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Automated Quality Management in Life Sciences Supply Chain: Combining SAP QM with GenAI for Regulatory Compliance

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Abstract- The project focuses on the possibility of applying Generative AI (GenAI) to SAP Quality Management (QM) advancing quality management in the life sciences supply chain. SAP QM is focused on guaranteeing compliance with the company's regulated activities as well as its performance, while the use of GenAI incorporates the benefits of analytical as well as automotive approach. The framework tackles problems of conventional models, optimizes the decision process, and guarantees adaptability. Johnson & Johnson, AstraZeneca, and Sanofi are emerged as reference cases that can illustrate their practical use. Issues at stake include costs of setting up implementation processes, security of data processing, and information resistance to change. Based on that, the recommendations concern training activities, further integration, and constant improvement. The issues with the application of conventional quality management are described in this research by using life sciences as the field of study that may benefit from automation and prognosis analytics. The integration of SAP QM and GenAI demonstrates better compliance, work efficiency and even predictive traits

Index Terms: Quality Management Systems, Automated Quality Management, SAP Quality Management, Life Sciences Supply Chain, Generative AI, Intelligent Automation, SAP, GenAI, S/4HANA

I. INTRODUCTION

A. Background to the Study

The life sciences supply chain is characterized by strict quality management in its activity because these are used to treat various diseases and the products have to meet international regulations on quality and safety [10]. Classic methodologies of quality management face such problems as inefficiency, absence of scalability, and too long decision-making. The combination of SAP *Quality Management (QM)* with *Generative AI (GenAI)* is a revolutionary tool in the quality management approach because it will help to minimize time and manpower, increase data analysis, and predict results [10]. This synergy allows one to perform predictive quality management, timely have effective deviance recognition, as well as conform to constant changes.

B. Overview

Automated quality management (AQM) in the life science supply chain translates to the effective implementation of SAP QM and Generative AI (GenAI) for improving regulatory compliance and supply chain performance [11]. SAP QM delivers functional frameworks for quality management, and GenAI overloads the approaches with predictive analysis, outlier identification, and automation. Together, they control quality, make certain that organizations meet regulatory demands in real-time, and minimize operational risks. Current industry issues are acknowledged at this stage as the approach is advanced, enabling innovation, scale, and better decisions in a competitive and highly regulated environment [11].

C. Problem Statement

The Automated Quality Management in Life Sciences Supply Chain SAP QM with GenAI for Regulatory Compliance has offered a solution to the problem of weaknesses and slow performance in conventional **quality management systems (QMS)**. These issues can also delay or stop real-time decision-making and compliance within a highly regulated industry [12]. This study calls for solution-specific approaches that are efficient in terms of the possible cutting down on both time and human effort, and reduction in errors to enhance conformity to established regulations.

D. Objectives

The primary goals of this study are: 1. To identify the inefficiency in traditional quality management systems. 2. To analyse the role of SAP QM in ensuring product quality and assurance. 3. To evaluate GenAI's potential for predictive analysis and automation. 4. To propose an integrated framework for streamlined compliant and scalable operations. These objectives aim to explore how integrating SAP QM with generative AI can optimize the quality management process

in the life science supply chain while ensuring regulatory compliance.

E. Scope and Significance

This study examines the **scope** of combining SAP QM with Generative AI (GenAI) in the lives science supply chain. This is oriented to improve the quality management procedures, refine the methods of predictive analysis, and use the features of monitoring their work for automation of the problematic areas and noncompliance [13]. Relative to this scope, the study includes outlining the deficiencies of the conventional system and presenting an enhanced and interconnected process flow system. **Significance** shows implications for enhancing organizational effectiveness, minimizing compliance damages, and maintaining product quality in the stringent biopharmaceutical market [13]. The integration of both SAP QM and GenAI enables organizations to drive scalable value, encourage innovation, and act proactively to meet quality assurance goals, thus creating valuable, sustainable competitive advantages in addition to satisfying regulatory requirements.

II. LITERATURE REVIEW

A. Gaps in traditional quality management system

Organisation	Product/service provider	B2B/B2C	Public/Private	Number of employees (rounded to the nearest thousand)
Manufacturing A	Product, product-related services	B2B	Private	100,000
Life Science Firm	Product	B2B	Private	60,000
Government Body	Service	B2C	Public	15,000
Manufacturing B	Product, product-related services	B2C	Private	40,000

Figure 1: Gaps of employees in the organization

[1]

Traditional quality management systems in the life science supply chain often struggle with manual processes and limited real-time capabilities. Most of these systems are problem-solving oriented; they deal with a problem after it has occurred. The problem of data fragmentation and reporting inconsistency provides poor support for decision-making, while the lack of automation results in time delay as well as high operational costs [1]. Furthermore, it

also becomes difficult to meet many high and continuously rising standards set by these regulations raising the risk of non-compliance and related penalties. These gaps call for creative approaches to improving the efficiency, effectiveness, and more importantly, anticipative control of quality assurance activities.

B. The role of SAP QM in driving quality and assurance

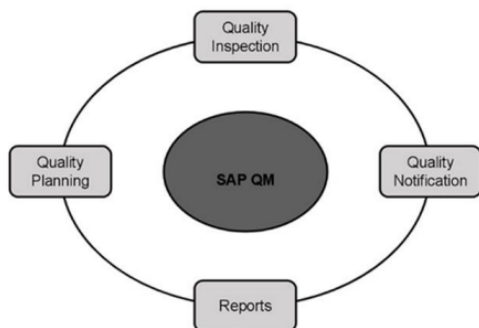


Figure 2: Roles of SAP QM

[2]

SAP Quality Management (QM) is a powerful system aimed at controlling the quality of the products and their compliance with the regulations in an extended supply chain. It simplifies the management of quality as it combines different quality processes in procurement, production, and delivery [2]. This also provides capabilities of real-time monitoring, defect tracking, and comprehensive reports, which make it overcome several issues of the traditional system of SAP QM. It also helps to enforce compliance with global regulatory requirements by automating tests, assessments, and documentation [2]. Applying SAP QM to every step of the supply chain brings not only improved efficiency of the procedures but also a reduction of the potential consequences of non-conformity and quality issues thus, SAP QM becomes the foundation of modern quality control.

C. Harnessing GenAI for predictive analytics and intelligent automation

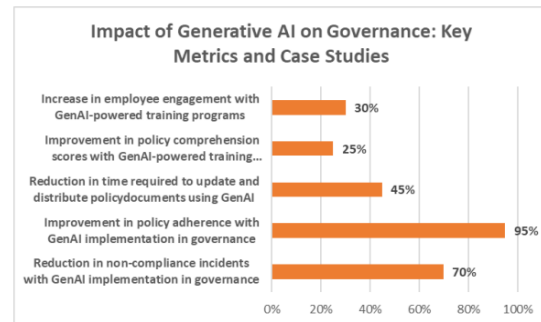


Figure 3: GenAI impact

[3]

GenAI provides disruptive potentials for enhancing accurate prediction and self-optimizing smart automation solutions for quality assurance and improvement. Due to the use of machine learning and extensive data sets, GenAI empowers the identification of quality problems and risks a priori [3]. Forecast analysis determines deviations and anomalies before they go out of hand and form a basis for preemptive action. Furthermore, on using GenAI 8%, boring activities like data manipulation, exception identification, and reporting are handled by the GenAI framework to a minimal level of human interference, which implies a decrease in human errors [3]. This brings workflow efficiency, quickens all process decisions, and improves operational aspects. Many sciences require following strict regulations therefore in the life science supply chain, GenAI facilitates compliance with quality guidelines and relevant regulations as addressed in Figure 3. This is then instrumental in analyzing the swirls, offering pointers for action, and realigning action based on emerging dynamics, giving modern quality management systems the fills that are wanted [3].

D. Proposing an integrated framework for scalable and compliant operations

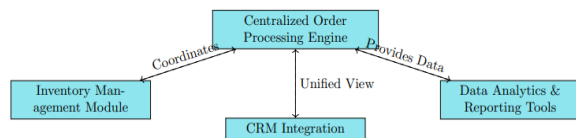


Figure 4: Integrated SAP framework
[4]

Integrating SAP Quality Management (QM) with GenAI results in robust, compliant, and scalable operational structures in the life sciences supply chain. The framework connects SAP QM for quality control, compliance features with GenAI for the best analytical and automation tools. Hence this integration fosters efficient flow of information, visibility, and even quality control within every process in the supply chain [4]. Thus, it reduces procedural unnecessary tasks, controls risks, and complies with constant changes in the regulations integrated into the framework. The ever-growing concept makes it possible for organizations to expand since capability meets growth to combat increasing business operations pressures while maintaining quality [4]. The promoted framework enables ongoing quality management and monitoring, smart decision-making, and adaptability in the current organization. This integration turns the former static quality management systems into future-proof solutions ideal for the challenges of the life sciences market.

III. METHODOLOGY

A. Research Design

The research employs an explanatory research design and secondary research method to examine the implementation of SAP QM with Generative AI (GenAI) in the life science supply chain. The proposed framework gathers information from industry reports, academic journals, government regulations, and previous studies to investigate existing research gaps, SAP QM

functionality, GenAI solutions, and an integrated solution. This manner of presentation allows for an understanding of how these technologies tackle these shortcomings, strengthen the compliance agenda, and develop sustainable, anticipative quality management systems.

B. Data Collection

This research utilizes qualitative data that are collected from secondary sources like books, journals, company records, government publications, internet materials, newspapers, magazines, journals, and online databases [14]. Gathering quantitative data for this study is necessary to interface SAP QM with sensors and ERP systems, which relay current figures such as defect rates, batch quality, as well as, compliance deviation those are also collected from secondary sources. This is accomplished with GenAI to exploit trends, highlight outliers, and synthesize predictive analytics to meet robust supply chain quality and consistent performance in the most compliant way.

C. Case Studies/Examples

Case study 1: Proactive quality control for Jhonson and Johnson

Johnson & Johnson has set up AI centres of excellence to enhance the firm's AI healthcare concepts on scalability and effectiveness [6]. The specific information of the application of **Google Bard** in the **SAP S/4HANA QM** system is not openly disclosed [8]. However, SAP's focus on AI solutions is a future direction for deepening quality management [6].

Case study 2: Intelligent automation at AstraZeneca

AstraZeneca the narrative extends well beyond that company and the confines of the pharmaceutical industry [5]. Though there is no direct indication of how **ECC 6.0** contains components for integration with **IBM Watson** for **SAP QM**, the application of AI seems to have the potential to support the automation of inspection and to maintain the

IV. RESULTS

A. Data Presentation

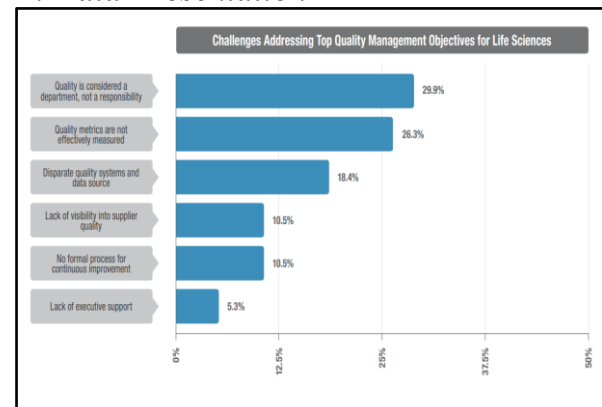


Figure 5: Quality Management challenges in traditional life science organisations
[18]

The graph gives an understanding of areas that life sciences organisations struggle with when it fulfilling key quality management directives. The statement “*Quality is considered a department, not a responsibility*” is confirmed by 29.9% of respondents. This is an indication that there is no sense of common responsibility and ownership for quality within an organisation. Other important issues are identified as; measuring quality indicators properly (26.3%), quality management systems and data sources dissimilar (18.4%), having no visibility into suppliers’ quality (10.5%), and no regular quality improvement program (10.5%). This highlights the need to transform towards automated quality management.

corporate policy of adhering to international regulations among the organizations such as AstraZeneca [5].

Case study 3: Scalable framework at Sanofi **Sanofi** in the adoption of AI technologies To increase the overall operations efficiency and effective compliance with regulatory policies [7]. However, there is no evidence of specific applications that involve the integration of **OpenAI Codex** and **SAP Cloud QM**, however, the company’s direction aims at providing solutions that include quality management assurance aimed at augmenting scalability and integrating real-time monitoring and predictive maintenance solutions [7].

D. Evaluation Metrics

In the case of the evaluation metrics of SAP QM and GenAI, the general evaluation criteria refer to potential gains in efficiency and other benefits in the form of compliance levels and defects found by the system [9]. Where output time and involvement of human input are counted as lost, then efficiency is the value obtained. Reduced compliance rates measure the extent of conformity to set standards. Defect detection accuracy defines how efficiently the system detects the problems associated with quality [9]. Further, the impact of the cost-reducing drivers such as automation and scalability to accommodate higher operation requirements also measures the framework’s success in improving quality management activities.

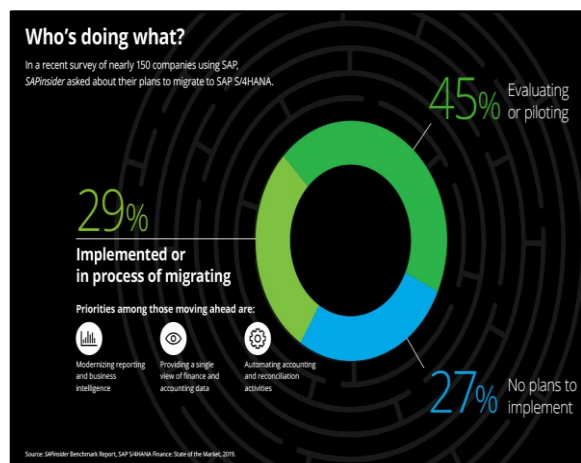


Figure 6: Progressive implementation rate of SAP in Quality Management
[19]

According to the above graph, 29% of companies using SAP have either adopted SAP S/4HANA fully or are in the process of doing so, 45% have considered it or currently testing, and 27% have no intention of implementing the system. This means that SAP S/4HANA is slowly being adopted by companies but there is still much room for improvement.

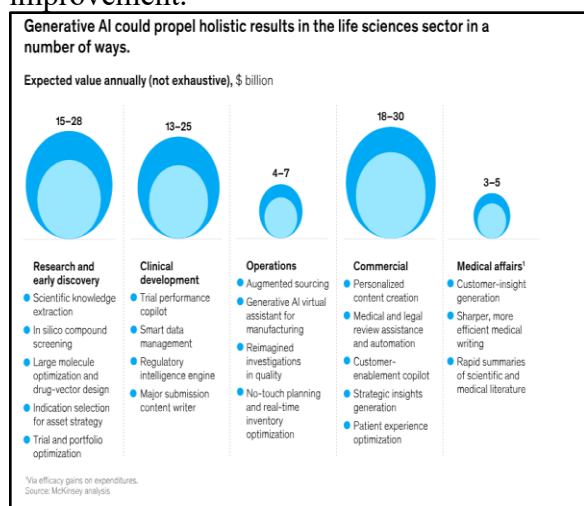


Figure 7: Gen AI in predictive analysis of Life Science sectors
[20]

The graph shows how GenAI could generate monetary value across the functions in the life sciences sectors. This showed that GenAI could have the prospect of delivering substantial value to the entire

biopharmaceutical value network as an R&D and early discovery enabler (\$15-28 billion), clinical developer (\$13-25 billion), and operations optimiser (\$18-30 billion). Such numbers show how GenAI can disrupt such sectors as pharma, clinical research, and production. This is considered with the present research goals of assessing the applicability of GenAI for analytical predictability and automated processes in the life scientific supply chain.

B. Findings

The presented data effectively aligns with the study's objectives. Figure 5 highlights the challenges of traditional approaches to quality management, thus enforcing the first study objective. Figure 6 exhibits the pattern of SAP QM uptake of organisations; it fulfils the second objective, showing how progressively it adapts to quality management purposes. Figure 7 confirms the usefulness of GenAI in prediction and automation, thereby achieving the third objective and providing strong support for the recommendation of an integrated model.

C. Case Study Outcomes

Case Study	Key Outcomes	Relevance to the Present Study
Case study 1: Proactive quality control for Jhonson and Johnson	Johnson & Johnson has implemented proactive compliance and risk management programs, strengthened their quality measures and resulted in a downward	Demonstrates the effectiveness of proactive quality management systems in ensuring product quality and safety, aligning with the study's objective to identify

	trend in product recalls [6].	inefficiencies in traditional quality management systems.
Case study 2: Intelligent automation at AstraZeneca	AstraZeneca developed an AI-driven drug discovery platform using AWS, increasing quality and reducing the time required to identify potential drug candidates. “Robotic Process Automation” for automating basic quality control increased productivity by 40% and eliminated human errors [5].	Highlights the role of intelligent automation in enhancing operational efficiency and product quality, pertinent to analysing SAP QM's role in quality assurance and evaluating GenAI's potential for predictive analysis and automation.
Case study 3: Scalable framework at Sanofi	Sanofi adopted a hybrid cloud strategy with Azure, achieving increased	Illustrates the implementation of scalable frameworks to support digital transformation, relevant to proposing an

	speed, agility, and reliability necessary for innovation [7].	integrated framework for streamlined, compliant, and scalable operations.
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Table 1: Case Study Outcomes

(Source: Self-developed)

These case examples show the use of automation, analytics, and best practices on how quality management could be improved. The outcomes of Johnson&Johnson, AstraZeneca, and Sanofi elaborate on how automation and SAP QM integration influence product quality management.

D. Comparative Analysis

Authors	Focus	Key Findings	Gaps
[1]	Digitalisation of Quality Management	Identifies challenges and roles of QM practitioners in digitalisation initiatives. Explores the impact of digitalisation on quality processes and value creation. Six key challenges and corresponding roles for	Focuses mainly on the QM practitioner's role, missing the broader organisational implementation of digital QM. Study limited to Swedish organisations; lacks a broader, global perspective.

		QM were identified .	
[2]	SAP QM Implementation in Manufacturing	SAP QM optimised incoming quality control processes , improving traceability, reducing inspection times, and increasing data accuracy. Enhanced quality control and production control through automated inspections, rigorous procedures, and nonconformity management.	Focused primarily on a single company's implementation, limiting its generalisation to other industries or companies . Does not discuss integration with other digital technologies like GenAI, which is central to the study.

[3]	GenAI in Governance, Risk Management, and Compliance (GRC)	GenAI enhances GRC processes by automating policy enforcement, predictive risk management, and real-time tracking of compliance. Provides real-life examples and demonstrates GenAI's potential to improve efficiency and security.	Limited to cybersecurity and GRC applications, missing the broader scope of GenAI's potential in quality management and supply chain.
[4]	SAP Integrated DOM Framework for Global Supply Chains	Proposes a framework for integrating SAP-based DOM systems to improve supply chain efficiency.	Does not directly focus on quality management systems, missing a key aspect of this study. Lacks discussion on automatio

		Highlight s benefits like reduced lead times, better visibility, and enhanced order accuracy. Identifies challenge s in integratio n and data managem ent.	n and advanced AI, which are central to the present research.
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Table 2: Comparative Analysis

(Source: Self-developed)

The table elaborates digitalisation trends, SAP QM, and GenAI can contribute positively to the advanced quality management and supply chain. Some of the findings include; increased traceability, use of automated inspections, use of a predictive risk model and increased real-time compliance. All these findings explain the importance of using technology in enhancing the efficiency of various companies and industries.

V. DISCUSSION

A. Interpretation of Results

The entire system was fit for the objectives revealed and provided some valuable insights for the life sciences quality management system. Thus, the data interpretation reveals several ideas reflecting the range of outcomes that may be of interest to enhance the quality management of life sciences. This also uncovers areas of high inefficiencies no one takes ownership of quality (29.9%), and problems with measurement of the quality indicators (26.3%), suggesting a need for a

more coherent and systematic pattern [18]. The results presented provide some insight into the issues that the life sciences industry faces in terms of quality management these are lack of ownership of quality, quality indicators, and visibility of the suppliers. SAP S/4HANA adoption is incremental and there is still much potential for increasing rates of adoption. The fields in which GenAI can demonstrate significant value are research and development, clinical development, and operations in the biopharmaceutical and life science industry.

B. Practical Implications

Integration of SAP QM with GenAI in life science offers *transformative implications*. This allows for monitoring of quality in real-time, risk profiling, as well as integration of processes, all done to meet the standards and minimize the occurrence of mistakes [15]. SAP QM only manages the data and integrates with the systems, and GenAI leads to better decision-making on the large dataset that is available [15]. This combination enhances the supplier's quality visibility, promotes the growth of the continuous improvement process, and speeds up the issue-solving process. The approach in turn enables scalability, reduces compliance and legal exposure, and enhances supply chain agility.

C. Challenges and Limitations

The research study faces challenges including a lack of secondary data from SAP QM and GenAI implementation from the life sciences firms due to the proprietary nature of the data. Insufficient available documentation of the particular cases of implementing the GenAI with the actual use of SAP S/4HANA hurts the depth of the study. The risks the analysis identified also include data security and compliance to regulations in the management of sensitive supply chain information [17]. Moreover, reluctance to adopt AI-driven frameworks

and high implementation costs are the main drawbacks to the study.

D. Recommendations

Integration of SAP QM with GenAI in life sciences, IT, and regulatory departments should be in closer proximity when implementing the software. Work out a lifecycle implementation to address resistance and high costs of implementation [16]. Most of the AI projects fail due to a lack of employee training to enhance AI adoption and increase the efficiency of the system. One should conduct Pilots before applying GenAI at a large scale within the organization. Working with hardware and software vendors to observe new advancements and an ability to integrate SAP S/4HANA for supply chain efficiency [16].

VI. CONCLUSION AND FUTURE WORK

This study has shown primary issues with conventional quality management models, including poor accountability and fluctuations in quality metrics that can be solved by automation and predictive analysis. Based on the Johnson & Johnson, AstraZeneca, and Sanofi experiences, it has learned about the importance of quality control as an extensive strategic activity, the use of intelligent automation, and approaches enabling global compliance with the desired safety standards. Future investigation should be done to explore areas where GenAI can be used in life science other than cybersecurity to enhance supply chain efficiency.

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