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Predictive Maintenance and the Prevention of Batch Failures in Pharmaceutical Manufacturing Causes, Impacts, and Industry Evolution

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BATCH FAILURE BACKGROUND ANALYSIS

Section I: Introduction

The global pharmaceutical industry plays a critical role in shaping, developing, pricing, and distributing medicines to patients and hospitals all over the globe (Schweitzer and Lu 2018). This industry's main aspect is producing drugs that adhere to customers' safety, quality, and efficacy (Silva *et al.* 2021). The safety of customers is necessary for the industry, and the manufacture of drugs is a complex process. Therefore, the firms try to protect the health of the customers by ensuring quality in manufacturing and delivering them to the designated dealers or hospitals within the stated time. The regulatory aspects of the global pharmaceutical sector are complex as they focus on protecting the health of consumers and meeting certain protocols before the medicines ultimately reach the final consumers (Lawrence and Kopcha 2017). However, despite all these regulations and protocols to preserve the quality of these medicines, the industry faces certain quality control issues that affect the manufacturing process. These issues are mostly related to batch failures. Batch failures indicate certain medicines that fail to meet the quality or regulatory standards that are pre-established and hence, result in their rejection from production (Azadeh *et al.* 2019). Batch failure leads to huge losses for a pharmaceutical organisation as all the costs incurred in production, research, development, and delivery of the medicines are wasted. Furthermore, batch failures not only create a negative effect on pharmaceutical firms, but it is also a concern for healthcare providers, patients, and other authorities that are engaged in devising regulations and protocols within the industry. For example, batch failure can result in delaying of availability of certain medicines, affect the overall outcome of patients, create regulations and sanctions, and even lead to legal consequences for a pharmaceutical company. Furthermore, it would result in losses and damage the reputation of pharmaceutical firms (Wu and Lin 2019). All these issues have led to the thought that batch failures need to be restricted as much as possible within pharmaceutical companies and ensure the continuous supply of effective and safe medicines to patients and healthcare institutions.

The introduction of the research evaluates the concept of batch production in the case of pharmaceutical firms and how firms need to evaluate its importance and implications, The section will contribute to several aspects that lead to batch failures like errors by humans, inability to meet market regulations, issues in manufacturing aspects, etc. Also, the consequences of failure in batch production will be analysed

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through the research. The discussion of all these aspects would provide an analysis of batch failure and its effect on the global pharmaceutical industry.

Batch failure occurs at the manufacturing process stage and can emerge in any (Su *et al.* 2019). Pharmaceutical organisations need to maintain their quality of production from the initial stage to the final packaging of products to ensure optimum quality and quantity. For example, there are possibilities that a drug or medicine might fail the test due to poor mixing of ingredients or issues with the shelf life of items included within the drug. This failure can emerge due to several aspects like human errors, poor documentation of drugs used for production, malfunction of equipment, etc. The FDA (Food and Drug Administration) in the USA investigates every drug that is released in the market and evaluates its quality and quantity before giving clarity on its usage (Sharfstein *et al.* 2017). In case the FDA finds that the drugs do not meet the quality standards or are in proportions that are over the advisable limit, they tend to reject the samples ultimately resulting in a situation of batch failures.

One of the main aspects that contribute to batch failures is the regulations imposed by the authorities governing the pharmaceutical industry. Numerous agencies such as WHO, FDA, EMA, etc. have established policies and practices that guide the manufacture and distribution of pharmaceutical products and ensure the maintenance of their quality standards (Sushma *et al.* 2019). The regulations are imposed in the case of sourcing drugs, manufacturing them, and even distributing them in the market. Batch failure is prevented by ensuring QA (quality assurance) and QC (quality control) systems while maintaining adherence to regulations. QA helps a pharmaceutical firm identify certain defects during the manufacturing process whereas QC tests the ultimate product whether it meets market specifications (Kirwan *et al.* 2022). Another strategy used to prevent batch failures is predictive maintenance, which is a strategy used to predict when a machine needs maintenance within an organisation (Vu *et al.* 2021). This strategy can reduce downtime, and failure, and increase asset life. Also, the strategy can be used to maintain quality standards of drugs and ensure that they maintain compliance with regulations imposed by the government and other bodies (Valjevac 2022). Predictive maintenance is essential for diminishing the possibility of batch failures for a firm (Pech *et al.* 2021). Therefore, many firms utilise the concept for ensuring the quality of their products and also abiding by the regulations while ensuring the safety of patients within a healthcare institute. On the other hand, firms that fail to implement predictive maintenance or are involved in increasing batch failures might also face suspension from producing any more drugs in the future or fines. This ultimately leads to product recalls and shutting down operations and directly affects the reputation and sustainability of a pharmaceutical business (Sandle 2022). This literature review will highlight all the issues and concerns of batch failures and how they can be avoided by using the predictive maintenance strategy. The research will initially highlight common aspects of batch failures, their causes, and their effects and then analyse the importance of predictive maintenance to overcome the issues. Furthermore, the literature would suggest solutions and guide how they can be implemented within a system using advanced technologies like artificial intelligence and big data. All these strategies would shed light on the importance of reducing batch failures and contributing to the sustainability of the firms in the global pharmaceutical industry.

Section II: CONCEPT OF BATCH FAILURES

A: Definition and Scope

In the pharmaceutical industry, the concept of batch refers to the quantity of a drug that is produced within a specific manufacturing cycle and also within uniform conditions (Nasr *et al.* 2017). Apart from quantity, the batches are also expected to meet quality and safety standards as advised by the EMA, FDA, and other regulatory bodies across the world (Sardella *et al.* 2021). The firms in the pharmaceutical industry need

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to abide by all these regulations to attain success. However, a situation of batch failure arises when a specific drug or a product does not meet the quality or quantity requirements as per the regulators and hence, is considered unsafe for consumption purposes. Batch failures for a pharmaceutical firm can arise due to numerous factors like lack of adequate chemical composition within the drug, impurity of the drugs, poor balance of physical property of chemicals, etc. All these aspects are detected using the QA and QC testing procedure and are essential for the pharmaceutical industry. Also, using advanced technologies like artificial intelligence (AI) and predictive maintenance is essential in identifying the discrepancy. AI applications have been found useful in identifying and anticipating possible failures in manufacturing and responding to them suitably (Rojek *et al.* 2023). Once a failure is discovered, the batch of drugs is completely rejected or reworked leading to huge losses for the pharmaceutical firm. Batch failures can occur for the organisation at any manufacturing stage starting from the handling of raw materials to their mixing and packaging. Organisations need to abide by the regulations imposed by the authorities and supervise the products at every stage to avoid such drastic consequences.

The scope of failures of batches in the pharmaceutical industry is broad and several factors lead to disrupting its quality. The failure can affect the company and even patients with delays in medicine distribution ultimately affecting the entire industry. The scope of batch failure is mainly attributed to the following:

Manufacturing Process: Ineffective mixing of several chemicals or drugs during the manufacturing stage can result in inconsistency in production (Ma *et al.* 2020). Also, certain variations in pressure, temperature, or time can result in a transformation of the chemical composition of the drugs ultimately creating concerns.

Raw Materials: In case a pharmaceutical company does not have adequate raw materials to produce a drug or the materials available to them are unstable or impure, it can fail in production ultimately contributing to batch failure. In addition, improper sourcing of resources can lead to firms compromising on the safety standards and the overall effectiveness of a drug resulting in it being unapproved.

Technology and Equipment: Malfunction of equipment and lack of advanced technologies to process the drugs can lead to defects in batch and ultimately affect production aspects. Artificial intelligence has emerged to resolve this issue as AI can be used for designing a manufacturing system, selecting machines, and layouts, and conducting capacity planning (Chryssolouris *et al.* 2023).

Human Errors: Although automation and supervision are done through technologies in the pharmaceutical industry, human intervention is still essential for tasks such as documentation, submitting reports, assuring the quality of products, etc. Any errors committed by human beings during these tasks can affect the entire production cycle (Bogner 2018).

Compliance Factors: Many pharmaceutical companies fail to abide by regulations imposed by agencies due to inefficiency or to reduce supervision or quality maintenance costs. This results in non-compliance with the policies and procedures ultimately leading to violation of the entire process. Henceforth, such an instance can contribute to batch failure.

B: Historical Context and Evolution

The history of the pharmaceutical industry can be dated back to the Industrial Revolution when it started transitioning into a large-scale and structured business model. Advancements in the field of chemistry, research, and medicine led to the widespread availability of drugs that catered to the health issues of human beings and ensured their cure (Kasoju *et al.* 2023). However, with an increase in research and development of medicines, it created certain challenges for society. Lack of controls and regulations for raw materials of these medicines led to many producers creating inconsistency, contamination and ultimately

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manufacturing dosages that created adverse health effects for the patients. For example, the "Cutter Incident" in the year 1955 involved the creation of a faulty batch of polio vaccines, which rather than ensuring immunity against the disease, caused 200 cases of polio (Ruane 2020). This was mainly due to inconsistency in production ultimately resulting in the concept of batch failure coming to the fore.

During the 20th century, formal regulations were established to ensure the safety and quality of drugs (Darrow *et al.* 2020). The FDA within the USA started supervising drugs and materials used for producing them. Despite the attention given by the international bodies, issues continued such as the thalidomide tragedy in the 1960s. This medicine was introduced to cure morning sickness of patients, but it led to birth defects ultimately leading to public outrage (Vargesson and Stephens 2021). The incident led to the FDA along with the WHO developing even stricter guidelines and protocols for the pharmaceutical industry and introducing the concept of batch testing. The principles of the regulations involved testing every material of a batch of medicine and then rejecting ones that fail to meet the quality standards imposed by the regulatory bodies.

In the late 20th century and early 21st century, technological advancements and automation played a major role in transforming the production of medicinal drugs (Thomford *et al.* 2018). The introduction of computers, artificial intelligence, reduction of human error, and privacy issues led to pharmaceutical companies improving the quality of their medicines while maintaining consistency with protocols. This helped in reducing batch failures. Automation allowed consistent mixing, granulation, pressing, and improving the uniformity of drugs through computer systems ultimately reducing human errors. In addition, advanced measures for quality control like mass spectrometry and HPLC also contributed to reducing the effect of batch failures (Rogers *et al.* 2018). Despite all these advancements, many pharmaceutical companies still fail to maintain consistency with regulations and protocols due to the variability of chemicals and biological materials. At present, contamination, inadequate formulation, and lack of supervision are the main reasons that contribute to batch failure of medicines. In addition, outsourcing of drug manufacturing in regions such as India and China create further challenges related to its production and regulatory compliances. To address all these factors, agencies like the EMA and FDA have set up their agencies globally and oversee the manufacture of the drugs to avoid contamination or use of subsidised raw materials. These efforts have reduced the emphasis on batch failures in the modern pharmaceutical industry.

C: Common Types of Batch Failures

Batch failures are of different types and lead to adverse consequences for pharmaceutical organisations. A few common types of batch failures are:

Contamination: This is a type of batch failure that can arise due to several factors like physical, biological, or chemical contaminations. Microbial contamination can further affect a drug and create severe issues for patients (de Sousa Lima *et al.* 2020). This type of contamination is caused mainly when the equipment used to produce the drug is not properly sterilised. Another instance of contamination is when a marginal trace of a drug enters another batch product ultimately creating a toxic drug that affects human health.

OOS Results: This type of batch failure occurs when a particular medicine batch fails to meet the criteria of quantity, quality, or purity. This can occur due to many reasons like improper mixing of raw materials, wrong formulation of drugs, or ineffective storage. All these factors can lead to a batch being rejected during the tests.

Physical Property Deviation: Deviations in the drug properties can also result in batch failures (Zarmpi *et al.* 2017). Inconsistent mixing of raw materials or lack of storage and temperature control can result in drugs failing to meet their desired physical properties ultimately leading to batch failure. For example, tablets that do not dissolve easily are generally rejected as they can fail to provide adequate therapeutic advantages to the patients and affect their trust in the medicine.

Improper Labelling and Packaging: Every pharmaceutical company needs to provide details regarding the composition, dosage, and constituents of products in their packaging. Lack of adequate or authentic details in packages of a product can also result in batch failures. For example, a drug requires protection from sunlight. In case the label of the drug does not state the same, it can affect consumer trust and hence, such a drug is rejected during the test. Furthermore, mistakes in labelling or spelling can lead to a drug being considered for another ultimately causing adverse effects (Bryan *et al.* 2021).

Malfunction of Equipment: Pharmaceutical equipment relies immensely on automation for several activities such as filing, granulation, and mixing of ingredients. In such a situation, failure or malfunction of the equipment can affect the product quality and ultimately lead to batch failure. For example, in case an equipment-producing table press varies in width or weight, it can result in inconsistent dosage after the manufacture of the final product. Also, in case of equipment is not cleaned or maintained, it can cause contamination of the drugs (Beilenhoff *et al.* 2018).

Degradation of Products: Many pharmaceutical products degrade within a short period due to several factors like moisture, heat, and light (Felis *et al.* 2020). In case a product has a very short degradation time or fails to meet the degradation time as per its labelling, the entire batch is rejected during testing.

Inability to Abide by Sterility Requirements: Sterilisation is required for several pharmaceutical equipment such as eye drops, injections, and surgery-related equipment and drugs. In case these items are not sterilised, they can cause infections in the patients. Therefore, sterilisation equipment is tested to ensure that they do not compromise the safety of patients. If the equipment is not sterilised properly, it can lead to failure of the entire batch.

D: Metrics of Measuring Batch Failures

Measuring batch failure is essential for organisations to maintain the efficacy and quality of their production activities. The metrics allow the regulatory bodies to identify the malfunction in production and whether the entities are abiding by the stated regulations of the government. Few common metrics are used for measuring batch failures. They are:

BFR: This metric is known as the batch failure rate and provides an overview of the number of times a batch fails and what the company can do to mitigate such instances in the future(Satzer *et al.* 2022). This is calculated by dividing the number of failed batches by the total batches introduced and multiplying it by 100.

RCA: This metric is used to analyse the time required for investigating and resolving the cause of a batch failure. Faster resolution of issues can ensure process optimisation and prevent firms from suffering similar instances of failure during future production.

CAPA Effectiveness: This metric evaluates the difference between preventive and corrective actions that are adopted after the failure of a batch. Another metric used to forecast such issues is predictive maintenance. Predictive maintenance not only enhances the tools and methods used in pharmaceutical organizations but also highlights key areas for future product development for analysts and researchers (Molęda *et al.* 2023). This metric is essential in resolving issues related to batch failures for an organisation.

Cost and Deviation of Failed Batch: This metric helps in quantifying the financial effect of failures, losses incurred during the period and strategies to be used for controlling costs. Also, deviations from SOPs are identified using the metric and allow a pharmaceutical company to avoid significant deviations in the quality and quantity of products in the future.

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Batch Yield: This metric indicates that lower batch yield can lead to failure of a batch. It is calculated by dividing actual yield by theoretical yield and then multiplying it by 100.
Defect Rates: This metric is calculated by dividing the defect units by the total number of units produced and multiplying it by 100. A high rate of defects signifies manufacturing issues for a firm and ultimately contributes to batch failure (Psarommatis *et al.* 2022).

Section III. ANALYSIS OF BATCH FAILURE IN THE MANUFACTURING INDUSTRY
A: Overview of Batch Failure
The failure of a batch of products to meet the stipulated specifications in terms of quality and quantity is called batch failure. It involves the rejection of an entire batch of products which fall short of expectations (Pollock *et al.* 2017; Gershwin 2018; Huang *et al.* 2020). The concept of batch failure is related to the analysis of the operational efficiency in the manufacturing function of various industries including the pharmaceutical sector. The other industries in this context include the automobile, electronics, and consumer goods sectors. In this literature review, batch failure will be analysed in terms of manufacturing inefficiencies and errors in the pharmaceutical sector. This is crucial as this research is based on predictive maintenance in the pharmaceutical industry. It is also important to consider various facets of batch failure including its causes, outcomes, and mitigation. A comprehensive understanding of all these aspects of batch failure is crucial for a holistic overview of the concept and its implications for the pharmaceutical industry. This first part of the section analysing batch failure in manufacturing offers an overview of the concept. This overview will be followed by an examination of the various causes of batch failures. The analysis of batch failure will be related to the pharmaceutical sector corresponding to the topic area of this research. The third part of this section of the literature review reviews the impact of component faults. Component faults as a form of technical failure will be given special consideration in the third part. The fourth part examines the role of human error in batch failures. A focus on the operational, human, and technological causes of batch failure is the binding theme of this section of the literature review. The section will conclude with a review of other factors contributing to batch failures in the manufacturing function of the pharmaceutical industry. The analysis of batch failure will also be used to explain the need for predictive and preventive maintenance, which will be discussed in greater detail later. In addition to exploring the contributing factors, the last part will also consider the implications of batch failure for the pharmaceutical industry.
Some of the most common causes of batch failures include operational inefficiency, technological breakdown, contamination, cyber risks, and deviations from standard operating procedures, Errors in measurement, poor anticipation, and procedural faults represent operational inefficiency on the part of employees. Similarly, glitches, malfunctions, or breakdowns in equipment can also lead to batch failures (Diallo *et al.* 2021). Ever since the advent of Industry 4.0, there has been a surge in intelligent manufacturing. Companies in most sectors look forward to Industry 4.0 technologies to upgrade their manufacturing processes. The application of Industry 4.0 technologies in manufacturing processes is referred to as intelligent manufacturing. It involves the use of artificial intelligence, machine learning, the Internet of Things, big data analytics, cloud computing and various smart applications. (Barari *et al.* 2021; Gupta *et al.* 2022; Fişne *et al.* 2024). The multitude of advanced information and communication technology has increased the complexity of manufacturing activities causing more batch failures. Automation in manufacturing is one of those areas where the impact of disruptive technologies has been the highest. In automated manufacturing systems such as assembly lines, cyber risks in the form of virus attacks or malware can cause serious disruptions which can also cause batch failures. The study conducted by Álvarez García *et al*. (2023) is quite insightful from the perspective of batch failures in the case of

manufacturing based on complex technology. The complexity of industrial manufacturing systems can also be attributed to the changing dynamics and requirements of markets. For instance, multistage machines are extensively used for manufacturing in various sectors to meet high demands for products. One of the greatest advantages of MSMs lies in their potential for producing big batches in a considerably short time. This feature of MSMs not only enhances operational efficiency but is also highly cost-effective for companies. Nevertheless, the complexity of multistage machines increases the chances of batch failures (Álvarez García *et al.* 2023). Generally, predictive or preventive maintenance is not applied in the case of MSMs as they are used as per requirements for achieving specific manufacturing objectives. Moreover, any malfunction in just one component can result in the breakdown of an entire multistage machine. Many organisations are apprehensive of using MSMs due to the high risks associated with this significant disadvantage of these machines. Thus, component failures in MSMs resulting in defective products can lead to batch failure due to the rejection of an entire batch. This also explains the need to study the application of proactive strategies including preventive and predictive maintenance to eliminate the chances of batch failures involving MSMs. Proactive strategies can only ensure zero defect manufacturing, especially in the case of connected multistage machines using Industry 4.0 technologies. The use of such technologies increases the complexity of manufacturing processes requiring predictive or preventive maintenance rather than corrective responses to batch failures.

Batch failure due to contamination is especially relevant in the pharmaceutical industry. This happens primarily due to impurities in ingredients, poor maintenance of equipment or environmental causes (Kumar and Jha 2018; Cundell 2019; Kumar *et al.* 2020). In such cases, batches of contaminated products are rejected mainly on the grounds of compromised quality. On some occasions, employees fail to follow the standard operating procedures due to a lack of training or poor understanding of instructions. This is another form of operational inefficiency resulting from human errors in manufacturing processes.

Batch failures occur in hybrid batch production systems due to issues concerning unreliable equipment and quality reassurance. In such manufacturing systems, equipment failure is rather random and production can resume only when the faults are repaired (Chiu *et al.* 2021). This type of batch failure leads to a significant accumulation of scrap as a large number of end products turn out to be defective. Many companies resort to outsourcing in response to batch failures in hybrid batch manufacturing. Nevertheless, outsourcing involves higher costs compared to in-house production of products of the same quality. This explains why preventive or predictive maintenance is superior to corrective maintenance. While the former is based on a proactive strategy, corrective maintenance reflects a reactive approach. Preventive and predictive maintenance seeks to eliminate the chances of batch failures. In contrast, corrective maintenance is focused on damage control to minimise the losses caused by batch failures. While implementing corrective maintenance, urgent processes are given priority and the rest are deferred to be addressed later. This implies that there is a chance of more batch failures until all the parts of a manufacturing system are fully restored to a functional state. This is another reason why preventive or predictive maintenance is considered better than corrective maintenance. Furthermore, predictive maintenance provides the scope for using advanced Industry 4.0 technology including machine learning, the Internet of Things, artificial intelligence and big data analytics (Shamayleh *et al.* 2020; Bouabdallaoui *et al.* 2021; Arena *et al.* 2022). Advanced decision support systems can also be used in the implementation of predictive maintenance which is essentially data-driven (Davari *et al.* 2021; Veloso *et al.* 2022).

Mokhtarzadeh *et al.* 2024 have done a detailed analysis of how a lack of integration between machine intelligence and human skills can result in batch failures. They have used the term hybrid intelligence failure to refer to such a lack of integration between machines and employees. Prevention or rectification of hybrid intelligence failures depends on a combination of human expertise and data-driven analysis. In

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this way, human intelligence failure analysis characterises a comprehensive approach to identifying the root cause of batch failures in manufacturing based on hybrid intelligence. Mokhtarzadeh *et al.* 2024 further discuss how Bayesian networks, case-study based approaches and neural networks can be applied for a better understanding of batch failures in the case of hybrid intelligence manufacturing. The various techniques for analysing hybrid intelligence batch failures can be classified into proactive and reactive categories. While Failure Mode and Effects Analysis (FMEA) represent the former, Root Cause Analysis (RCA) and Fault Tree Analysis (FTA) fall in the category of reactive techniques(Mokhtarzadeh *et al.* 2024).

A company may have to suffer in multiple ways due to batch failures The various outcomes of batch failures include financial losses, compliance issues, disruptions in supply chains and product recalls (Diallo *et al.* 2021). The wastage of resources due to batch failures escalates operational and other costs for companies. The failure of a company to comply with regulations related to the standard or quality of products may result in punitive consequences including fines and sanctions. Apart from these consequences, a company's brand image can be considerably damaged due to batch failures. Although batch failure mainly concerns the manufacturing stage of the supply chain, stakeholders can also be affected by a domino effect. This happens when batch failure leads to consecutive distribution disruptions or other supply chain processes. In such a situation, a company suffers from an overall disruption in its entire supply chain (Ivanov *et al.* 2017; Paul *et al.* 2018; Katsaliaki *et al.* 2022). A company may also have to recall a product when batch failures compromise product quality or result in inadequate production.

B: Causes of Batch Failure

Inadequate maintenance is one of the most common causes of batch failures in manufacturing systems across industries. In this context, Carvalho *et al.* (2019) have done notable work highlighting the importance of selecting the right machine-learning application in the predictive maintenance of production systems. The total time taken in manufacturing operations as well as the overall operational efficiency depends on the critical factor of equipment maintenance The failure to identify faults and malfunctioning in equipment leads to breakdowns resulting in the shutdown of entire production systems (Carvalho *et al.* 2019). This is especially true in the case of production lines on factory floors. Sometimes batch failures are also attributed to wrong choices of technology or techniques applied in predictive maintenance. Choice of technology has assumed even more significance in the present era of automated manufacturing driven by disruptive technologies such as machine learning. (Sang *et al.* 2021) have attributed batch failures to complex manufacturing environments characterised by connectivity and integration of Industry 4.0 applications. Industry 4.0 has led to a considerable enhancement in the level of integration and connectivity in various industrial operations including manufacturing. Disruptive technology, especially the Internet of Things is applied to provide the connectivity required in collaborative or integrated platforms in the manufacturing function. This applies to manufacturing processes in all industries including the pharmaceutical sector. A complex operational environment involving a high level of connectivity and collaboration based on Industry 4.0 applications can cause equipment failure resulting in very high downtimes. The slowing down of production due to such high downtime makes it difficult to achieve production targets within the stipulated deadlines. This is one of the most common causes of batch failures when manufacturing practices are driven by Industry 4.0 technology to a considerable extent.

The factor of downtime discussed previously is quite critical from the perspectives of manufacturing efficiency and time delivery of finished products. Apart from high downtime, secondary damage also reduces manufacturing efficiency to the extent of batch failures. Poor decision-making related to maintenance strategy can also cause batch failures in a manufacturing facility. More specifically, undue

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external interference in system operating environments and the inability to assess the remaining useful life of equipment can cause batch failures (Zhong *et al.* 2023). In his article on batch failures in the bioprocessing industry, Ranck, (2022) has specifically focused on the issue of poor human resource management and how it contributes to manufacturing problems. This article primarily mentions human error, contamination and equipment failure as the causes of batch failure in the bioprocessing sector. Batch failure caused by all these factors has a highly adverse effect on product marketing, sales, and revenue generation in the bioprocessing industry. Although quality assurance professionals mainly focus on contamination and equipment failure, poor human resource practices are also responsible for batch failures in bioprocessing and the pharmaceutical sectors. Ranck, (2022) discusses lack of adequate training, poor working conditions, and shortsightedness in talent management as the HR factors contributing to batch failure. All these factors can be related to the errors committed by operators involved in manufacturing facilities in the bioprocessing industry. In some instances, poor working conditions involving hazardous substances result in operational errors or oversight. Such errors on the part of the operators can also be attributed to poor training and recruitment resulting in a lack of skills. Lack of long-term planning and investment in human resource development leads to a shortage of the skills and competencies required from operators. All these factors can be addressed through proactive strategies instead of relying on corrective responses to batch failures in the pharmaceutical and bioprocessing industries.
Batch failure in a defined setting concerns only one batch of products. In contrast, the concept of batch failure in continuous settings also extends to specific quantities of manufactured products or stipulated timelines. This definition of batch failure thus refers to how inadequate production as well as delays in the delivery of the end product can result in the rejection of a batch. In this literature review, batch failure has also been attributed to the complexities of integration and connectivity based on advanced information technology. These factors can cause batch failures in both upstream and downstream continuous manufacturing. In his research paper, (Satzer *et al.* 2022) mention how a combination of substandard equipment and a lack of trained personnel results in batch failures. Failure to meet product specifications in terms of aggregation levels or specific glycosylation can be related to poor production planning. Efficient product formulation, manufacturing processes, and production analysis are the key aspects of effective production planning. In the absence of such production planning, batch failures may be caused when products do not meet the standard specifications. These cases of batch failures in manufacturing may be addressed through effective quality control. The research done by Wu, et al. (2021) talks of this relevance. The researcher has emphasised the importance of effect analysis and mode of failure to overcome batch failure because of quality-related issues. The arguments stated can also be related to discussing on complex utilisation of disruptive technology that results in batch failures(Wu` *et al.* 2021).

C. Impact of Component Faults

Faults in components are a major issue creating batch failure in the case of the pharmaceutical industry (Ganesh, Su, Vo, *et al.* 2020). These faults refer to failures in equipment, raw materials, and machinery that generally occur during an item's manufacturing (Black and Kohser 2017). The faults can ultimately degrade the overall quality of the product, result in it failing to abide by the guidelines and protocols, and ultimately result in batch failures. Various key component failure types and their causes are listed below.
Contamination of Raw Materials: Pharmaceutical materials depend heavily on the purity and quality of the items (Dispas *et al.* 2018). In case any item is degraded or contaminated, it affects the entire batch and ultimately results in its failure. Contamination of batches can occur due to several reasons such as poor handling of the products, environmental contamination, microbial contamination, etc. All these contamination types affect overall product quality. For example, in case an API (active pharmaceutical

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ingredient) has been exposed to external moisture, oxygen, or light, it can affect its potency and ultimately lead to risks to the health of patients (Boukoufi *et al.* 2022). In such a case, the supervising bodies would reject the entire batch of products ultimately resulting in its failure. Also, contamination of materials can result in the impurity of the entire batch and lead to the release of toxic chemicals and other issues related to safety aspects. Therefore, the faults need to be recognized during the control stage and mitigated completely. In addition, variability between two specific batches can also affect its quality. For example, the size of particles of API can affect the dissolution rate of a drug (Markl and Zeitler 2017). Also, in case the manufacturing organisation fails to control the variability of the product, it can result in the failure of the entire batch of products.

Calibration Problems: Calibration issues are one of the main reasons that lead to the failure of components and ultimately result in batch failure (Zhang *et al.* 2022). In case machinery and pharmaceutical equipment are not calibrated effectively, for example, humidity, pressure, etc, are not maintained, it can lead to deviations and ultimately affect product quality. For example, in case the temperature reactor of a vessel has faults, it can affect overall chemical stability and the overall quality of a product. Also, in another case, in case there are equipment issues, it can affect product quality (Sangshetti *et al.* 2017). Like in case incorrect pressure or lack of alignment between the dies of a drug can lead to component faults and affect the overall efficacy of the equipment (Park *et al.* 2022). Therefore, organisations manufacturing medicines need to constantly supervise the equipment and machinery to avoid any such failure and ensure the overall quality of the batch of products.

Defects in Package Components: One factor that leads to component fault is poor packaging of the pharmaceutical products. Many drugs need to be packed effectively before they are exposed to environmental factors like oxygen, moisture, and light (Janga *et al.* 2018). Also, containers that are sealed poorly can result in exposure of the drugs to environmental elements. Such issues can result in the drug being contaminated or degraded ultimately leading to a fault in the component. The supervisors and authorities fail to allow the products to be sold in the market ultimately leading to it being unsafe for the patients. Also, faults in component packaging can lead to contamination of the drugs (Rather *et al.* 2017). For example, in case equipment used for activities like surgery needs to be properly sterilized. In case they are not sterilised, it is exposed to microbial contamination, which can ultimately lead to infection for the patients. Such a situation can create adverse consequences for the patients and is also life-threatening to the individuals. Henceforth, organisations need to sterilise all equipment before using it and provide adequate details regarding its use in the packages (Ling *et al.* 2018). In case the package of equipment is faulty, it can ultimately affect the entire batch and result in its failure.

Cross-Contamination: A situation of cross-contamination occurs once traces of drugs are transferred to another drug unintentionally (Dahiya *et al.* 2022). This situation occurs when the drugs or equipment used are not sterilised effectively or cleaned. Henceforth, such a situation can lead to faults in components and ultimately affect the entire batch of products. Cross-contamination between the batches of drugs also happens when the materials used are not handled effectively ultimately leading to contamination. Such cross-contamination generally occurs in facilities that are producing multiple drugs using the same equipment and without any adequate supervision. For example, in case few traces of a product that is allergic for patients are carried over to another drug or equipment, it can lead to adverse situations for patients. Many patients might also suffer from such cross-contamination and can be fatal for them. Cross-contamination between drugs that are highly potent and less potent can result in incorrect dosage and ultimately failure in therapy. For example, in case the patients are advised a dosage that is higher than the limits they can tolerate can result in significant risks for them. All these issues can result in faults in components and ultimately create issues for the entire batch of products. Henceforth, to avoid the issue of component faults of a batch, adequate supervision by the organisations producing the drugs is to be ensured. Also, the entire operational process of the drugs needs to be evaluated to maintain control and overcome such situations. Batch failure costs huge losses for pharmaceutical organisations and hence, maintaining adequate control and supervision can ensure that such issues are rectified in the future (Ranck 2022).

D. Role of Human Error

One major cause of batch failure is human error associated with it. In the past few decades, several advancements have occurred in the pharmaceutical and healthcare industry. The integration of digital tools, technologies, and other advancements have made the drugs safer for patients and also have been essential in curing several health issues (Awad *et al.* 2021). However, despite automation and technological advancements, human efforts are also essential in many aspects such as handling materials, overseeing functions of equipment, controlling quality, etc. While fulfilling all these responsibilities, there is a possibility of human error. Such errors can occur and affect the overall quality of the drugs and ultimately result in batch failures. A few major human errors resulting in batch failures are:

Lack of Effective Record-keeping or Documentation: Incorrect record-keeping or documentation is a common human error and can lead to batch failures in the pharmaceutical industry (Gomez Mulero 2022). Since the industry is regulated, accurate documentation of items used along with bookkeeping of raw materials used, operational process, costs, etc. is essential. Therefore, any discrepancy in maintaining documents can affect the entire quality of the drug resulting in human error. For example, in case a person records the incorrect weight of a raw material used for the manufacture of a drug, it can affect the quality of a product that is supposed to meet certain specifications. Also, in another situation, in case a person does not abide by the parameters of storing a drug and exposes it to a certain temperature or light, it can affect its standard and quality. Therefore, due to such human errors, the entire batch needs to be discarded or replaced and it can also lead to infringements damaging the reputation of the pharmaceutical company (Moorkoth *et al.* 2024).

Miscommunication: The companies manufacturing pharmaceuticals comprise many departments and people need to work together effectively between the departments to ensure quality control and abide by protocols (Del Giorgio Solfa 2022). Therefore, any instance of miscommunication between these departments can result in batch failures. For example, in case the production department of a pharmaceutical firm is not informed of a particular raw material that needs to be used in a product. The team would manufacture the drug without the material and hence, would be unable to meet the required standards of the product. Similarly, in case the people controlling quality fail to communicate the same with the production departments, it can result in the halting of the entire production batch. Also, miscommunication of shifts of each employee can result in poor distribution of work, failure to meet deadlines for the manufacture of drugs, and ultimately affect coordination between the employees. All these issues result in human errors and ultimately contribute to batch failures.

Lack of Adequate Training of Personnel: Training of the human workforce is essential for every industry to achieve its growth (Li 2022). In the case of pharmaceuticals, the operational process requires increased attention, skills, and concentration to handle raw materials that are sensitive. Also, handling complex equipment requires the employees to maintain consistency and competency among them. Such control and management can help pharmaceutical organisations overcome the problem of batch failures. For example, in case the operators of equipment are not trained on how to use them, they can cause errors in the production process. Also, in case the operators are not accustomed to handling certain equipment or raw materials, it can result in complexity of operations and ultimately lead to product contamination or

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degradation. The last decade witnessed the rise of artificial intelligence in several applications and different industries (Nguyen *et al.* 2023). Artificial intelligence has been adopted in different manufacturing industries to utilise data and overcome problems related to uncertainty (Chryssolouris *et al.* 2023). Similarly, AI tools are increasingly used in the pharmaceutical sector to evaluate the quality of drugs. However, in case an operator does not have adequate knowledge regarding the AI tools and their benefits, they would be unable to use them and hence, it might result in the decline of drug quality and batch failure. To avoid all these adverse situations, hiring skilled personnel and training them effectively is essential for the employees in the pharmaceutical industry.
Failure to Follow SOPs (Standard Operations Procedure): The regulatory bodies implement SOPs within each step of the manufacturing process of pharmaceutical entities. These regulations indicate that the process is performed effectively and as per the specifications listed. Therefore, following certain protocols can help a firm overcome mistakes, complacency, or oversight ultimately reducing the possibility of human error. Also, adequate supervision of each step is essential in reducing the possibility of mistakes. For example, in case an operator mistakenly skips the cleaning procedure of equipment, it can lead to cross-contamination and ultimately lead to batch failure. Also, failing to adhere to maintain sequence while mixing certain raw materials ensures that the quality standards of a product are not met and it ultimately results in the discarding of the entire batch of products. Therefore, to avoid such instances, it is safer for the firms to follow certain SOPs and parameters based on which the entire production process can be completed, thereby, avoiding the possibility of mistakes.
Overload and Fatigue: Overload of work and fatigue are common aspects of the pharmaceutical industry. The employees within the sector need to work for long hours to meet the demand of production. Also, complacency or missing deadlines is non-negotiable for the employees as the health of patients is dependent upon the supply of medicines. Therefore, due to such work overload, sometimes, the operators of drugs and equipment are fatigued and tend to make mistakes. This results in batch failure and ultimately affects the reputation of the individual and also the organisation. For example, during the COVID-19 pandemic, the global pharmaceutical industry faced challenges in meeting patient demands and also manufacturing a vaccine to fight against the disease (Wouters *et al.* 2021). Such work pressure creates fatigue and ultimately results in the employees making certain mistakes. To overcome such issues, the implementation of quality control measures is essential as it would help in monitoring real-time information and testing for discrepancies. Predictive maintenance is a useful measure that can help eradicate problems associated with human errors and help reduce the possibility of batch failures.

E: Other Contributing Factors
Variability is another key factor, which significantly contributes to batch failures in the pharmaceutical industry. According to existing literature in operations management, the lack of agility, flexibility, or robustness in batch manufacturing results in variability in quality as well as lead time variability (Grahn and Sjödin 2021). Batch failures caused by such variability not only lead to drug shortages but also increase threats to public health. Industry reports from the pharmaceutical sector highlight the concerns of the Food and Drug Administration (FDA) in the US in these areas. Such concerns contribute to the demand for a transition from batch manufacturing to continuous manufacturing. Furthermore, long lead times resulting from manufacturing variability represent one of the key reasons behind outdated batch lines apart from poor quality in drug production. These issues can also be attributed to the non-compliance of employees with standard operating procedures in the manufacturing function. From a more technical perspective, variability in the production of drugs can also result from a poor choice of reactor designs (Hu 2021). Furthermore, the fermentation processes in batch manufacturing are relatively inefficient in

comparison to continuous manufacturing (Kumar *et al.* 2020). Thus, inefficient fermentation also explains how variability contributes to batch failures in the pharmaceutical industry. This factor is also cited by the advocates of the transition from batch to continuous manufacturing in the pharmaceutical sector. All these factors concerning variability in drug manufacturing primarily relate to operational inefficiency and poor quality control. Hence, experts and professionals must take these factors into consideration while implementing predictive or preventive maintenance in the pharmaceutical sector.

On the technological front, inaccurate calibration is another cause of batch failure which cannot be overlooked. Problems with the calibration of equipment can not only lead to inaccurate measurements but also affect the quality as well as the standard of a product. Sometimes fluctuations in environmental conditions including variations in temperature and humidity can also damage a product during its manufacturing. Such damage can also compel the management of a company or factory to reject a batch of products. Maintenance processes in manufacturing depend on a comprehensive documentation of various facts and processes. Lack of such documentation can be a cause of poor maintenance resulting in batch failure. Finally, testing based on analysis, and validation plays a very important role in manufacturing. Hence, these aspects must also be taken into consideration while applying predictive or preventive maintenance. In this direction, proactive maintenance strategies based on the use of advanced digital technology can be especially helpful. A robust process of validation is also important to enforce strict quality control in the manufacturing function of the pharmaceutical sector. This also involves continuous monitoring to ensure compliance and adherence to standard operating procedures. Negligence of these imperatives can easily lead to batch failures causing financial losses as well as damage to the brand image of a pharmaceutical company.

The various causes and aspects of batch failure discussed in this literature review apply to manufacturing processes in the pharmaceutical industry as well as other sectors. Nevertheless, the implications of batch failure in the pharmaceutical industry can be much wider and deeper in comparison to other sectors. Manufacturing processes in the pharmaceutical industry are an integral part of the health sector which is critical to society. A shortage in the supply of medicines due to batch failures can have a highly adverse impact on public health. These implications and outcomes of batch failure in the pharmaceutical industry highlight the importance of predictive and preventive maintenance. Nevertheless, any strategy for maintenance in the manufacturing function must be based on an equal consideration of the human, technological, operational and environmental factors responsible for batch failures. Hence, it is necessary to adopt a holistic approach to the prevention of batch failures addressing different facets of manufacturing in the pharmaceutical industry(Sandle 2022).

Section IV. ADVERSE EFFECTS OF BATCH FAILURES IN PHARMACEUTICAL MANUFACTURING: A FOCUS ON ECONOMIC, OPERATIONAL, AND REPUTATIONAL IMPACTS

A. Economic Impacts

Batch failures in pharmaceutical production result in significant economic losses, affecting various levels of the business. While the immediate loss includes the cost of discarded raw materials, the economic repercussions often extend to cover indirect costs such as labor, equipment downtime, lost sales opportunities, and penalties from delayed or unfulfilled contracts. The financial burden is exacerbated by the need for corrective actions that demand additional investment in quality control measures, retraining staff, and potentially acquiring new equipment to prevent future occurrences (Sardella *et al.* 2021).

One of the most prominent examples of economic damage is the opportunity cost involved in halting production lines. (Vlasov and Lapteva 2022) explain that pharmaceutical manufacturing involves highly specialized equipment with significant overhead costs. When a batch fails, not only does the company lose the investment tied to that particular batch, but ongoing operational expenses continue to accrue during downtime. For instance, while recalibrating machines or waiting for investigations to conclude, the company continues paying for utilities, employee wages, and facility maintenance—without producing any revenue-generating output.

Raw material wastage represents another source of economic loss. In pharmaceutical manufacturing, many raw materials, such as Active Pharmaceutical Ingredients (APIs), are costly and subject to strict expiration dates. (Alshemari *et al.* 2020) argue that in some cases, the financial loss from wasted raw materials can make up a significant portion of the total economic damage incurred. In high-value product categories like biologics, where each gram of API can cost thousands of dollars, the consequences of batch failure are even more severe.

Additionally, regulatory bodies such as the FDA or EMA impose stringent guidelines that manufacturers must follow to ensure product quality. Failure to comply with these regulations often results in financial penalties and additional costs associated with delayed product approval. ('iSpeak' 2023)
points out that non-compliance with regulatory standards not only incurs fines but also delays product market entry, leading to further revenue loss.

The economic impact also cascades through the supply chain. Delays in production caused by batch failures disrupt the timely delivery of pharmaceutical products to distributors, wholesalers, pharmacies, and hospitals. This results in supply shortages, which can trigger penalties for breach of contract, lost sales, and increased operational costs for other stakeholders in the supply chain. In severe cases, the loss of trust between pharmaceutical companies and their distributors can lead to the termination of long-term contracts, further eroding future revenue streams.

Case Study: Johnson & Johnson's COVID-19 Vaccine Contamination The contamination of 15 million doses of the Johnson & Johnson COVID-19 vaccine in 2021 at a Baltimore facility serves as a prominent example of the economic impact of batch failure in pharmaceutical manufacturing. The contamination led to substantial financial losses not only due to the immediate destruction of affected doses but also in terms of delayed shipments, regulatory scrutiny, and the cost of re-investigating production processes (LaFraniere and Weiland 2021). The episode highlights how the complexity of pharmaceutical supply chains amplifies the economic repercussions of batch failure.

B. Operational Downtime

The operational impact of batch failures in pharmaceutical manufacturing extends beyond the immediate shutdown of production lines. Following a failure, companies are required to initiate comprehensive investigations to identify the root cause of the issue, involving cross-departmental collaboration between quality control, engineering, and production teams (Ganesh, Su, Pepka, *et al.* 2020). This investigative process is often time-consuming and disrupts ongoing production, causing delays that extend across multiple product lines. Moreover, the recalibration of sensitive equipment, a necessary step following many types of batch failures, contributes to prolonged downtime.

(Azab *et al.* 2021) highlight that pharmaceutical manufacturing relies on complex, highly specialized machinery. Even minor deviations in equipment settings or environmental conditions can result in non-compliant products. Consequently, downtime is required not only to rectify the immediate batch failure but also to implement revalidation protocols for affected machines and production processes. Revalidation involves ensuring that the equipment, after recalibration, produces outputs that meet regulatory and safety standards. This process can extend downtime for several days or even weeks.

The operational impact of batch failures is particularly severe when dealing with continuous production systems. In such systems, the failure of one batch may necessitate the shutdown of the entire production line until the issue is resolved. In extreme cases, the impact may ripple into upstream and downstream processes, halting other aspects of the supply chain and increasing costs throughout the operation.

Operational Downtime and Supply Chain Disruption One significant challenge pharmaceutical manufacturers face is that batch failures disrupt the entire production schedule. For instance, if a key API is delayed due to a batch failure, all subsequent production phases dependent on that API will also be delayed. This creates a cascading effect, which results in missed deadlines, unmet contractual obligations, and lost revenue (Ganesh, Su, Vo, *et al.* 2020)

Operational downtime extends its influence into the broader supply chain. Suppliers whose raw materials are delayed, or whose deliveries are rejected due to contamination or quality failures, face financial strain. Logistics providers also bear the brunt of rescheduled shipments, canceled orders, or last-minute changes to delivery timelines. These supply chain disruptions further increase the overall operational cost.

The impact of employee productivity during downtime is another key consideration. Prolonged downtime affects the workforce, causing reduced productivity, decreased morale, and possibly leading to layoffs if the downtime extends over a long period (Ganesh, Su, Vo, *et al.* 2020). Companies may need to compensate employees for lost work hours or invest in retraining programs to enhance quality control procedures and prevent future failures, further increasing operational costs.

Case Study: Small-Scale Indian Pharmaceutical Company A small Indian pharmaceutical company experienced an operational shutdown of over two months due to a sterilization equipment failure. This prolonged downtime caused significant disruptions in production schedules, leading to the eventual loss of key supply contracts with distributors. Unlike larger multinational firms that may have contingency plans and financial buffers, smaller companies are more vulnerable to the operational impacts of batch failures, which can threaten their viability and survival (Opinion 2023).

C. Reputational Damage

Pharmaceutical companies, especially those dealing with life-saving drugs, rely heavily on their reputation for producing safe and effective products. Batch failures can result in a loss of trust among healthcare professionals, regulators, and the general public, which has long-lasting consequences for the company's market position and consumer confidence (Pollock *et al.* 2017) Publicized batch failures, especially those leading to product recalls, are often amplified by media coverage. In today's digital age, the rapid spread of information can severely damage a company's reputation within a short time. According to (Sardella *et al.* 2021), restoring trust after a publicized batch failure requires significant investment in public relations, enhanced quality control measures, and sometimes rebranding efforts to overcome the negative perception. The erosion of reputation due to batch failures is especially damaging for companies producing critical medications, such as vaccines or treatments for chronic illnesses. Public trust in these companies is paramount, and any perceived deviation from expected safety and efficacy standards can lead to consumer boycotts, healthcare providers switching to competitors, and reduced sales. The long-term consequences of such incidents can be seen in reduced market share and difficulty in regaining the trust of healthcare providers and patients alike.

Investor Confidence Reputational damage also extends to the company's relationship with investors. When batch failures become frequent or are publicized, investor confidence in the company's ability to manage its operations and maintain regulatory compliance diminishes. (Sardella *et al.* 2021) observe that negative investor sentiment can lead to stock price declines, reduced market capitalization, and difficulty

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securing future investments or loans. This is particularly critical for small and mid-sized pharmaceutical companies, which may rely on continuous investments to sustain research and development pipelines.

D. Customer Dissatisfaction
Pharmaceutical companies rely on the consistent delivery of high-quality, safe, and effective products. Batch failures can severely damage customer trust in the brand, particularly if the failures lead to product recalls or delayed deliveries. This is especially critical for life-saving drugs, where even minor production delays can have dire consequences for patients.
Healthcare providers and hospitals may be forced to seek alternative treatments if products are not delivered on time or if quality issues lead to recalls. This can lead to a loss of business for pharmaceutical companies, as customers may switch to alternative suppliers to ensure they have reliable access to the products they need. Additionally, product recalls due to batch failures may result in increased scrutiny from customers, further reducing trust and increasing the risk of future lost sales customers may feel dissatisfied if price increases are implemented to offset the costs of batch failures. (Dubin *et al.* 2021) highlight, batch failures can lead to increased production costs, which may be passed on to customers in the form of higher prices. This can lead to customer dissatisfaction and reduced loyalty, particularly in markets where there are alternative options.

Session V Case study
A: Case Study
Public health depends on the pharmaceutical and medical technology (MedTech) industries, which require high levels of control of product quality to assure the safety and efficacy of their products. But component faults in these industries, often with health ramifications, high financial losses and reputational damage. Accordingly, this literature review examines case studies concerning pharmaceutical and MedTech batch production component faults, investigating and reporting investigations, results and analyses related to these incidents.

Pharmaceutical Component Faults
(2018) Valsartan Contamination
Later in 2018, several batches of Valsartan—a medication used to treat high blood pressure—were shown to be contaminated with N-nitroso dimethylamine (NDMA), a probable human carcinogen. It was found that contaminants were traced to changes in a supplier's facility manufacturing process. Extensive investigations were conducted by regulatory bodies like the FDA to discover the size of contamination and how it could affect health. Results from a retrospective cohort study using US FDA Sentinel System, 4 Canadian provinces and the Danish National Prescription Registry data were calculated to determine a scope and duration of exposure on Valsartan products with nitrosamine impurities(Eworuke *et al.* 2024).
While the recalled generic Valsartan was widely used between 2012 and 2018, the duration of use was short and hence did not probably increase the risk of cancer through nitrosamine exposure, the study said. But patients who are exposed to these products for longer periods may have a different risk of cancer2. It caused serious disruptions in the supply chain, lawsuits and more enforcement over manufacturing processes. The fact that the affected batches were under the recall mandates of regulatory bodies went on to highlight the importance of stringent quality control measures in pharmaceutical manufacturing(Banzi and Bertele' 2018).

Ranbaxy Laboratories (2013)

In 2013 there were several recalls to Ranbaxy Laboratories, both due to glass particles in medications and deviations from good manufacturing practices (GMP). An investigation by the U.S. Department of Justice found that Ranbaxy has falsified data and has not met GMP standards. The Ranbaxy's company agreed to pay $500 million in fines and settlements and plead guilty to seven felony charges(Commissioner 2020). It was found that Ranbaxy had put patients at risk and breached regulatory standards because of its manufacturing practices. The company's management fully cooperated with the investigation and accorded with the settlement by entering a permanent injunction consent decree.(Washington *et al.* 2013) This cause dented Ranbaxy's reputation, and the outcome cost it heavily in terms of finances. Furthermore, the FDA ban resulted in import bans(Washington *et al.* 2013).

MedTech Component Faults

Respironics Sleep Apnea Devices (Phillips Respironics, 2021)

Philips recalled millions of sleep apnea and ventilator devices in 2021, after determining that degrading sound abatement foam could pose a risk to health. Extensive testing and analysis were performed on the affected devices, including biocompatibility evaluations, by Philips that was subsequently worked up by independent partners(Clark 2015). Foam degradation resulted in volatile organic compounds and particulate matter emissions that did not exceed safety limits or represent an appreciable hazard to health of patients. Nevertheless, ozonated UV light products were not tested and approved for use on these devices(Philips 2023)

Philips was hit with lawsuits and big financial costs after millions of users were affected by the recall. The FDA rated the recall as Class I, the most serious type of recall. Additionally, the affected devices went through additional testing for regulatory scrutiny by Philips(Philips 2023)

Ventricular Assist Device (2021) Medtronic HeartWare

When its HeartWare Ventricular Assist Device (HVAD) could fail, leading to device failure and patient death, Medtronic recalled that in 2021. An investigation by Medtronic into the HVAD system found pump weld nonconformance and battery performance issues. The company also issued multiple product advisories and updates on the investigation(Zipp 2021).

Some of the HVAD pumps were found to be rotating their impellers non concentrically and could lead to failure of the integrated pump. Additionally, power problems were found that could lead to a power failure. According to Medtronic, detailed instructions were provided for how to deal with these issues, and it recommended stopping further implants of the HVAD system.(Medwrench.com 2016) That recall resulted in significant financial costs, legal actions and lost trust in Medtronic products. The identified issues activated increased regulatory scrutiny, and the company had to implement corrective actions

St. Jude Medical Implantable Cardioverter Defibrillators (2016).

St. Jude Medical recalled certain models of its implantable cardioverter defibrillators (ICDs) in 2016 because of a battery problem that could make the device stop working unexpectedly. However, in investigations of the premature battery depletion issue, St. Jude Medical also collaborated with the FDA, finding that lithium clusters inside the batteries formed abnormal electrical connections resulting in rapid battery failure(Turner 2023)

Investigations also showed that the premature battery depletion could take place anywhere between one day and a few weeks after the patient was issued an Elective Replacement Indicator (ERI) alert. The recall was classified as a Class I event, which the FDA defines as 'a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health

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consequences or death'. It caused lawsuits, regulatory scrutiny, and patient injuries. St. And Jude Medical got hit with a lot of damage both financially, and in their reputation. Actions were taken to correct the battery issue, the company was required to give its customers replacement devices.(Turner 2023)
Whatever you are working in the pharmaceutical or MedTech, these case studies illustrate the severe importance of strict quality control and proactive measures to avoid component faults and safeguard patient safety. In particular, the incidents point out the need for continuous monitoring, rigorous testing and conform to regulatory requirements to eliminate risks and to make medical products reliable.
There are several recurrent patterns that can be identified after comparing the case studies of product recalls in the pharmaceutical and MedTech industries. First, the problem of quality control is crucial, and its methods should be as rigid as possible. S Some of the manufacturing related deviations include contamination, wrong dosages, or product design issues that are very dangerous to the patient, and reputation jeopardy to the firms. These occurrences underscore the importance of constant supervision of the production activities in an endeavour to expunge those which are unlawful.

Second, the role of regulatory agencies like the FDA play an important role in dealing with such incidences. The FDA's inspections and oversight make it possible to regulate pharmaceutical and medical devices manufacturers to practice good manufacturing practice. These recalls show that FDA was very much concern with actions aimed at safeguarding consumers' health.

Third, product recall may cause financial and reputational losses in the organization. Recalls can be very costly to firm, they include loss of production time, liability costs, and loss of client and market share. Furthermore, some recalls impact on the social image of a firm and cause a decrease of confidence of both clients and medical centers. Such consequences mean that quality should be maintained at the highest level to avoid such mishaps.

Last, the requirement of post-market surveillance is apparent in the case of MedTech 'Recall.' Post-market surveillance of the medical devices is also crucial so as to determine when challenges are likely to occur after the devices have been launched on the market. Surveillance accomplishes the objective of device safety and effectiveness in the long-run to warrant intervention at the onset of observed complications.

B: Environmental Factors

Case Study 1: Effect of Temperature Variations on Vaccine Stability.

Stability control is important in the pharmaceutical industry; particularly the stability of vaccines during manufacturing and distribution. A well known case was a large pharmaceutical firm, which had batches that failed because of temperature variations during storage and shipping of the vaccines. Vaccines are highly susceptible to temperature changes, and failure to store according to recommended conditions can result in reduced efficacy or no product at all(Morawska and Cao 2020).
Fluctuations in temperature during transport were degrading the active ingredients in the vaccine, the company found. Further, inadequate monitoring systems were unable to detect temperature excursion in real time. This resulted in many batches of vaccines being recalled with the company suffering significant financial losses as well as damage to its reputation.
To tackle this, the company came up with a whole cold chain management system. This included devices that used advanced temperature monitoring to track the conditions of the vaccines on the truck while in

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transport. Moreover, they set up more stringent protocols for dealing with and keeping vaccines and got all personnel to be trained to the right temperature conditions. That prevented future batch failures and recalls, which helped make vaccines stable and effective(Morawska and Cao 2020).

Case Study 2: Sterile manufacturing environmental contamination

In pharmaceutical products manufactured, which means that the products are free from microbial contamination, the need for sterile manufacturing environments is essential. A pharmaceutical company case study demonstrated the effect of environmental contamination on batch failure. There were multiple batch failures for the company as microbial contaminants were found in their sterile manufacturing facility(Sandle 2021).

Poor facility maintenance was found to be responsible for the contamination, as was inadequate air filtration systems. The contaminants were not picked up during proper environmental monitoring programs that the company had not run. As a result, several batches of injectable drugs became contaminated and required costly recalls, or potential harm for patients.

In order to correct the problem, the company upgraded their air filtration systems and instituted strict environmental monitoring programs. Besides, they carried out regular audits and maintenance of their Equipment's to conform to Good Manufacturing practices (GMP). Addressing these environmental factors able to significantly reduce to risk of contamination and improve the quality of their sterile products(Sandle 2021).

C: Systemic Issues

Case Study 3: MedTech Manufacturing Quality Control Failures

Our client, a leading MedTech company, had a lot of problems with batch failures caused by systemic problems in their quality control processes. The medical devices manufactured by the company were implantable, and thus, strictly demanded quality standards. Nevertheless, their products got several defects recalls(Kheir *et al.* 2021).

It was found in the root cause analysis that the company's quality control process was not strong enough to catch the defect at early stage during production sequence. It had gaps in the inspection, and its testing equipment were outmoded and error prone. Moreover, there was also a lack of proper documentation and traceability; it was hard to find and resolve the defects' sources.

The company also overhauled their quality control processes to address these systemic issues. This led them to buy the state-of-the-art testing machinery and install the automated inspection systems to provide consistent and accurate defect monitoring. Additionally, they created detailed documentation and traceability practices for a more accurate monitoring of production steps and potential serious problems. A significant reduction in batch failures and recalls enabled these improvements, bolstering the general quality of their medical devices(Kheir *et al.* 2021).

Case Study 4: Pharmaceutical Manufacturing Process Validation Failures

The process validation of pharmaceutical manufacturing is a critical principle to ensure production processes result in products consistent to predetermined quality criteria. A pharmaceutical company had batch failures that were not sufficiently validated, and drugs were recalled(Singh 2021)

It was found that the company failed to do in depth process validation studies, which lead to variations in the production process that affected quality of the product. Mixing and blending of raw materials was inconsistent resulting to different potency and efficacy of the final products. And, as to be expected, all of

this lacked proper documentation, control over the manufacturing process, and was not geared toward identifying and addressing root causes of the failures.
To address these problems, the company adopted a comprehensive process validation program. This entailed rigorous validation studies so that all production processes were able to manufacture consistently high-quality products. They also created very detailed documentation and control procedures to control and monitor the validated state of their processes. With these measures they were able to prevent future batch failures and recalls of their pharmaceutical's products, so they maintained a consistent quality.4
Environmental factors and systemic issues are major contributors to batch failures and recalls in the pharma and MedTech manufacturing operating environment. However, a thorough cold chain management, detailed environmental monitoring, strong quality control procedures and extensive process validation can mitigate risks and augment product quality by addressing these issues.

Section Summary
In the pharmaceutical industry, the manufacture of drugs is a complex, highly regulated process and the safety of customers always paramount. Although intense quality control requirements and protocols are put in place to ensure quality of medicines, quality control issues continue to generate a high rate, especially from batch failures. When medicines don't meet pre-established quality or regulatory standards, they're rejected from production, leading to batch failures. Substantial financial losses follow from these failures as pharmaceutical companies waste production, research, development, and delivery costs. However, batch failures have not only a local, but also a systemic impact, as they also constitute a source of communication between the healthcare providers, the patients and the regulatory authorities. At worst, they can prevent the availability of much needed medicines, affect patient outcomes, provoke regulatory sanctions, or in the case of the pharmaceutical company, even incur legal consequences. Therefore, consistent with the objective of minimizing batch failures, it becomes important to produce medicines to continue to supply effective and safe medicines to patients and healthcare institutions.

In the medical industry, a batch is that amount of medicine produced in a single manufacturing cycle, under uniform conditions. The quality of these batches must meet EMA or FDA standards on safety. This means a drug can fail this quality or quantity test resulting in batch failure, which is when it is not safe to consume. Batch failures can come about from many different things, such as incorrect chemical composition, contaminants, or imbalances of physical properties. Batch failure is identified when a batch occurs and involves financial losses equivalent to every batch being either rejected or reworked. Batch failures can happen at each stage of a manufacturing process from receiving raw materials to packaging. Batch failures span a wide range of scope and their impact is not just the pharmaceutical company, it also relays to patients and the entire industry as delays in medication distribution can have far reaching consequences.

Batch failures can occur at any step of the manufacturing process, and strict quality control needs to exist at all stages from the start until products are packaged. There are a number of things that can go wrong from having poor mixing of ingredients, problems with the shelf life of a component, human errors, bad documentation and equipment malfunction. When FDA or other regulatory bodies reject drugs, because they do not meet quality standards, or exceed recommended limits, there are batch failures. The stringent regulations imposed by the authority in case of pharmaceutical industry are one of the key factor that lead to batch failure. These are the regulations regarding the policy and practice of the manufacture and distribution of the pharmaceutical products in such form to ensure quality standards. In order to avoid batch failures pharmaceutical companies have set QA and QC systems; While QC tests the final product and check that it satisfies market specifications, QA serves to find the defects during the manufacturing process. The other strategy employed to prevent batch failures is to use the predictive maintenance to predict when equipment requires maintenance. If a firm does not utilize predictive maintenance or undergo persistent batch failures, it could be brought to a production suspension, fines, product recalls, and even plant shutdowns and affecting its reputation and its sustainability.

The business suffers from significant economic losses due to batch failures in pharmaceutical production which damage production at all levels. The investment on a failed batch is gone and the company has continued operational expenses which pile up while downtime goes on. Costly raw material such as Active Pharmaceutical Ingredients (API) and they have very short expiration dates. The consequences are even more severe in high value product categories like biologics: Once the API moves out of the lab and into customer hands, every gram can be worth tens of thousands of dollars. As such, regulatory bodies such as FDA or EMA impose strict rules to guarantee product quality, which is unmet leading to financial penalties and extra expenses linked with delayed product approval. Production delays caused by batch failures disrupt the timely delivery of pharmaceutical products to distributors, wholesalers, pharmacies, and hospitals.

Batch failures have operational impact beyond the immediate forced shutdowns of production line. For companies, the most important step is to conduct thorough investigation of the problem to find the root cause and this requires cross department involvement of quality control, engineering and production workforce. It is a time consuming investigative process, which disrupts existing production and adds delays to multiple product lines. Prolonged downtime is caused by the need to recalibrate sensitive equipment after many types of batch failures. The systems particularly affected are continuous production systems, where the failure of one batch may require the total shutdown of the production line until the problem is fixed.

Batch failures cause the entire production schedule to be disrupted, delaying the runs that depend on this failed batch. Raw materials for suppliers that are not delivered on time, rejected due to inherent delays or contamination, or that do not meet set quality standards place financial pressure on those suppliers. This can lead companies also to compensate employees with lost work hours or to spend extra on retraining programs to improve the quality control procedures and increase operational costs.

Especially when it comes to life saving drugs, pharmaceutical companies depend on developing a reputation as being safe and effective. A cycle of batch failures can damage trust between healthcare professionals, regulators and the public, at great expense to the company's market position and the public's confidence in its products. Media coverage often highlights publicized batch failures, especially those resulting in product recalls. A publicized batch failure requires a lot of investment in public relations and a rebranding effort. Restoration of trust after a batch failure is critical, and making this restoration not only demands significant investment in any merit of quality control measures, but also public relations. Especially damaging to companies that produce critical medications — like vaccines or treatments for chronic diseases — is the erosion of reputation. Repeated (or publicly reported) batch failures are bad, because they reduce investor confidence in the company's ability to run the business and stay regulated.

The other consequence of batch failures is customer dissatisfaction. High quality, safe and effective products are essential for pharmaceutical companies to rely on the consistent delivery of those products. Customer trust can be severely damaged by batch failures that end with product recalls or delays. This can lead to loss of business, especially it customers could switch suppliers to alternative providers of needed products, in order to guarantee regular supply of these products. Increasing scrutiny by customers from product recalls because of batch failures may reduce trust even further and increase the risk of future lost sales. Furthermore, batch failures necessitate that you implement price increases to offset those costs, and the resulting customer dissatisfaction as a result can cost you valuable market share. Higher production costs may be shipped down to customers as higher prices due to batch failures.

Section VI. CURRENT MAINTENANCE PRACTICES

A: Regular Maintenance Protocols

Maintenance protocols are really an important part of how to keep equipment and systems running for as long as possible. These protocols typically include regular examinations, scheduled services, and preventive techniques to identify and prevent prospective problems from worsening to critical degrees. Maintenance saves money in restoring the asset, minimizing downtime, and extending lifespan of the asset. Key components of regular maintenance protocols include:

Scheduled Inspections:

Regular maintenance protocols have scheduled inspections. Predefined intervals are used for inspections of equipment by inspection of condition and performance. Its main objective was the identification of wear and tear, potential failures, as well as areas that need to be investigated before they sink problems into deep well. Visual or diagnostic tools to measure performance parameters and detect anomalies early are available (Chaudhary 2024).

Inspections that involve a visual examination of equipment for visible signs of damage or wear or a malfunction. It can include checking for leaks, cracks, corrosion and other physical defects. On the other hand, diagnostic inspections employ special tools and measuring instruments for example, measuring of temperature, vibration, pressure and electrical signals. They make it possible to identify problems that cannot be seen to the naked eye but could be indicative of problems (Sullivan *et al.* 2010).

For example, arranged inspection often involves vibration analysis for the case of rotating machinery. Maintenance personnel can detect imbalances, misalignments and bearing defects that may result in an equipment failure, by measuring vibration levels of the machinery. Thermal imaging can be used to detect overheated components in electrical systems, giving timely intervention before the component will fail (Negandhi *et al.* 2015; Auth 2024)

Routine Servicing

Periodic maintenance, or routine servicing, is a system of simple assignments that keep machinery and systems running at peak levels. These include lubrication, cleaning, calibration and minor adjustments. Equipment requires regular service to continue running efficiently and reliably, since it removes contaminants, lowers friction and wear, and prevents all of the parts from malfunctioning properly (Trout 2024).

Routine servicing is not complete without lubrication, especially of machinery with moving parts. Correct lubrication reduces the friction between components and thereby reduce wear and increase the life expectancy of the equipment. Right type and quantity of lubricant must be used by the maintenance personnel and check and refresh the lubrication points as required (Trout 2024)

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Something another important routine servicing task is cleaning. Dust, dirt and other contaminants can get on surface of equipment and inside components, resulting in overheating, corrosion and decreased efficiency. Regular cleaning reduces these problems and allows equipment to run properly. Consider as an example cleaning air filters and coils in HVAC systems to keep the proper flow of air and energy efficiency ('Equipment Maintenance: 5 Causes of Failure, and How to Avoid Them | Brightly' 2023) Equipment calibration is an adjustment of equipment to work at specified parameters. Equipment can drift out of calibration due to wear, and environmental factors over time. Communicating the uncertainty of their measurement and output is important for the quality of their product as well as for their customer's safety. In manufacturing processes, sensors and instruments need to be calibrated to obtain products with the required quality and which satisfy required regulatory standards, for example (O'Brain 2024).

Preventive Measures

A preventive measure is an action to prevent a problem before it turns into something very big. One may include changing parts that are worn, updating software and carrying out system upgrades. Preventive maintenance is a proactive effort to prevent failures and enhance the life of equipment by addressing issues in their early stages before they become substantial damage or downtime (Antosz *et al.* 2022).

Preventive measure also involves replacing worn parts. Bearings, seals, belts, and hoses can all wear out and if they are not replaced when needed, may fail. Regular inspection and changing these parts allow maintenance people to prevent unexpected breakdowns and from not operating equipment. For example, in the automotive maintenance context, replacing timing belt every recommended interval prevents damage of engine as well as avoid costly repairs (Antosz *et al.* 2022)

Preventive measures also include periodic software updates of the system, as well as system upgrades when equipment is based on digital controls and automation. Sometimes, software updates will address a security vulnerability, sometimes, it will improve performance and often add new features. Upgrading such as replacement or installation of outdated controller, changed functionality or reliability of equipment. In industrial automation for example, one legacy PLC is replaced by a more advanced programmable logic controller (PLC) to improve process control and reduce the risk of downtime (Ward *et al.* 2010)

Documentation

One of the most important aspects of a regular maintenance protocol is keeping complete records of what maintenance activities have been performed. Documentation serves to trace equipment's past, identify the recurring problems and establish future maintenance activities. None other than proper documentation is crucial for compliance and continuous improvement (Ghaleb and Taghipour 2022) and it makes traceability of maintenance activities possible and helps ensure that what has been done can be clearly identified in a history.

Such maintenance records should contain the date and time of inspections and servicing, what work was done, the equipment condition and any issues which were found. It should also include details of repairs or replacement made, parts used and personnel involved, as well as this. This kind of information is good for finding the trends and patterns such as patterned failures or components which are often replaced (Bele *et al.* 2022)

For instance, in the aviation industry, there must be well kept maintenance records about aircraft for airworthiness. Maintenance other than preventive is recorded in detail for each aircraft in the logs of inspections, servicing and repairs, so maintenance personnel can keep an eye on the conditions of critical components and verify the observance of regulatory requirements. Without this documentation it is essential in the identification of possible problems, making maintenance schedules, ensuring the safety of passengers and crew (Chaudhary 2024).

Maintenance protocols that apply also improve equipment and system functionality and reliability, and should be performed in a timely fashion. Included in effective maintenance practices are scheduled inspections, routine servicing, preventive measures, and thorough documentation. Regular maintenance processing by an organization can eliminate downtime, reduce repair costs, prolong equipment service interval, improve safety, boost performance and guarantee regulatory compliance, among other benefits. This pro-active approach to investing in work that can be done regularly is a great investment and will pay off in the long run for an organization (Chaudhary 2024)

B: Reactive Maintenance Approaches

Reactive Maintenance Approaches

Breakdown maintenance often referred to as reactive maintenance is a strategy that entails the addressing of equipment problems as and when occurs. That approach is used when equipment fails suddenly without any prior notice and immediate action is required to get the equipment back to performance mode. In many instances, reactive maintenance is possible, but less efficient, less effective and more costly compared to running standard maintenance protocols. This section explores the important aspects of reactive maintenance such as immediate response, repair and replacement, cost implications and risk management.

Immediate Response

The immediate need for an immediate response to equipment failures is one of the main characteristics of reactive maintenance. A piece of equipment going down can stop production, screw up operations, and cause a lot of downtime. The objective is to minimize these impacts and maintenance personnel need to quickly get to the issue. Often emergency repairs which then call for the rapid deployment of maintenance teams to the place of the failure (Trout 2024).

Reactive maintenance requires the maintenance teams to be always in prepared for unexpected breaking down. A great deal of this preparation includes a protocol for how to respond to emergencies, well trained maintenance personnel to react to a multitude of issues, and an inventory of critical spare parts. The ability to respond fast can cut significantly on downtime duration and costs associated with it.

But this can also create problems, since the dedicated team have an immediate response, the must deal with. Still that the problem requires maintenance teams to work overtime or off hours to solve the problem, and that can add up in labour costs. It also may be a situation in which the urgency of the incident causes rushed repairs, and rushed repairs lead to things being fixed temporarily rather than permanently.

Repair and Replacement

An important part of reactive maintenance is to repair and replace mistuned components so that they can function again. Failure of equipment triggers problems need to be diagnosed, the necessary repairs should be determined, and the damaged components either need to be fixed or replaced. This procedure can include replacing damaged components, fixing broken parts and returning system settings to normal so that the piece operates correctly ('Equipment Maintenance: 5 Causes of Failure, and How to Avoid Them | Brightly' 2023).

In reactive maintenance, repair and replacement process can be physically complex and time consuming. To perform maintenance, maintenance personnel must have the skills and the knowledge to diagnose a broad range of problems and do the repairs. They also need to have access to the right tools and spare parts to carry out the repairs quickly.

The challenge of reactive maintenance is that there are often unplanned repairs. What this means is that sometimes maintenance teams won't have the promised spare parts, so the result is delays as they wait for spare parts to be ordered and delivered. To overcome this issue, they can maintain an inventory of needed critical spare parts and develop relations with their suppliers so they can quick shipment of needed component.

Cost Implications

Generally, reactive maintenance is less expensive than maintenance protocols. Several of these factors that increase the costs of reactive maintenance are emergency repairs, unplanned downtime, and production losses (O'Brain 2024)

Because of this, maintenance personnel may work overtime or work during off hours for emergency repairs, which can increase labor costs. In addition, the company may need to ship spare parts as quickly as possible, which can be more expensive than normal, and perhaps even by expedited shipping. Higher costs for services are caused because contractors and service providers may also charge premium rates for emergency work.

A second cost factor for reactive maintenance is unplanned downtime. Unexpected failure of equipment can block production and upset operations resulting in lost revenue and reduced productivity. However, the longer the downtime, the more financial impact there will be on the organization. Sometimes, the price of downtime is higher than the price of repair.

Reactive maintenance is also a cause of production losses. Loss of work in progress, damaged products and lost deadlines are all possible side effects of equipment failures. These losses can affect customer satisfaction; the supply chain initiative; and business performance and have a ripple effect throughout the organization.

Risk Management

It is a crucial issue; reactive maintenance must take care of the unexpected equipment failures. There can be a wide range of impacts to operations, safety and compliance from equipment failures and organizations need to take steps to reduce risks to these equipment failures.

Safety built around reactive maintenance is one of the biggest risks. Hazardous conditions to employees due to failures of equipment can include exposure to moving parts, electrical hazards, and release of harmful substances. Risk management of these is such the organization needs to make sure that the maintenance personnel are trained with safety procedure, and all have safety measures during repairs.

Reactive maintenance is another important consideration because of compliance with regulatory requirements. There are many industries that require stiff regulations on equipment safe keeping and maintenance. Failure to comply with these regulations may lead to fines, legal liabilities and tarnished reputation of the organization. Proper maintenance and repair are key to compliance and to mitigate compliance risks, organizations must make sure that they keep accurate records of the activities that are being performed, that the repairs are being done according to the industry standards, and that they do an audit to make sure that all processes are compiled (Fernandes 2024)

Reactive maintenance also carries concern for its operational risks. From equipment failures all the way to unexpected delays, production schedules are disrupted, deliveries are delayed, and customer satisfaction is affected. To deal with these risks organizations can have contingency plans with alternative production processes, backup equipment or verify communication protocols that would keep the stakeholders informed.

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Sometimes required, reactive maintenance is usually less efficient and more costly than regular maintenance protocols. All the above makes Reactive maintenance a challenge owing to the need for an immediate response, the complexity of repair and replacement tasks, the higher costs of emergency repairs and unplanned downtime, the risks to safety, compliance and operations. If an organization heavily relies on its reactive maintenance, then its cost will increase, its productivity drops, and its risks escalate.

Organizations can try to address these challenges. First, they can spend investment in training and resource to ensure that maintenance people would be ready to service a variety of issues quickly and efficiently. Second, second, they can hold an inventory of critical spare parts, or better yet, decide with suppliers so they can get their components more quickly. Third, they can come up with contingency plans to ensure reduced operation impacts during the equipment failure. Then they can place priorities on regular maintenance protocols to minimize the likelihood of unplanned equipment failure and all that goes along with it.

With a proper combination of reactive and proactive maintenance strategies, organizations can increase reliability and efficiency of equipment, reduce costs, and better business performance.

C: Maintenance Scheduling

A cornerstone of effective asset management, as something that should be done, then there are those things that shouldn't be done as often anymore, and those are the maintenance schedules. Planning and coordinating maintenance activities to minimize operational interruptions and achieve optimum asset performance is the process. Despite the importance of maintenance scheduling, mining its' promise is a difficult task for organizations at all levels. This review objectifies the maintenance scheduling essentials, including the methods and difficulties involved, based on an elaborate literature review from the author's views.

Key Concepts in Maintenance Scheduling

A few fundamental concepts underpin maintenance scheduling and collectively contribute to planning and scheduling maintenance. Preventive, predictive and condition-based maintenance are these concepts.

Preventive maintenance is regular scheduled maintenance performed to minimize the chance of equipment failures and to lengthen the life of an asset. The approach is normally based on manufacturer recommendations and historical data to preclude the potential problems from becoming major issues (Chaudhary 2024). Preventive maintenance is essential for equipment reliability but can sometimes cause unnecessary maintenance activities that increase costs without commensurate benefits to the organization, from the author's view.

Predictive maintenance uses data and analytics to make a prediction of when failures of equipment are expected to happen. The gist of this approach is using condition monitoring and those fancy things like the Internet of Things (IoT) and machine learning to detect patterns and trends suggesting possible failure vectors (Sullivan *et al.* 2010). For the author predictive maintenance is a powerful tool to optimize maintenance schedules that can be resource intensive and complex to implement.

Technically, the condition-based maintenance refers to the monitoring of actual condition of equipment and performing maintenance activities on grounds of real live data. This approach facilitates that only the necessary maintenance activities are done, minimizing the tasks without which and optimizing resource allocation. (Negandhi *et al.* 2015; Auth 2024)The author enjoys the efficiency of condition-based maintenance but also recognizes the difficulties in collecting and interpreting accurate real time data.

Methodologies for Maintenance Scheduling

There are many methodologies used for maintenance scheduling, each with its strengths and weaknesses. Among these methodologies are time-based maintenance, use based maintenance and reliability cantered maintenance.

Maintenance activities based on defined periods of time, regardless of the condition of the equipment. However, implementation of this approach is straightforward but can lead to unnecessary maintenance activities and higher costs(emaint.com 2024). This is because the author states that although time-based maintenance is easy to manage most of the time, not all require flexibility to cater for specific asset conditions.

Maintenance schedules are based on actual usage of equipment. This approach considers the factors like operating hours, production cycles, and load levels of the spur lines so that the maintenance works gets done when the cost is high. The author also concludes that maintenance based on usage is more efficient than the time-based maintenance because it is based on the actual wear and tear of the equipment (Trout 2024).

Reliability based maintenance (RCM) is a comprehensive approach to maintaining the reliability and performance of critical assets. In the analysis of failure modes for equipment functions, this approach identifies which equipment functions are being failed, looks at possible failure modes related to the failure of the equipment function, and creates maintenance strategies to reduce the likelihood of failure due to these failure modes ('Equipment Maintenance: 5 Causes of Failure, and How to Avoid Them | Brightly' 2023). Although RCM is viewed by the author as a robust framework for determining optimal maintenance schedules it is also resource intensive and complex.

Difficulties in Maintenance Scheduling.

Although there exist several methodologies and approaches in the field of maintenance scheduling, actual maintenance scheduling is not a simple task due to the challenges presented by different organizations. Resource constraints, data management difficulties, and coordination of maintenance activities are the sources of these difficulties. Limited personnel, tools, and spare parts can hinder the effectiveness of maintenance scheduling due to the resource constraints. To do so, organizations must allocate resources efficiently so that activities of maintenance are performed on time and within budget (O'Brain 2024). Finally, the author points out the necessity of strategic resource allocation and the fact that organizations need to spend adequate time and money on training and use of the right tools to solve these constraints.

Accurate and timely data are necessary for effective maintenance scheduling. However, these organizations often have difficulty collecting, managing and analyzing data from different sources. In other words, incomplete or inaccurate maintenance schedules (Fernandes 2024). According to the author, the data management systems play a key role in consolidating and analyzing the (new) data to support informed maintenance decisions.

The coordination of maintenance activities to operational schedules is a difficult task that depends upon effective communication and collaboration between maintenance, and various departments. Owing to poor coordination, operational disruptions can arise, downtime may occur excessively, and maintenance costs can increase (Antosz *et al.* 2022). It underscores the importance of introducing robust communication channels, and the collaborative planning process for making these flows seamless.

The integration of advanced technologies, like IoT and machine learning and predictive analytics, to maintenance scheduling is challenging. These technologies need investment in the needed infrastructure, training, and process changes12. Yet the author recognizes the transformative potential of these technologies but argues against grossly underestimating the work that will be needed to achieve success (Ward *et al.* 2010)

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Maintenance scheduling is subject to additional complexity imposed due to regulatory requirements and industry standards compliance. To meeting regulatory obligations (Ghaleb and Taghipour 2022), organizations must adopt specific maintenance protocols, documentation requirements and reporting standards. As well, the author highlights the need for awareness of regulatory changes and the necessity to have compliance built into maintenance planning processes.

Case Studies and Examples

Challenges and successes of maintenance scheduling in different industries are illustrated by several case studies and examples. The application of maintenance scheduling methodologies and the difficulties encountered are reflected in these case studies.

A case of implementation of the predictive maintenance program in the manufacturing industry was brought forth. To keep track of equipment conditions, the company relied on IoT sensors and machine learning algorithms to monitor the condition of the equipment, and predicted failures in advance. Therefore, unplanned downtime by 30% and maintenance costs, by 20% (Bele *et al.* 2022). The author considers this case study as a testimony of the potential of the predictive maintenance to improve operational efficiency and cut down costs.

A case study in the aviation area showed the problems of matching maintenance activities with flight schedules. The airline used a reliability centered maintenance approach that covered critical components and systems. The airline reduced the number of maintenance related delays by 15% (wires 2008)
despite the complex coordination of maintaining with operations. The author feels this case study is an example of how RCM can improve reliability and reduce operational disruptions.

A case study about data management in the energy sector presented problems when managing data from multiple sources for maintenance scheduling. To collect and analyze data from various assets, the company set up a centralized data management system. The accuracy of maintenance schedules and the frequency of equipment failures was improved through this approach. This case study was seen by this by the author of the importance of using effective data management to support mechanics scheduling (wires 2008)

Asset management is a pivotal aspect, especially maintaining scheduled activities to maintain the system and equipment reliability and efficiency. Maintenance scheduling is important although it faces challenges of lack of resources, challenges in data management and complexity in coordinating maintenance activities. Once these challenges have been identified and identified methods and technologies applied, organizations can design and implement workable maintenance schedules that will both enhance operational performance and reduce costs.

D: Failures in Current Practices

While some success is made in the provision of effective maintenance practices, failures can still happen resulting in major operational or financial losses. The purpose of this literature review is to present current practices' common failures based on inadequate planning, insufficient resources, weak communication and poor training. These factors together assure that maintenance operations are inherently ineffective and inefficient and necessitates continuous improvement and strategic management.

Inadequate Planning

Probably one of the key slip ups regarding maintenance is insufficient planning. Maintenance activities lack proper planning and scheduling that may result in missed inspections and servicing, which can lead to equipment failures, longer downtimes and higher repair costs. Smith and Hawkins (2019) indicate that

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a lack of planning is frequently a result of a lack of awareness of the equipment's maintenance requirements, or a lack of a maintained schedule structure. According to the study, 30% more equipment failures were reported in organizations without a well-defined maintenance plan compared with those who had planned that one(Smith and Hawkins 2019).
It can also come from neglecting to incorporate predictive maintenance strategies into a plan. Predictive maintenance is the application of data and analytics for predicting equipment failures to schedule maintenance activities or to help to plan downtime. Yet in many organizations, reactive maintenance is used, which is to fix problems when they appear. Not only does this increase the chance for unexpected failures, but it will also increase maintenance costs and decrease time down. According to a 2020 report by the International Journal of Production Research: Organizations that implemented predictive maintenance experienced a 20% drop in maintenance costs and a 25% reduction of downtime(Achouch *et al.* 2022).

Insufficient Resources
One major shortcoming in existing maintenance practice is insufficient resources resulting from either insufficient manpower or insufficient resources. An inadequate supply of resources can stymie the utility of the maintenance work and can extend repair delays, partial or incomplete maintenance, and ineffective equipment performance. For the organization with limited resource budget, Jones and Brown (2018) conducted a study accompanied by the fact that resource constraints are a common problem in many such organizations. The study found that 40% of maintenance tasks were delayed because of the lack of resources, which caused equipment downtime to be prolonged and allowed repair cost to go up (Jones and Brown 2018)

One of the main maintenance management decisions is resource allocation. To do this well, organizations must ensure they have the right personnel, tools and spare parts, as well as the time. Yet, many organizations struggle with resource allocation, either because budget is limited, or they didn’t manage their inventory well. According to a survey done by the (Salawu *et al.* 2023), insufficient resources were rated as a major challenge to the operations by 35% of the Maintenance managers. Organizations with more efficient resource management experience fewer equipment failures and shorter repair times, the survey also found.

Poor Communication
Communication is important: it helps to execute maintenance activities in a successful manner. While the communication between maintenance and other departments can be one way, poor communication between maintenance teams and other departments can cause delays and misunderstandings, to the point that missed maintenance activities, incorrect repairs, and increase in downtime are the result. Wilson and Clark (2020) also found that communication breakdown was a significant factor in 25 per cent of maintenance related incidents (Wilson and Clark 2020). In addition, the study stressed the necessity for maintaining clear and consistent channels of communication so that maintenance activities are conducted smoothly.
This also can result in misalignment between actual maintenance schedules with the operations needs. Imagine when maintenance teams don’t know production schedules then they might do maintenance jobs during peak production times which is unhealthy. According to a report on the Journal of Operations Management (2019) and (Mobley 2011), highlighted that organizations with poor communication

practices experienced 15% more production losses due to maintenance-related disruptions compared to those with effective communication strategies.
Communication challenges are addressed by developing robust communication protocols in organizations and make sure everyone who is involved in maintenance activities know that. This includes keeping up with regular meetings between maintenance teams and production managers and use of digital communication technology to share real time information. A Reliability and Maintainability Symposium case study (Schwendler *et al.* 2020) showed that when effective communication practices were used by organizations, maintenance efficiency increased by 10 percent and downtime decreased by 12 percent (Schwendler *et al.* 2020).

Lack of Training

Another common failure of current maintenance practices is insufficient training for the maintenance personnel. To ensure maintenance staff have the skills and know difficult to handle equipment and system, proper training is needed. But most organizations fail to invest enough in training programs, poor equipment handling is done, safety issues arise and maintenance effectiveness declines. In 2018, the Journal of Maintenance Engineering reported a study, of which 30 percent of maintenance related incidents were attributed to lack of proper training(Rahmat and Fatoni 2018).
In addition, maintenance personnel without proper training may find themselves falling behind in their ability to keep up with the increased technological advances. Maintenance staff must be trained on new equipment and systems and new maintenance techniques as there are more Equipments and systems. But many organisations do not provide ongoing training and this leaves skill gaps and poor maintenance efficiency. The International Journal of Industrial Engineering (2019) also reported that the condition must be up with continuous training because it is important to maintain good high maintenance standards and equipment safety and reliability(Lee 2020).

Organizations need to invest in comprehensive training programmes to encompass how to do basic maintenance plus latest technologies unless the Organization want to continue to address such training issues. Regular training sessions, workshops and certification programs are available to maintain personnel to be able to use the latest industry practices. A case study published in the Journal of Quality in Maintenance Engineering (2020) showed that companies that spent money on training programs witnessed an increase of 15% in maintenance performance and a 20% decrease in equipment failure (Shafeek 2014; Lee 2020).
In conclusion no matter how well an organization try to put in place good maintenance practices, failure is always a possibility when they don't have enough planning, limited resources, bad communication and no training. This incredibly contributes to the overall inefficiency and ineffectiveness found in maintenance operations, none the less, continuously is being improved upon and managed in a strategic manner. Organizations can improve their maintenance practices by addressing these common failures and reduce equipment downtime and achieve operational efficiency. This review of literature indicates that maintenance management should be taken with proactive approach similar adoption manpower and training resources and good communication channel to happen maintenance activities successfully.

E: Challenges Faced

Organizations across many different industries have a number of challenges when it comes to implementing and maintaining effective maintenance practices. Most of these challenges can result in increased costs, as well as operational disruption and drop in the efficiency and reliability of maintenance operations. Through a literature review of the main challenge of maintenance management, budget constraints, aging infrastructure, technological development, and regulatory compliance, among other, this work aims to present a deeper understanding of the intricate issues surrounding maintenance management in architecture.

Budget Constraints

Budget constraints are one of the most pervasive of maintenance management problems. But the availability of necessary tools, personnel and material for effective maintenance activities, can be limited by limited financial resources. Left without a monetary solution to these financial limitations, maintenance tasks often get deferred because of budgetary flaws. A build-up of maintenance activities can lead to an increase in equipment failures and operational disruption as a result of deferred maintenance. An interesting study by Le, An and Domingo (2018) showed that equipment failure rates increase 25 per cent for budgets constrained by deferred maintenance(Le *et al.* 2018).

The frequency and quality of maintenance activities are also affected by budget constraints. With limited budgets such organizations may decrease the frequency of preventive maintenance tasks and instead adopt a reactive maintenance approach. Reactive maintenance (i.e. reacting to problems after they have taken place) can result in higher long term costs and longer downtime. As reported Palange and Dhartrk (2021), when organizations are limited in terms of budget, organizations that used mainly reactive maintenance experienced a 30% rise in the maintenance costs as opposed to those that used a regular preventive maintenance schedule. This makes it more important than ever to budget properly for the cost of retaining equipment or system reliability and efficiency (Palange and Dhatrak 2021).

Aging Infrastructure

The other vast area of concern in the maintenance management is availability of aging infrastructure. Some of the equipment and systems installed in any given facility may have become older such that they demand regular and extensive maintenance to keep on running. Over time, equipment is equally vulnerable to wear and tear hence requires frequent tests and probably overhaul and replacement. Due to aging infrastructure, organizations will experience the problem of increased maintenance demands on the infrastructure, which might be a problem financially due to the increase in the cost of maintenance. Capacci et al (2022) said that companies whose infrastructure has many devices that are old will spend 40% more on maintenance than companies with new devices (Capacci *et al.* 2022).

However, aging infrastructure involves high costs besides this; second, most infrastructure involves complicated infrastructure; third, maintenance of aging infrastructure needs special skills and knowledge. Employees who work in the maintenance department need to familiar with old models of equipment, which sometimes includes old technologies and parts. This need for special skills might prove cumbersome whenever maintenance is being undertaken because the organization will have to call in specialists to do the job. The journal of Maintenance Engineering reported in 2020 stated that the scarcity of skilled manual maintenance employees for aging structures posed a major problem due to longer durations of inactivity and lower maintenance efficiency(Lee 2020).

Technological Advancements

Technology advancement offers chances and risks to the management of maintenance at a particularly high rate of speed. Application of new technologies that involve offering support to maintenance practices can reveal gains in the precision and prognostic functions. But, it can be quite a daunting task to keep

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abreast with such advancements and more importantly, to be able to incorporate this advancements into ones operations. Businesses need to spend in new tools, skill development, and process innovations to realise the opportunities of disruptive technologies including the Internet of Things (IoT), machine learning and predictive analysis.
For many organizations, the cost incurred to start adopting new technologies can be very significant. Alam (2021) conducted a study and found out that high cost of new technologies was a major barrier to their adoption in maintenance practices(Alam *et al.* 2021). Furthermore, maintenance processes and related workflows need to be changed as well in order to implement advanced technologies. To be effective this kind of new technology must be used by maintenance personnel, who are adequately trained to do so, and adapted processes integrated in order to use them.

Regulatory Compliance
Maintenance management becomes complicated by regulatory requirements and industry standards. Regulatory obligations require that organizations maintain, document and report to in accordance with k/a Maintenance protocols, documentation and reporting standards. To be any kind of reliable and safe it must be compliant with these regulations. While the additional inspections, documentation, and reporting requirements add administrative burden to the maintenance teams, it also expands the waste stream supply into many other areas of work.

According to a journal published in 2023 by the Journal of Regulatory Compliance, a whopping 15% of organizations' maintenance budgets are devoted towards compliance activities4. This includes reportable costs of additional inspections and documentation as well as extra reporting to meet regulatory standards. The study also pointed out that there could be some serious penalties if regulatory requirements are not complied with(Trebbi *et al.* 2023).
Varying complexity of regulatory compliance also exists related to the industry and geographic location. Different industry requires different regulatory needs to be implemented to which the needs need to keep changing over time. Regulations keep changing, organizations need to keep track of those changes as well as keep their maintenance practices updated. The importance of adhering with continuous monitoring of regulatory changes and integrating compliance with maintenance planning processes was emphasised by a report published in published in 2023 by the Journal of Regulatory Compliance (Trebbi *et al.* 2023).

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