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Quality Management Software Design for AS9100 Compliance in Defense and Aerospace Advanced Ceramic Manufacturing

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Abstract

The digital transformation, empowered by tools like Manufacturing Execution Systems (MES) and Enterprise Resource Planning (ERP) systems, significantly enhances operational efficiencies within manufacturing. However, the intricate nature of quality management in the defense and aerospace industries necessitates tailored solutions. Varied and critical products, diverse customer specifications, and adherence to stringent standards like AS9100 RevD underscore the necessity for specialized approaches. This study focuses on crafting specialized software, acting as a Quality Control System Management framework, specifically tailored for a company specializing in advanced ceramics within the defense industry. This software operates as an integrated system that derives data from MES and ERP systems to generate work orders and subsequently transmits the results back to these databases. Compliance with AS9100 standards demands meticulous risk management and traceability, necessitating comprehensive data storage. The developed software ensures an encompassing management system, overseeing critical stages such as input quality control, supplier assessments, device calibration, and maintenance tracking. It further supervises final product oversight, semi-finished product quality control, risk management, personnel competency verification, and adaptive testing protocols. This system functions not only to enhance operational efficiency but also to ensure compliance with the stringent demands inherent in the defense and aerospace industries.

Keywords
Quality Management, EQMS, AS9100, Defense Industry, Advanced Ceramics

1. Introduction
The advent of digitization and Industry 4.0 has wrought transformative changes in the realm of corporate quality management methodologies. The conceptual emergence of Quality 4.0 has precipitated a paradigmatic shift, wherein conventional approaches are yielding ground to the integration of Enterprise Quality Management Software (EQMS). Particularly discernible is the adoption of EQMS in sectors characterized by rigorous quality management systems, most notably in industries such as aerospace and defense, wherein compliance with the AS9100 standard is paramount.

AS9100, as an augmentation of the ISO 9001 framework, introduces supplementary requirements encompassing configuration management, risk management, product safety, and counterfeit parts prevention. The inherent intricacy of AS9100 mandates meticulous documentation and process management, emphasizing a nuanced focus on risk management, continuous risk assessment in dynamic sectors, and the critical significance of supply chain

management. The standard underscores the imperative of careful supplier selection, evaluation, and collaboration, accentuating a robust emphasis on product and service safety, particularly in sectors where reliability stands as a linchpin. The meticulous documentation and continuous monitoring inherent in AS9100 underscore the multifaceted challenges it presents for organizations, encapsulating an industry-specific, process-oriented, risk-focused, and supply chain-centric nature.

Despite the burgeoning adoption of EQMS among AS9100-certified firms, the limitations of off-the-shelf EQMS products in achieving seamless compatibility with AS9100 standards inhibit the attainment of optimal performance. Consequently, there is a discernible trend wherein organizations are progressively gravitating towards the development of bespoke software solutions. This departure from off-the-shelf EQMS products is motivated by the imperative for alignment with the idiosyncrasies of the organization's production processes, structural nuances, and overarching priorities.

This study centers its focus on the development of software tailored to the unique needs of a company specializing in advanced ceramics within the defense industry. Serving as an integrated system, this bespoke software synergistically interfaces with MES and ERP systems, generating work orders and subsequently funneling results back into these databases. With a concomitant commitment to compliance with AS9100 standards, the software intricately manages risk and traceability, demanding comprehensive data storage. Beyond mere compliance, the bespoke software orchestrates a comprehensive management system, overseeing critical stages inclusive of input quality control, supplier assessments, device calibration, and maintenance tracking. It further extends its supervisory purview to encompass final product oversight, semi-finished product quality control, risk management, personnel competency verification, and adaptive testing protocols. In essence, this bespoke system is engineered not only to augment operational efficiency but also to ensure unwavering adherence to the stringent exigencies inherent in the defense and aerospace industries.

2. Literature Review

With the impact of Industry 4.0, Quality Management Systems (QMS) underwent a significant evolution, transforming into Quality 4.0. Industry 4.0, bringing technological innovations such as digitization, automation, and data analytics, fundamentally changed production processes and business models. This transformation allowed QMS to evolve into a more intelligent, connected, and data-focused structure (Asif, 2020).

Quality 4.0, fully leveraging the technological capabilities offered by Industry 4.0, made quality management more effective. It refers to the digital transformation of quality management through the integration of traditional and Industry 4.0 technologies (Maganga et. al, 2023; Narahari et.al, 2023). At its core, Quality 4.0 involves the digitization of quality processes, leveraging data from various sources such as manufacturing, machine sensors, supplier management, and in-service data throughout a product's lifecycle. This digital continuum enables the derivation of new analytical insights and transparent dissemination of these insights across the organization (Liu et. al, 2023; Narahari et.al, 2023).

Quality 4.0 stands out with its focus on data-driven decision-making, continuous improvement, and transparency (Sisodia et.al, 2020). Unlike traditional quality management approaches, Quality 4.0 centers around using data systematically to manage content. Encompassing the entire value chain, from innovation to sustainment, and from the supply base to customers, its overarching goal is to enhance performance, make informed decisions, and achieve operational excellence (Wells, 2022).

In response to the challenges posed by conventional quality management systems, such as paper-based or standalone digital systems, Enterprise Quality Management Software (EQMS) has emerged as a pivotal solution. EQMS, as a critical component of Quality 4.0, empowers organizations to leverage digitalization and data-driven insights for improved quality management. Its evolution has been propelled by the critical need for heightened efficiency, compliance, and overall quality control within organizations (Bruun, 2023). Particularly prevalent in heavily regulated sectors, EQMS finds primary adoption among companies adhering to stringent standards like ISO 22000, AS9100, or ISO 9001(Greenwood, 2023). In the realm of Quality 4.0, EQMS offers distinct advantages. Serving as a foundational element in the digital continuum of quality data, EQMS transforms traditional document-centric approaches into dynamic, data-centric methods. This transition revolutionizes how organizations capture, manage, and leverage quality information, fostering a more explorative association between quality data and contextual details such as lots, parts, suppliers, and failure modes. Moreover, by capturing quality information as data, EQMS facilitates advanced analytics

and insights, empowering organizations to analyze performance variations across diverse contexts. This data-driven approach not only provides a deeper understanding of the factors influencing quality outcomes but also contributes significantly to informed decision-making throughout the entire product lifecycle (Liu et. al, 2023; Dan, 2018).

Embracing an EQMS constitutes a strategic imperative for organizations, ushering in a transformative era characterized by a myriad of profound advantages that transcend traditional quality management practices (Aravindan et.al, 2020 ; Qualityze, 2023; Greenwood, 2023; Bruun, 2023; Dan, 2018; Liu et. al, 2023). This paradigm shift isn't a mere checklist of improvements; rather, it reshapes the very fabric of organizational dynamics:

- Elevated Standardization and Compliance Efficiency: EQMS seamlessly integrates with industry standards such as AS9100, not just as a compliance tool but as a catalyst for standardizing processes and refining compliance management. This not only ensures consistent operations but also cultivates a proactive approach to meeting and exceeding regulatory requirements
- Efficiency Redefined in Compliance Endeavors: EQMS transcends the role of a tool; it emerges as an ally in the pursuit of operational excellence. Its automation prowess in handling compliance-related tasks revolutionizes the landscape, reducing errors, and optimizing operational efficiency. Compliance ceases to be a mandatory chore; it becomes a strategic advantage.
- Empowering Workforce Development and Continuous Enhancement: EQMS isn't confined to technical functionalities; it becomes a driver of organizational evolution. Beyond managing data, it actively supports ongoing training, skill development, and instills a culture of perpetual improvement. It's not just a system; it's a commitment to the growth and empowerment of the workforce.
- Ensuring Product Excellence, Every Time: At the core of EQMS lies an unwavering commitment to the consistent delivery of aerospace and defense products that not only meet but exceed customer requirements. The system provides a robust toolkit for monitoring and controlling quality throughout the entire product development and manufacturing lifecycle.
- Proactive Risk Intelligence and Mitigation: EQMS is not a passive repository; it evolves into a guardian against potential risks. By centralizing comprehensive risk-related information, EQMS enables organizations to foresee challenges and implement preventive measures. It transforms risk management from a reactive process to a proactive strategy, ultimately saving costs and fortifying resilience.
- Unlocking Centralized Visibility into Product Development: EQMS serves as a lighthouse, offering centralized visibility into intricate product development processes and the broader portfolio. This heightened visibility fosters collaboration, fuels informed decision-making, and propels efficient project management strategies.
- Simplified Document Dynamics: EQMS transcends the role of a mere document manager; it becomes an architect of streamlined processes. The system simplifies the entire lifecycle of document development, review, and approval. It ensures that the right information is available to the right stakeholders at the right time, thereby streamlining workflows.
- Swift Resolutions Through Accelerated Quality Investigations: EQMS isn’t confined to compliance obligations; it emerges as a catalyst, accelerating investigations through robust traceability features. Rapid identification of root causes leads to quicker resolutions, minimizing disruptions, and enhancing customer satisfaction.
- Facilitating Rigorous Process and Departmental Audits: EQMS orchestrates a harmonious audit symphony. By facilitating systematic and well-documented audits, it enhances organizational resilience, aligning audit processes with industry standards and minimizing vulnerabilities.
- Bolstering Relationships Through Transparency: EQMS transcends its role as a system; it becomes a testament to organizational transparency. By adhering to stringent quality standards, EQMS builds trust among stakeholders, suppliers, and government entities. It's not just about compliance; it's about fostering enduring relationships.

In essence, EQMS is not a mere technological implementation; it’s a strategic investment in organizational excellence. It becomes a navigator steering organizations towards a culture of quality, responsibility, and safety. Beyond the checkboxes of compliance, EQMS becomes a dynamic force reshaping how organizations perceive and achieve quality in the modern landscape. Despite the capabilities of EQMS, it is essential to recognize that it alone is insufficient to achieve Quality 4.0. For comprehensive quality management in the Industry 4.0 era, seamless integration with MES and ERP systems is imperative (Qualityze, 2022).

As highlighted earlier, EQMS is particularly favored in heavily regulated sectors, with primary adoption occurring among companies that adhere to rigorous standards. A prominent example of such standards is AS9100.

AS9100 stands out as a quality management system developed specifically for organizations in the aerospace, space, and defense sectors, first published by the Society for Automotive Engineers (SAE) in 1999. Significant collaboration involving major aviation companies, the American Aerospace Quality Group (AAQG), ANSI-ASQ National Accreditation Board (ANAB), and Independent Association of Accredited Registrars (IAAR) contributed to the creation of this standard. Its primary objective is to provide guidance on quality management and process control for companies operating in these critical sectors (Tomic et.al, 2012; IAQG, 2020; Oschman, 2019; Barker, 2002; Foster, 2015).

AS9100 builds upon the foundation of the ISO 9001 format, incorporating additional requirements such as configuration management, risk management, product safety, and counterfeit parts prevention (Tomic et.al, 2012; Oschman, 2019; Sprycha et.al, 2013; Göv, 2018) While the standard comprises a total of 10 clauses, the essential principles are laid out in clauses 4-10 as shown in Figure 1.

Clause 4, titled "Organization's Context," highlights the foundational elements for establishing a robust Quality Management System (QMS). Unlike ISO-9001, AS9100 introduces stricter traceability requirements, mandating documentation procedures for capturing and storing necessary records, particularly critical in safety-critical applications like aviation (Sprycha et.al, 2013; Hammer, 2020; IAQG, 2019).

Clause 5, titled "Leadership," emphasizes the crucial role of leadership in QMS success. In addition to ISO-9001's acknowledgment of top management commitment to quality, AS9100 requires certified organizations to appoint a specific management representative, focusing on critical QM issues (Hammer, 2020; IAQG, 2019; IAQG, 2020). 5.1 introduces a customer-centric perspective, emphasizing customer focus.

Clause 6, "Planning," emphasizes the vital role of planning in a robust QMS, with a focus on risk management and quality objectives. It emphasizes systematic planning involving the organizational hierarchy, especially for changes (Hammer, 2020; IAQG, 2020). Subclause 6.1, "Action to address risks and opportunities," advises comprehensive risk analysis, highlighting the dynamic nature of risk management with periodic updates using techniques like PESTEL and SWOT analysis (Hammer, 2020; Cressionnie, 2023). Subclause 6.2, "Quality objectives and planning to achieve them," underscores the importance of establishing measurable, quantitative, and time-based quality objectives, with a unique emphasis on involving the entire organization in transforming them into organizational goals. Subclause 6.3, "Planning changes," stresses a systematic approach for implementing changes in the QMS. Instead of ad hoc modifications, organizations are encouraged to plan changes by evaluating their purpose, consequences, impact on QMS integrity, required resources, and the allocation of responsibilities and authorities. This ensures controlled execution, considering relevant stakeholders and contributing to effective and sustainable organizational management (Cressionnie, 2023).

Clause 7 of the standard focuses on acquiring necessary tools, implementing monitoring procedures, and ensuring a skilled workforce to support the Quality Management System (QMS). It stresses employee commitment to best practices, emphasizing their understanding of roles and the impact of activities on product quality. The standard advocates for ethics training and digital data protection. Subclauses within 7.1, "Resources," highlight the importance of assigning and managing resources essential for QMS, including human resources, infrastructure, environmental considerations, monitoring resources, and organizational knowledge. The standard emphasizes a systematic approach to ensure individuals are trained and competent (Hammer, 2020; BSI, 2016). Subclauses 7.1.2 and 7.1.5 detail the significance of appropriately trained personnel and calibration requirements for measurement devices. Clause 7.1.6 addresses corporate knowledge management, emphasizing the need to understand, plan, and sustain information required for product and service support. Moving to 7.2, "Competence," the standard underscores the identification of necessary competence for effective QMS processes, considering education, training, and experience. Clause 7.3, "Awareness," emphasizes employees' understanding of critical elements like the quality policy, objectives, and the impact of tasks on the QMS, including personal performance and its implications. Subsequent subclauses, 7.4 through 7.5, highlight communication processes and management of documented information within the QMS. Communication plans ensure effective relay of information, and managing documented information involves proper

identification, protection, storage, distribution, retrieval, and control to prevent unintended use of obsolete information (IAQG, 2019; IAQG, 2020; Harun et.al, 2010).

Clause 8, central to ISO-9001, guides operational processes, product requirements, and product conformance (Hammer, 2020; IAQG, 2019; IAQG, 2020; Cressionnie, 2023; Weheba et.al, 2006). AS9100 expands focus on operational planning for risk management and extends product safety considerations throughout the entire product lifecycle. Operational planning and control (8.1) include identifying requirements, defining processes, determining acceptance criteria, addressing operational risk management, configuration management, product safety, and preventing counterfeit parts. In 8.2, effective communication with customers is emphasized, requiring processes for collecting and managing customer information. 8.3 stresses alignment between design outputs and inputs, rigorous review processes, and well-planned testing procedures; while 8.4 covers purchasing, with criteria for supplier selection and evaluation. Clause 8.5 underscores meticulous control, traceability, and conformity throughout production. It requires operating under controlled conditions, comprehensive documentation, well-defined acceptance criteria, and identification of outputs. Specific requirements for identification and traceability include suitable methods, maintaining configuration details, and complying with legal and customer traceability specifics. Clause 8.6 mandates not releasing products and services until meeting all requirements, with documented evidence. Clause 8.7 addresses identifying, controlling, and preventing nonconforming outputs, requiring disposition processes, verification of conformity after correction, and detailed documentation describing nonconformity and actions taken.

Clause 9 necessitates establishing criteria for product and performance assessment, implementing monitoring processes, incorporating Key Performance Indicators (KPIs), and conducting customer surveys (Hammer, 2020). In 9.1, monitoring, measurement, analysis, and evaluation focus on QMS effectiveness and adherence to customer requirements. Internal audits 9.2 and management reviews 9.3 comprehensively evaluate various factors for holistic assessment and improvement opportunities.

Clause 10 is crucial for leveraging quality data to enhance products and services continuously (Hammer, 2020; Stadnicka, 2015). It emphasizes continual improvement, requiring organizations to identify opportunities and plan corresponding actions. Nonconformity and corrective action mandate promptly correcting nonconformities, determining corrective actions, and communicating them to external providers if necessary. Continual improvement is fundamental, ensuring ongoing adaptation and evolution of the QMS for excellence and customer satisfaction, with certification seen as a continuous process, including regular internal audits and activities aligning with the commitment to quality.

Due to the specific requirements and elevated standards of AS9100, it is emphasized that EQMS developed for general quality management may not be suitable. The unique demands of AS9100 necessitate the use of a specialized EQMS. The high security and quality standards applicable in the aviation and defense sectors can render general EQMS inadequate. The industry-specific complexity of AS9100 requires detailed documentation and management of processes. Its focus on risk management requires organizations to continuously assess and mitigate risks in dynamic sectors. Additionally, AS9100 places significant importance on supply chain management, necessitating careful supplier selection, evaluation, and collaboration. The standard's emphasis on product and service safety is crucial in sectors where reliability is paramount. The detailed documentation and continuous monitoring of processes underscore the additional challenges AS9100 presents for organizations. In other words, the industry-specific, process-oriented, risk-focused, and supply chain-centric nature of AS9100 makes it imperative for organizations in these sectors to use a specialized EQMS, as general EQMS may prove insufficient. If the EQMS solution does not align with organizational goals, budget, structure, or the current stage of growth, companies risk squandering financial resources, creating confusion among their workforce, and ending up with a complex tool that loses its practicality and effectiveness [9]. Therefore, it is essential to emphasize that even for AS9100 compliance, a specialized EQMS is imperative. However, recognizing that generic out-of-the-box solutions may fall short of meeting the intricate and unique requirements of companies operating in aviation and defense, it becomes evident that a tailor-made software solution should be developed to ensure precise alignment with the distinct needs and objectives of each organization.

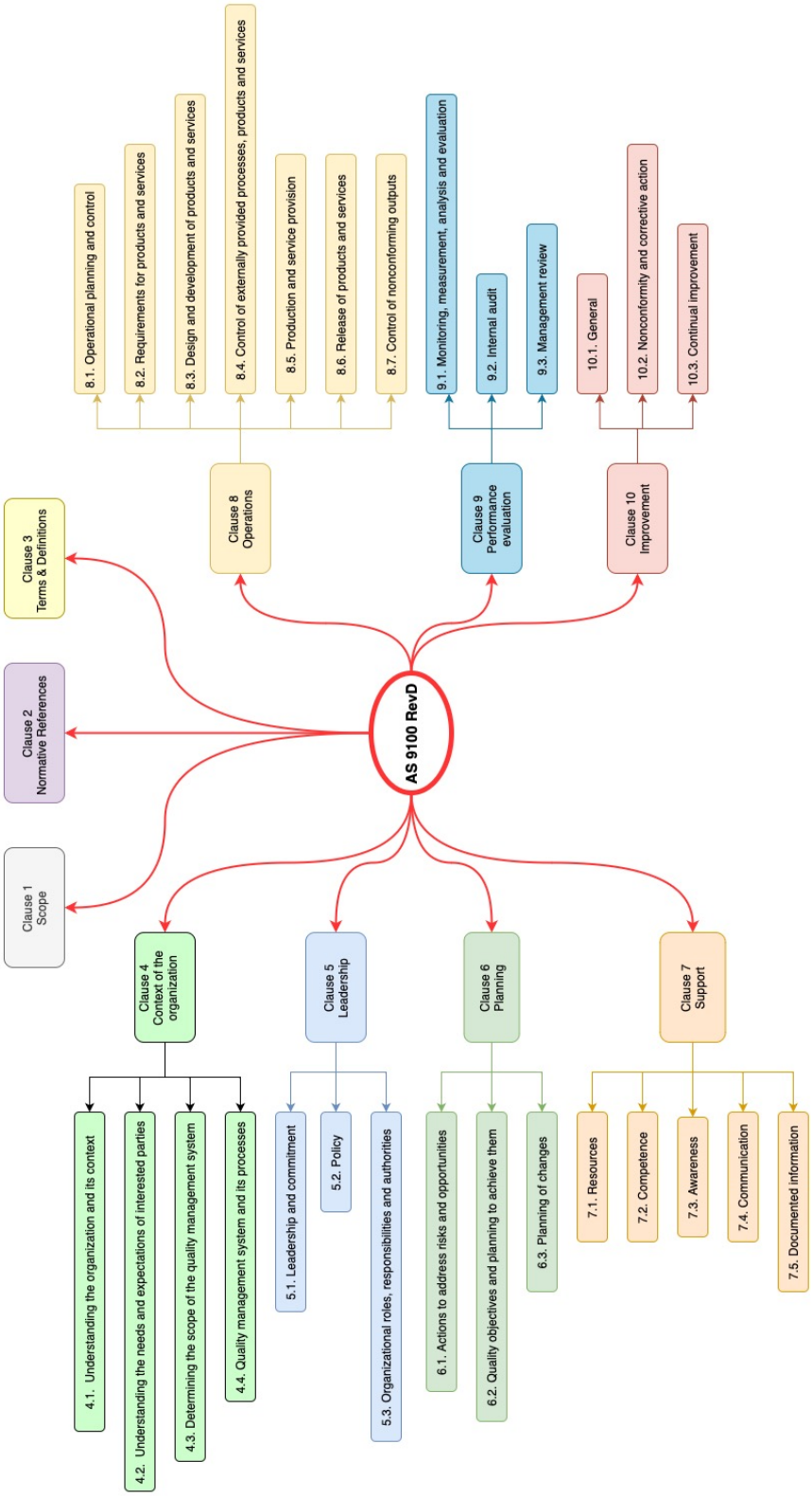

Figure 1. Clauses of AS9100

3. Tailor Made EQMS

The company provides services in the field of composite ceramic products for the defense and aerospace sectors. Classified under the SME category, the company has approximately 200 employees. Currently, the company utilizes ERP and MES systems and holds certifications for ISO 9001, ISO 18001, ISO 14001, and AS 9100 quality management systems.

Due to the inadequacy of the quality management module in the ERP system to fully meet AS9100 requirements, the company has developed a customized EQMS (Enterprise Quality Management System). The developed EQMS modules include Document Management, Maintenance Management, Training Management, Risk Management, Personnel Competency Management, Calibration Management, Audit Management, LIMS (Laboratory Information Management System), CAPA (Corrective Actions and Preventive Actions) Management, Stock Management, Ballistic Test Management, and Supplier Quality Management as shown in Figure 2. All modules are seamlessly integrated with the ERP and MES systems.

Figure 2. DEDA eQMS

In the scope of this study, the distinctive features of the software will be emphasized, showcasing its tailored approach to meeting AS9100 standards and the comprehensive range of integrated modules, ensuring effective management across various aspects of the company's operations.

- ***Calibration Management:*** This module addresses the crucial task of managing the calibration of measuring instruments. The calibration period is determined when defining measurement instruments, considering both temporal factors and frequency of utilization. Users are notified about the remaining time until the device's

calibration is due or the maximum duration for which it can be used. To maintain measurement accuracy, devices requiring calibration within the next 15 days or those that, considering daily usage, should be calibrated within this timeframe, are restricted from usage.

Information related to devices approaching their calibration deadline is conveyed to relevant personnel through the user interface as work orders. The work order interface provides comprehensive details about devices with imminent calibration dates, along with the current status of devices for which calibration orders have been initiated.

- ***The Laboratory Information Management System*** LIMS is specifically designed to efficiently manage offline quality control processes in the production workflow. This system encompasses critical processes such as the execution of quality control tests and the preparation and management of samples. For semi-finished goods requiring offline quality control in the ongoing production process, a quality control work order is pre-opened and kept in a passive state before the production work order is initiated; subsequently, it is activated. During the quality control test, four crucial criteria are meticulously considered to ensure the competence of the personnel conducting the test, the absence of calibration requirements for the designated device, the accuracy of the device selected for the test, and the readiness of the sample for this device.

  The quality control work order provides flexibility in using multiple testing methods and devices, driven by the need to measure and control specific features of the semi-finished goods. This approach allows for the use of another device to measure the same parameter in case the designated device is unavailable or malfunctions. Furthermore, the developed software allows for the flexible repetition of quality control tests. Laboratory personnel may sometimes wish to repeat a test more than the predefined number of times.

  Additionally, while the same sample can be used for all repetitions in some tests, others may require the preparation of a new sample for each repetition. The software defines the sample usage feature of tests and initiates a new sample preparation work order when necessary for test repetitions.

  Another critical feature of the developed software is its ability to instantly inform the user about test results. For instance, if multiple parameters are being measured during a test, and one of these parameters falls outside the desired range, the user is promptly notified of the parameter in question. In cases of multiple repetitions of the test, the non-compliance notification for a parameter is made considering both that specific test and the average of all tests (calculated using a t-test). For example, a notification might state, "Parameter A is not within the desired range for this test; however, when considering repeated tests, the parameter average is within the acceptable range."
  Additionally, complying with AS9100 standards requiring the retention of test reports, device report results are stored in a data repository in zip format, with nomenclature consistent with the work order.

- ***Supplier Quality Management*** Supplier evaluation is a critical aspect emphasized by AS9100 standards. According to AS9100, suppliers should be continuously assessed to minimize risks. Prior to engaging with a supplier, assurance must be obtained that the supplier can consistently uphold the existing quality of the company. Subsequently, continuous observation is required after the collaboration begins to ensure the ongoing quality of the supplier. Therefore, material and service procurement is only permitted from approved suppliers. With the developed software, when a purchase order is created through ERP, an entry quality control work order is initiated and kept passive through EQMS for the quality control department. After materials enter the warehouse and pass warehouse entry control (packaging, dimensional checks, etc.), the entry quality control work order is activated. Upon completion of the work order, an EQMS work order is opened for relevant personnel in the purchasing department to assess the management and supply processes of the supplier related to the current order. This process is referred to as post-order supplier assessment. Additionally, periodic supplier assessment work orders are opened at specified intervals based on the material and service category provided by the supplier, and the purchasing department is directed to the relevant personnel. Various methodologies (on-site inspection, surveys, AHP, ANP) are employed for supplier evaluations. If the post-order supplier evaluation score decreases, a warning is issued to the relevant personnel, and the supplier's evaluation result graph is presented. This proactive approach aims to minimize risks originating from suppliers.

- ***The Ballistic Test Management Module*** is a bespoke solution designed to efficiently oversee the intricate processes associated with ballistic testing of composite ceramic armors. Tailored to the company's specific requirements, this module is a key tool for orchestrating and scrutinizing ballistic testing procedures. The broader context emphasizes the pivotal role of ballistic standards, serving as benchmarks for assessing the performance attributes of both ammunition and armor materials. These standards, exemplified by STANAG (Standardization Agreement) within NATO countries, ensure seamless interoperability and optimal functioning of military equipment and materials. The module's purposeful design facilitates meticulous organization of ballistic tests and vigilant monitoring of outcomes specific to composite ceramic armors under production. This involves not only ensuring adherence to ballistic standards but also providing a nuanced understanding of the intricate dynamics between ammunition and armor. The module emerges as a specialized and indispensable asset, empowering the company to fortify its quality control processes and ensure the steadfast alignment of its products with exacting high-performance standards.

- ***Stock Management Module*** is seamlessly integrated with the ERP system, providing a comprehensive framework for the efficient oversight of both semi-finished goods and finished products. It meticulously records stock information, including parametric specifications, ensuring a detailed and organized approach to stock management. In adherence to the company's philosophy, classifications such as 'quality' or 'non-quality' are eschewed. Instead, each production batch is tailored to either meet or not meet the specific needs and requirements of individual customers. For example, if an armor produced to STANAG 4 standards is deemed unsuitable based on test results, it may still be applicable for a customer seeking a product compliant with STANAG 3 standards. This nuanced approach allows for the definition of stocks based on parametric attributes, taking into account data from the Laboratory Information Management System (LIMS). The objective is to ensure a sophisticated understanding of product capabilities, facilitating flexible adaptation to meet diverse customer requirements. This approach optimizes stock management, aligning it with stringent quality parameters.

4. Conclusion

The rise of digitization and Industry 4.0 has brought about significant transformations in corporate quality management methodologies. The conceptual introduction of Quality 4.0 has instigated a paradigm shift, with traditional approaches making way for the integration of Enterprise Quality Management Software (EQMS). This shift is particularly evident in sectors with stringent quality management systems, notably in industries like aerospace and defense, where adherence to the AS9100 standard is crucial.

AS9100, as an extension of the ISO 9001 framework, introduces additional requirements covering configuration management, risk management, product safety, and prevention of counterfeit parts. The complexity of AS9100 necessitates thorough documentation and process management, emphasizing a nuanced focus on risk management, continuous risk assessment in dynamic sectors, and the critical importance of supply chain management. The standard underscores the necessity for meticulous supplier selection, evaluation, and collaboration, placing a strong emphasis on product and service safety, especially in sectors where reliability is paramount. The meticulous documentation and continuous monitoring intrinsic to AS9100 highlight the multifaceted challenges it poses for organizations, embodying an industry-specific, process-oriented, risk-focused, and supply chain-centric nature.

Despite the growing adoption of EQMS among AS9100-certified firms, the limitations of off-the-shelf EQMS products in achieving seamless compatibility with AS9100 standards hinder the attainment of optimal performance. Consequently, there is a noticeable trend where organizations are increasingly turning to the development of customized software solutions. This shift from off-the-shelf EQMS products is driven by the need for alignment with the intricacies of the organization's production processes, structural nuances, and overarching priorities.This study centers on the development of a tailored EQMS for a company operating in the defense industry. The company, classified as a Small and Medium-sized Enterprise (SME) with approximately 200 employees, specializes in offering composite ceramic products in the defense and aerospace sectors. Possessing certifications for ISO 9001, ISO 18001, ISO 14001, and AS 9100 quality management systems, the company currently employs ERP and MES systems.

The research is situated in the context where the quality management module in the ERP system falls short of fully meeting the requirements of AS9100. In response to this inadequacy, the company has undertaken the development of a customized Enterprise Quality Management System (EQMS). The developed EQMS comprises modules such as

Document Management, Maintenance Management, Training Management, Risk Management, Personnel Competency Management, Calibration Management, Audit Management, Laboratory Information Management System (LIMS), Corrective Actions and Preventive Actions (CAPA) Management, Stock Management, Ballistic Test Management, and Supplier Quality Management.

The developed software seamlessly integrates with ERP and MES systems, ensuring compliance with AS9100 standards. This specialized software successfully manages critical functions such as calibration management, laboratory information management system, supplier assessment, ballistic test management, and stock management. Additionally, the study highlights that this tailored software, designed to meet stringent requirements in the defense and aerospace industries, serves as a crucial tool to enhance operational efficiency and align the company's products with high-performance standards.

References

Aravindan N, Seetharaman, Raju Kamaraj, "Change Control in Pharmaceutical Quality Management System", Research J. Pharm. and Tech, Vol.13(4),2020. doi: 10.5958/0974-360X.2020.00357.1

Asif, M., "Are QM models aligned with Industry 4.0? A perspective on current practices", Journal of Cleaner Production, Vol. 285, 2020, https://doi.org/10.1016/j.jclepro.2020.120820

Barker, E.M., "Aerospace's AS9100 QMS Standard", Quality Digest.Web, 2002. [Online], Available: http://www.qualitydigest.com/magazine/2002/may/article/aerospaces-as9100-qms-standard.html

Bruun, A.M., "What is an eQMS? (Plus the Best eQMS for Life Sciences)", 2023, Available: https://www.simplerqms.com/quality-management-system/

BSI Group, "S/EN 9100 series - Quality Management Systems for Aviation, Space and Defence - Transition Guide", 2016, Available: www.bsigroup.com

Cressionnie, L.L, "Did You Understand the Assignment?", ASQ Quality Progress, 2023, Available: https://iaqg.org/wp-content/uploads/2019/10/qp0923standardissues.pdf

Foster, S.T., "Quality Management and Techniques" , South-Western Cengage Learning, 2015.

Göv, S., 2018, "HAVACILIK SEKTÖRÜNDE AS 9100 KALite STANDARDI: ISO 9001 ile Karşılaştırma " İktisadi İdari ve Siyasal Araştırmalar Dergisi, 2018.

Greenwood, a., "EQMS: The Best Way to Crush Competition, Push Productivity & Reduce Recall", 2023, Available: https://www.process.st/eqms/

Hammer, M., "Clause-by-clause explanation of AS9100 Rev D", 2020., Available: adviser.com

Harun, K. & Cheng, K., "An integrated modelling method for assessment of manufacturing quality systems applied to aerospace manufacturing supply chains", Proceedings of the 6th CIRP-Sponsored International Conference on Digital Enterprise Technology, pp 1687-1708, 2010.

IAQG, "9100:2016-Series Clarifications, 2019., Available: https://iaqg.org/wp-content/uploads/2019/11/9100-2016-Series-Clarification-Table-10-2019.pdf

IAQG, "9100:2016 Executive Overview Presentation", 2020. Available:https://iaqg.org/wp-content/uploads/2020/01/9100-2016-Executive-Overview-1-2-2020.pdf

Liu, HC., Liu, R., Gu, X. et al., "From total quality management to Quality 4.0: A systematic literature review and future research agenda", Front. Eng. Manag, Vol.10, pg.191–205, 2023.

Maganga, D.P. &Taifa, I.W.R., "Quality 4.0 conceptualisation: an emerging quality management concept for manufacturing industries", The TQM Journal, Vol. 35 No. 2, pp. 389-413, 2023.

Narahari, N.S., Vijaya Kumar, M.N. & Nagendra Guptha, C.K., "Recent Developments in Quality Management in the Era of Digital Transformation – A Review", European Journal of Theoretical and Applied Sciences, 1(3), 360-375, dot: 10.59324/ejtas.2023.1(3).36, 2023

Oschman, J.J. , "A CONCEPTUAL FRAMEWORK IMPLEMENTING AN AS9100 QUALITY MANAGEMENT SYSTEM FOR THE AEROSPACE INDUSTRY", South African Journal of Industrial Engineering Vol 30(2), pp 1-16, 2019.

Qualityze, "7 Functionalities of the Best EQMS Software", 2022, Available: https://qualityze.medium.com/7-functionalities-of-the-best-eqms-software-5132913f084a

Qualityze, "Learn why your company needs an EQMS?", 2023, Available: https://qualityze.medium.com/learn-why-your-company-needs-an-eqms-8e92639e0127

Sisodia, R.; Villegas Forero, D., "Quality 4.0—How to Handle Quality in the Industry 4.0 Revolution", Chalmers University Of Technology: Gothenburg, Sweden, 2020.

Sprycha. I & Piasecka, A., "Aerospace QualityManagement System According to Selected Quality Standards", Active Citizenship by Knowledge Management & Innovation: Proceedings of the Management, Knowledge and Learning International Conference 2013, ToKnowPress, 2013.

Stadnicka, D. & Antosz, K., "Continuous improvement practice in large enterprises: Study results", International Journal for Quality Research, Vol. 9(1), pg. 9–26, 2015.

Tomic, B. , Spasojević-Brkić, V. & Klarin, M., "Quality management system for the aerospace industry", Journal of Engineering Management and Competitiveness, 2 (1), 2012.

Weheba, G., Mahmassani, A. & Malzahn, D., "AS 9100 Registration Difficulties and Organizational Benefits: A Supplier Satisfaction Survey", JOURNAL OF AEROSPACE, Vol. 115:1, pp. 752-760, 2006.

Wells, J., "Next-Gen EQMS does not equal Quality 4.0", Available: https://blog.lnsresearch.com/next-gen-eqms-does-not-equal-quality-4.0, 2022.

Biography

Tugba Danaci is an accomplished industrial engineer and production management consultant with a diverse educational background. She pursued a double major in Management Engineering and Mechanical Engineering, specializing in System Dynamics and Control during her undergraduate studies at Istanbul Technical University. Her academic journey continued with a Master of Science in Strategic Management in Defense Technologies and culminated in a Ph.D. in Industrial Engineering from Cleveland State University and Erciyes University. Alongside her academic studies, she has held various consulting and managerial roles within companies operating in the defense industry. Her focus includes the implementation of AS/EN 9100 Rev D quality management systems, digitalization and optimization of production processes, their migration to cloud platforms, bespoke software development tailored to specific company needs, and spearheading projects ensuring compliance with NATO and National standards for facility security.