complete overhaul of our workflow. But, management broke it down into phases, which helped us not only understand but also adapt gradually."

Participant H "Change is hard, and it's even harder when you feel like you're in the dark. Regular updates and being included in the process made a big difference."

Analysis - By segmenting the process into manageable steps, phased implementation lowers resistance and increases acceptance, assisting staff in adjusting to changes. In discussing this within the framework of knowledge management projects, Horak (2001) points out that a phased approach can assist in addressing human aspects like anxiety and cultural shift, which will finally result in successful implementation and the realisation of benefits.
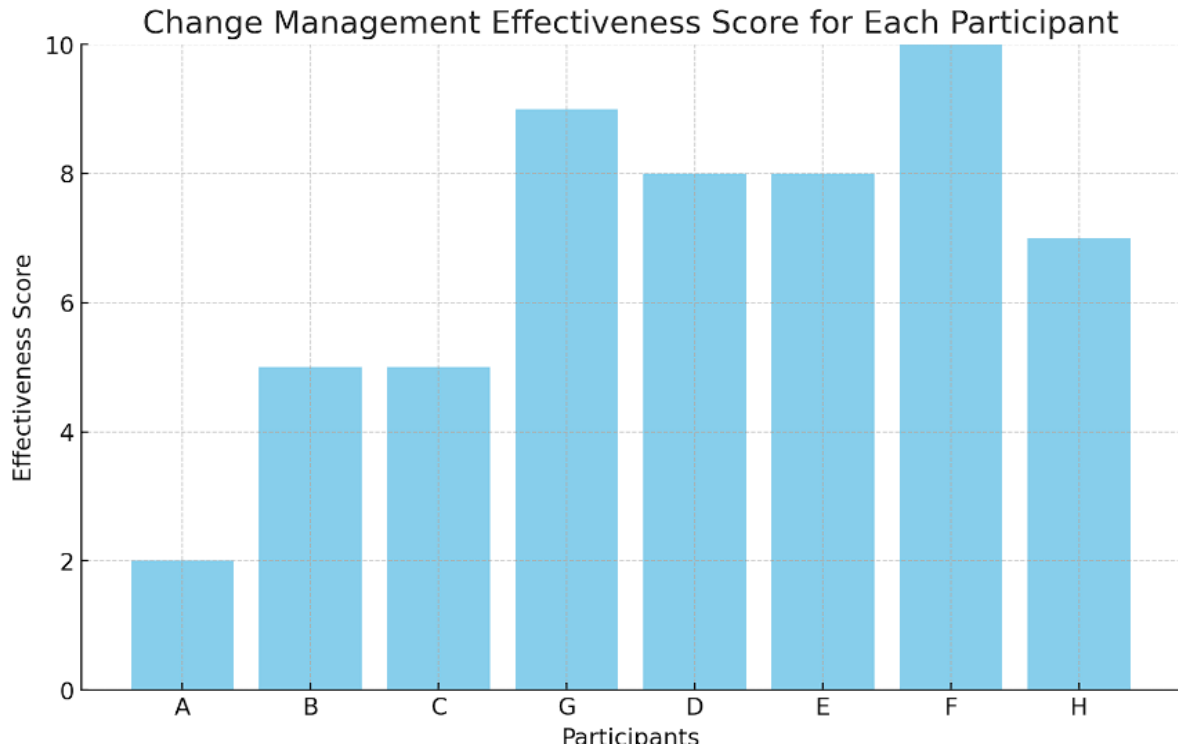
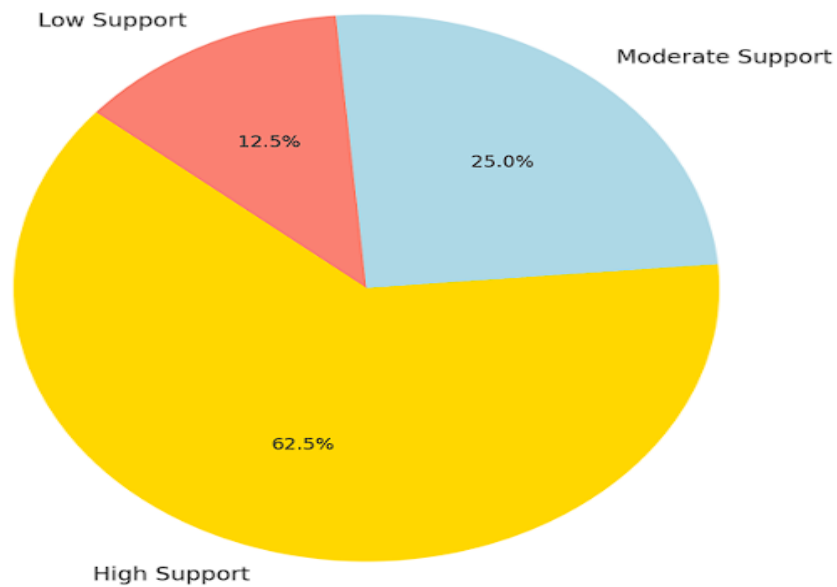*Figure 6: Change management effectiveness score for each participant.*

Figure 7: Proportion of participants experiencing different levels of support.

CONCLUSION - The "Management of Change" theme examines the impact of organisational change on individuals and groups, emphasizing the importance of strong support networks, efficient communication, and strategic preparation. Participants' experiences range from agile to formal change procedures, emphasizing the need for dedication and strategic oversight.

Effective change management in organisations relies on clear communication, regular updates, and support networks. Transitioning to agile approaches requires effective leadership and phased implementation, which can boost productivity by 25%. Feedback and inclusion are crucial for reducing stress and ensuring all team members are included in the change process. These components improve efficiency, adaptability, and make transitions easier for staff members.

6.6 EFFECT ON CULTURE OF THE ORGANISATION:

The "Effect on Culture of the Organisation" issue examines how organisational changes, managerial strategies, and internal dynamics impact workplace culture. Despite work being redundant, 80% of employees experienced positive outcomes and improved productivity due to organisational culture improvements, facilitated by effective management and leadership.

Finding – Participant A, "The introduction of cross-functional teams really broke down the barriers. It was a cultural shift that helped in more collabouration and innovation across departments"

Analysis - Effective and creative product development can be achieved by the integration of varied expertise through cross-functional teams, yet attaining high levels of collabouration can present some challenges (Jassawalla & Sashittal, 2006).

Findings - Participant B "The culture has become more competitive and less collabourative. It feels like we are more about numbers now than people, which has been a tough adjustment for many of us who valued the community aspect of our workplace"

Analysis - Research indicates that in many organisations, particularly in competitive industries, the emphasis on competitive advantage can overshadow collabourative culture, potentially leading to less cooperative work environments (Do Khoi Nguyen, Le Ba Phong, & Lei Hui, 2019).

Employees C, D, E, F, G, and H have demonstrated positive outcomes in their organisation's culture shift, according to the study. They talk about the advantages of working as a team, the disadvantages of efficiency and cost-cutting, remote work, moral conduct, openness, performance measurements, and layoff management. The report does, however, also show that the company's emphasis on efficiency has resulted in a less progressive and conservative culture. Transparency and inclusivity have increased with the open-door policy.

Findings - Participant E "The shift towards a more team-oriented approach has really helped us feel more connected and supportive of one another, improving our daily work atmosphere" while agile is short sighted most of the times, it is the best for team development.

Participant D, "The rapid changes in company policy have been confusing and have led to uncertainty and anxiety among staff, affecting overall morale"

Analysis - According to Zárraga and Bonache's (2005) research, a culture of "high care" among team members facilitates knowledge production and transfer within the team. This suggests that team-oriented techniques can enhance the work environment and foster team development.
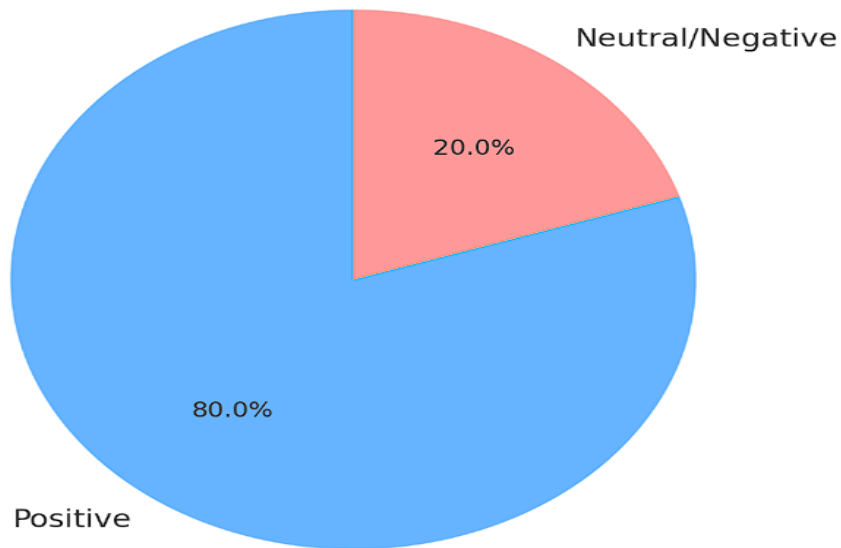
Sentiment on Cultural Changes

Figure 8: Sentiment on cultural changes.

CONCLUSION - The study on organisational culture change found that while Agile methodologies and cultural adjustments have improved performance, team bonding, and personal development, challenges and mixed feelings persist. The majority reported an 80% positive outcome, with cross-functional teams fostering greater collabouration and innovation. However, businesses face challenges in balancing success through metrics and efficiency with a community-focused culture. Some workers may feel the new atmosphere is less cooperative and more competitive, while others may become resentful of the growing emphasis on numbers. Effective change management techniques are essential for seamless transitions and staff awareness. Despite these challenges, the benefits of improved cooperation, moral conduct, openness, and openness suggest that cultural shifts have produced more transparent and inclusive work settings. However, companies must balance efficiency and agility while fostering a creative, cooperative, and encouraging work environment.

6.7 CONCLUSION

The pharmaceutical business faces complex challenges in implementing agile transformation, balancing effectiveness and flexibility with cultural and legal obstacles.

Challenges of Agile Transformation: Interviews reveal a significant divide in agile adoption, with half unfamiliar with methodologies, especially in R&D and pharmaceutical industries due to regulatory constraints, risk aversion, and cultural resistance.

Role of Leadership in Agile Transformation: Effective leadership is crucial for agile transformation, especially in the pharmaceutical sector, as it fosters adaptability and continuous development, despite regulatory limitations.

Management of Change: Agile approaches require effective change tactics like clear communication, gradual implementation, and continuous management training to reduce stress, increase operational effectiveness, and improve employee happiness.

Effect on Culture of the Organisation: Agile transformation boosts teamwork, creativity, and organisational culture by dismantling silos. However, abrupt policy changes can cause misunderstandings and weaken camaraderie, requiring sustained staff engagement and morale.

The report emphasizes the importance of agile transformation in the pharmaceutical industry to overcome cultural and regulatory obstacles. It calls for effective change management and leadership strategies, balancing agility with a positive work atmosphere. Agile techniques promote teamwork, creativity, and inclusivity, while avoiding abrupt policy changes and weakened camaraderie.

CHAPTER 7: DISCUSSION

7.1 INTRODUCTION

The interpretations, ramifications, and wider effects of the study's results on Agile transformation strategies in the pharmaceutical business are explored in detail in this chapter. In the previous chapters, a great deal of information was gathered and examined in order to comprehend how Agile approaches are being applied and modified in a field that is well-known for its strict legal requirements and risk-averse mentality. The conversation will address how the current literature aligns and deviates from it, as well as offer suggestions for further study and practical applications.

The examination uncovered a wide range of perspectives and experiences with Agile methods, emphasising the critical function of leadership and the complex difficulties of cultural adjustment in business settings. As we break these components down, we will concentrate on synthesising how these insights help to improve Agile implementation tactics in comparable high-stakes sectors. In spite of the inherent difficulties, this chapter provides a critical analysis of how Agile transformations might improve organisational responsiveness and creativity. Its goal is to close the gap between theoretical frameworks and practical applications.

7.2 CHALLENGES OF AGILE TRANSFORMATION

Agile development methods enhance the performance of the software industry by encouraging flexibility, rapid development, and change management. They guarantee relevance to market circumstances, promote open communication, and raise stakeholder satisfaction as given in the literature review. According to the participant response was a 50-50% it was a mixed response where they had no knowledge about agile or were early investors in the implementation of agile.

- **Scaling agile practices** (Dikert, Paasivaara, & Lassenius, 2016) stated that there are problems with agile scaling which was the case with some of the participants; participant A most effectively conveys this topic. They stress that Agile's implementation is difficult because of the delayed ROI and regulatory

constraints specific to the pharmaceutical business, highlighting the strict nature of the industry owing to regulatory considerations. In a direct response to this question, participant H notes that agile approaches might occasionally cause R&D teams' productivity to suffer because of their frequent meetings and iterative procedures, which take away from dedicated study time.

- **Management and cultural shifts (Boehm & Turner, 2005)** Participant F also addresses cultural resistance, noting that changing established ways is difficult and requires considerable effort and time.

- **Training and skill development (Reginaldo & Santos, 2020)** The experiences of Participant H draw attention to the difficulties in incorporating Agile principles into conventional pharmaceutical R&D procedures, highlighting the necessity of specialised training courses and calculated change management techniques in order to minimise disruptions and maximise efficiency.

- **Integration with existing processes (Dikert, Paasivaara, & Lassenius, 2016)** The integration of Agile techniques in regulated businesses such as pharmaceuticals presents certain hurdles, as demonstrated by Participant F's experience. This underscores the significance of flexibility and customisation in the integration process.

- **Resistance to change (Dikert, Paasivaara, & Lassenius, 2016)** Despite the challenges of managing change inside organisations with old methods, Participant F highlights the significance of addressing cultural elements in Agile transformation to effectively deploy new approaches.

7.3 ROLE OF LEADERSHIP IN AGILE TRANSFORMATION:

Agile transformation leaders foster adaptability, open communication, and iterative learning within organisations. They facilitate teams to embrace agile principles, overcoming resistance to change. They manage regulatory compliance pressures, promoting internal change and building strong, collaborative relationships over project oversight.

- **Effective leadership in agile development (Gren & Ralph, 2022)** in their discussion on the value of proactive leadership and top management participation in agile processes, Participant A emphasised the role that leaders play in encouraging teamwork, flexibility, and open communication. Which also backed up by other participants, with positive responses reiterating the importance of effective leadership

- **Agile leadership and digital transformation (Delioglu & Uysal, 2023)** was well explained by participant D and E Both entrepreneurs have demonstrated a proactive approach to agile methodologies, demonstrating dynamic capacity and strategic flexibility. Their strong leadership ensures the agile mindset is integrated into the organisation, while their focus on workforce management is crucial for managing changes in the context of digital transformation.

- **Leadership approaches in agile project management (Fischer, 2021)** Participant H's perspective is a good fit for talking about agile leadership in VUCA environments because his experiences and insights paint a clear picture of a flexible and nuanced leadership style that can integrate agile methodologies within a structured, traditional framework.

- **Leadership roles in agile teams must evolve (Spiegler, Heinecke, & Wagner, 2021)** Participant F offers a practical perspective on how leadership roles within agile teams can develop to enhance self-organisation and empowerment. This perspective closely aligns with the ideas presented by Spiegler, Heinecke, and Wagner (2021) and is based on insights into the dynamics of agile implementation and the required cultural shifts.

7.4 THE MANAGEMENT OF CHANGE

A multidimensional approach to change management, with an emphasis on strategic planning, quality control, cultural adaptation, and employee involvement, is necessary for successful agile transformation in pharmaceutical organisations. In such complicated situations, agile approaches may be made far more successful and sustainable by acknowledging and addressing these factors.

- **Strategic approach to change management (Gandomani et al., 2013)** Participant F's experience encapsulates the essence of a strategic approach to change management, emphasizing planned, phased implementation and successful outcomes, which are core aspects of the described strategy.

- **Change control in quality management (Aravindan et al., 2020)** Participant H discusses the challenges of managing change in R&D, a crucial aspect of pharmaceutical operations. She emphasizes the importance of communication, feedback, and adherence to Good Manufacturing Practices (GMP) principles. The focus on challenges and the need for regular updates aligns with the importance of effective change control in quality management for pharmaceutical companies.

- **Employee experience and coping mechanisms (Koutsikouri et al., 2020)** Participant A emphasizes the need for effective change management and coping mechanisms during agile transformations, highlighting the need for better communication and guidance to help employees adapt to new workflows and processes.

7.5 EFFECT ON CULTURE OF THE ORGANISATION:

Agile transformation has a significant impact on organisational culture in pharmaceutical organisations in addition to restructuring procedures and systems. In order to comprehend how agile techniques affect and interact with the cultural aspects of organisations in this industry, this study looks at a number of researches.

- In order to successfully modify organisational culture during agile transitions, Rosenberg's 2015 study highlights the significance of addressing cultural factors in addition to new agile approaches. In line with Rosenberg's research, Participant A highlights that effective transformation necessitates addressing cultural factors in addition to implementing new agile approaches. She emphasises the benefits of including cross-functional teams, encouraging cooperation and creativity.

- The research conducted by Jovanović et al. highlights the favourable influence of a team-oriented approach on workplace culture and highlights the significance of management support and cultural flexibility in the shift from traditional jobs to agile-specific positions.

- In their experiences with transformational leadership, Participant A emphasises the way in which this style of leadership promotes creativity and teamwork while dismantling conventional obstacles. Aydoğdu & Asikgil (2011) explore how leadership behaviours are essential for effective agile transformations and cultural shifts, especially when introducing and integrating cross-functional teams.

- In light of Participant E's experiences, Strode et al. (2009) highlight the significance of a team-oriented approach in assessing cultural shifts during agile transformations. They also draw on the Competing Values Framework (CVF) and its application to understanding cultural factors related to agile practices.

CONCLUSION - The obstacles, leadership responsibilities, and cultural effects related to implementing Agile techniques in the pharmaceutical industry—which is often defined by strict regulatory requirements and a risk-averse culture—have all been thoroughly examined in this area.

In pharmaceutical organisations, scalability, managerial and cultural transformations, training, skill development, integration with current processes, and resistance to change are just a few of the obstacles that the report highlights when it comes to Agile transformation. These difficulties draw attention to the complicated context in which Agile concepts must be modified to satisfy operational and legal requirements. Adopting Agile successfully requires effective leadership, which promotes flexibility, honest communication, and iterative learning. In pharmaceutical companies, change management necessitates employee interaction, cultural adaptability, quality control, and strategic planning. Agile transformation has a profound effect on the culture, requiring a change from conventional techniques to cooperative, team-focused

strategies. To create an agile environment, transformational leadership and a purposeful focus on cultural elements are crucial.

7.6 LIMITATIONS

The study's main weakness is its generalisability, as its qualitative data comes from a small sample of 10 experts in the pharmaceutical industry's R&D division. This may not accurately represent the entire professional population, especially those working in different companies or organisational levels. The findings may not be applicable to other sectors considering agile transitions due to the unique obstacles and cultural subtleties in these settings.

Selecting participants through LinkedIn, personal connections, and referrals can introduce selection bias, favouring professionals within the researcher's network, potentially skewing research outcomes towards a biased interpretation of agile adoption in the industry. To enhance the reliability of the research on agile transformation the author could have also, use stratified sampling, start with a small, intentionally diverse group, distribute anonymous surveys for a better analysis.

The consistency and dependability of findings from qualitative research in the pharmaceutical sector can be affected by researcher viewpoints and subjective interpretation of interviews, which can lead to bias. Additionally, qualitative research lacks quantitative data for statistical validation. The author could have made a form or data sheet to be filled by the participants after the interview to get some statistical data.

7.7 FUTURE RESEARCH

Agile approaches have a big influence on company culture because they encourage adaptability, quickness, and ongoing development. These ideas have the potential to drastically alter workplace relationships in the pharma sector. Successful implementation requires effective leadership that fosters transparency, adaptability, and a culture of learning. Nevertheless, there are obstacles to overcome when applying agile methods in a highly regulated sector like the pharmaceutical industry, such as tight

regulatory compliance and opposition to change. Within the regulatory framework, innovation and efficiency must be balanced through tailored agile techniques.

Recommendations for Future Research

- Future studies may examine how to use agile methods and digital technology to improve creativity and productivity in the creation and manufacturing of pharmaceuticals. Examining the integration of digital tools like as artificial intelligence and machine learning with agile methodologies may yield significant insights into optimising operational efficiency and enhancing regulatory compliance.
- Longitudinal Studies: Longitudinal studies may be helpful in understanding the long-term implications of agile approaches on organisational performance, culture, and employee happiness in pharmaceutical firms, given their transformational influence.
- Comparative Studies: Studies that contrast the results of agile transformation in various market sectors or regulatory regimes may offer more profound understanding of the ways in which outside variables affect the efficacy of agile methods.
- Leadership Strategies: More study on the tactics used by successful leaders to assist agile transformation may be able to pinpoint the essential skills and behaviours that best promote an agile culture.
- Barrier Analysis: Extensive research on the obstacles to the general adoption of agile techniques in the industry, such as cultural opposition and legal issues, may aid in the development of more potent change management and acceptance tactics.

These conclusions on the implications and suggested topics for more study indicate that, even while agile approaches have a lot to offer the pharmaceutical sector, their use has to be carefully handled to get around the particular difficulties this sector presents. Targeted study addressing these issues might improve our knowledge and efficacy of agile transitions in similarly regulated sectors.

CHAPTER 8: CONCLUSION AND RECOMMENDATION

8.1 INTRODUCTION

The chapter discusses the positive impact of agile transformation on the pharmaceutical industry, emphasizing the need for effective leadership and well-managed change processes. It also discusses how agile principles can be adapted to meet the unique demands.

8.2 RESEARCH QUESTIONS

This section will focus on answering the research questionsas well as sub-questions

1. **What are the primary drivers for agile transformation in pharmaceutical companies?**

- Agile transformation in pharmaceutical companies can enhance reactivity and efficiency, providing a competitive edge in a rapidly changing industry, which was also given in the literature review by Kulkarni et al., 2017, In order to "fasten the process faster," particularly in documentation cycles, participant D mentioned utilising agile technologies. This underscores the significance of agility in enhancing process efficiency.

- Agile methodologies foster improved collabouration and communication, ensuring successful project execution and aligning project outcomes with corporate objectives, Participant A highlighted the significance of effective leadership in agile transformation, highlighting its role in integrating agile rituals into business procedures, enhancing teamwork and communication which was also in the literature given by Srivastava, Mehrotra, Kapur, & Aggarwal, 2020.

- Agile frameworks are perfect for the pharmaceutical business because they can easily adjust to changes in project needs and scope resulting from new scientific discoveries or regulatory restrictions as given by Fernández-Sánchez et al., 2014., which as confirmed by Participant F emphasised the difficulties in implementing agile across several teams and the importance of agility in handling modifications to the organisational structure and operational procedures of the business

2. **What are the main challenges faced by pharmaceutical companies in implementing agile methodologies?**

- Pharmaceutical businesses face cultural resistance to agile methodologies due to their rigid approach, necessitating a fundamental adjustment in their thinking and operations, as highlighted by Participant F, requiring time and effort. Reginaldo & Santos, 2020.

- Agile approaches are difficult for pharmaceutical companies to integrate with their complex workflows, which frequently call for adjustments. Participant H emphasised the difficulties in integrating intensive research periods with agile methodologies as well as the possibility of production disruptions. (Khanboubi & Boulmakoul, 2021).

- Participant A highlighted the significance of senior management's strong leadership in energising change, navigating transitions, overcoming resistance, advocating for principles, and ensuring correct implementation and sustainability, as well as their active engagement in the agile transformation process (Fischer, 2021).

3. **How do leadership and change management influence the success of agile transformation in the pharmaceutical context?**

- Leadership is crucial for fostering agility in pharmaceutical firms through adaptability, transparency, and iterative learning. It requires workforce empowerment, strategic adaptability, and dynamic capacity (Gren & Ralph, 2022). Effective leadership significantly impacts well-being and performance, making it a vital component of agile change. Participants F and H emphasize the importance of leadership in fostering a culture of adaptability, openness, and iterative learning

- Strategic planning, effective communication, and robust support systems are necessary for effective change management in the pharmaceutical sector in order to enable quick adaptation to changing market and regulatory requirements (Spiegler, Heinecke, & Wagner, 2021). Participant G noted that staff adaption to new changes was greatly enhanced by excellent change management, which

included clear updates. This finding highlights the significance of effective communication and well-supported change procedures.

Agile transformation in pharmaceuticals is still an early concept, with potential for improvement if bottlenecks are addressed. As a professional in the industry, I believe that companies should invest equally in marketing and sales, as well as R&D, to better understand market and consumer needs and ensure that innovation is incorporated into the process.

In retrospect, a contentious issue that arose throughout the interviews was the idea that pharmaceutical businesses would not be able to compete in the market if agile is used excessively in R&D and product development moves too quickly. And what would happen to pharmaceutical corporations if all ailments are cured? Will there be an imbalance in supply and demand if time to market decreases? And how would an entire industry be affected if everyone is well? An item to consider for the future.

8.3 RECCOMENDATIONS

This section outlines the thesis structure, focusing on recommendations that summarize the research journey and transformative insights. It proposes actionable recommendations based on rigorous research, guided by principles of clarity and utility, ensuring they are directly linked to the findings (Kember, 2018).

Based on the extensive research here are the recommendations:

- Engagement and Training in Leadership: Encouraging agile change requires strong leadership. It is advised that executives at all levels participate fully in the transformation process and take part in specialised training focused on agile techniques and concepts.
- It is recommended that leaders cultivate a culture that is receptive to innovation and change, since this will enable the organisation-wide implementation of agile approaches.

As it was pointed about by many participants that leaders are necessacy for the development of teams for a better communication, for that it is necessary that

companies invest in training and development of future leaders, Yes, R&D is extensive work and this can be an additional responsibility but it only works in their favour as it promotes better communication and flow of ideas.

- Gradual Implementation: To reduce disturbance, use agile techniques piecemeal. Before implementing agile approaches across the entire organisation, start with pilot projects to determine their efficacy in particular domains.
- Before deploying on a bigger scale, use these pilot initiatives to collect data, learn from the experiences, and improve the method.
- Promote the creation of cross-functional teams with representatives from many departments, including marketing, regulatory affairs, and research and development. This will improve teamwork and guarantee that different viewpoints are taken into account during the decision-making process.

Participants also pointed about the implementation of agile, as agile is relatively new and companies are focusing more on other departments and not at all on R&D there can be small steps taken towards the integration of agile within departments.

- Feedback methods: To get opinions from staff members at all levels, regularly implement feedback methods. The agile procedures should be continuously improved using this feedback, and any issues that crop up should be addressed.

The only thing that the participants did not focus on was the feedback mechanism, a very important aspect of agile is getting ffeedback which helps in clearing bottlenecks, generally failure to implemt begins with feedback failure. There should be forms or monthly updates which can help in tackeling problems better.

- Evaluate and Assess Performance: Define precise metrics to gauge how well agile approaches are working to increase output, creativity, and time to market.
- Examine these KPIs on a regular basis to evaluate performance and decide on future course for implementing agile.

Performance assessment is important for R&D as these metrics are generally shared with top management, but this can also be a positive factor for better development of the teams.

Pharmaceutical firms can effectively use agile approaches and improve their responsiveness, innovation capabilities, and competitive advantage in the market by adhering to these tips.

CHAPTER 9: REFERENCES

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