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Deloitte's digital QMH: An innovative solution for the MedTech industry

Our innovative digital QMH solution helps MedTech companies to manage and maneuver QMS processes, achieve regulatory compliance and faster market approval and keep pace with evolving challenges in the competitive MedTech industry.

Challenges of the MedTech companies

MedTech industry is faced with the challenge of developing products in an increasingly complex environment of regulatory compliance. For active medical devices and Software as a Medical Device (SaMD), cybersecurity and other associated risks and safety issues pose an additional challenge. On one hand, medical devices are becoming increasingly complex, while on the other hand, a highly competitive market environment is pushing MedTech companies for rapid approval and launch of their products.

However, compliance with the evolving regulatory requirements comes at a cost, in terms of resource allocation. It is expected that compliance with the recently adopted Medical Device Regulation in Europe (EU MDR) will cost up to 5% of the annual turnover of medical device companies[1].

For medical devices, design control has emerged to be a major determinant of device safety and performance. Similarly, timely assessment of corrective and preventive actions (CAPAs), customer feedback, and device complaints as well as an active risk-management system is crucial to ensure product quality and to achieve regulatory compliance.

It has been reported by Schiel (2023) that violations of quality system regulations, including CAPAs and complaints, are major reasons that triggered FDA warnings for medical devices. Furthermore, an analysis of the market by Deloitte has revealed that poor management of processes from design to production of medical devices has the potential to compromise patient safety as well as the market competitiveness of the MedTech companies[2]. Therefore, it is evident that product quality and compliance issues, if not addressed, can affect the financial performance of MedTech companies and erode the trust of healthcare providers and patients in their products.

This highlights the importance of the Quality Management System (QMS) as a foundation for improving the quality of products, ensuring compliance with regulatory requirements, and achieving the trust of different stakeholders in the manufacturer and its products.

In a recent development, the US FDA has made an amendment to its regulatory framework and incorporated ISO 13485: 2016 into its Quality System (QS) regulation. This is expected to promote consistency and harmonize the QS regulation with other global regulatory bodies. As the existing US FDA QS regulation and ISO 13485 are substantially similar, this amendment will facilitate manufacturers, that are registered in the US and other countries, to avoid the redundant effort of separately complying with both regulations. As a result, this will reduce costs and the burden of document preparation, records for audits and inspections, internal activities and management reviews, for these MedTech companies. Deloitte offers MedTech firms to support a quick and cost-effective adaptation of their Quality Management (QM) systems to the new FDA QMSR. Furthermore, Deloitte's digital QMH is an efficient tool to facilitate the harmonization of different QM systems of company associations and to support the implementation and continuous improvement of the business processes.

Deloitte's digital Quality Management Handbook (QMH) solution

An efficient QMS, encompassing stages of the complete lifecycle of a medical device, is of immense importance for maintaining the quality of products and achieving regulatory approval. To effectively implement a QMS, the internationally accepted ISO 13485 standard for medical devices emphasizes commitment to addressing customers' concerns, adopting a quality policy, determining objectives, as well as focusing on responsibilities, communication, and representation. Moreover, it recommends adopting a process model that is focused on the input and output of processes and follows the "plan, do, check and act" principle[3].

To this end, Deloitte offers an innovative digital Quality Management Handbook (QMH) solution. It is intended to manage and maneuver processes and activities, thereby enhancing the efficiency and effectiveness of the QMS.

For more information click here.

Work and information flow

Deloitte's digital QMH is an end-to-end traceable model that provides a holistic and systematic overview of business processes and their interactions in the product lifecycle. It helps to streamline projects and routine work by showing the relationship between the tasks (SOPs), the artefacts (templates) and the information flow. The digital QMH reveals which processes and tasks need to be done sequentially and which can be performed in parallel to reach the project's goal fastest. Moreover, it identifies gaps and redundancies in the workstream of the QMS that can be resolved immediately during the implementation of the digital QMH to avoid unnecessary work or project delays. Deloitte's digital QMH can be published in the intranet, and project managers and stakeholders can navigate interactively through single processes. Suggestions for improvement can be communicated directly via the discussion threads. This facilitates continuous improvement of the QMS and the digital QMH. The digital QMH enables consistency in the implementation of development projects and routine processes, and is a great support for project managers, stakeholders, and auditors.

"The digital QMH is the basis for AI based process optimization and facilitates the introduction of an eQMS."

Ulrich Schoof
Deloitte

Responsibilities and training

The digital QMH provides an overview of the responsibilities assigned to the business processes, work instructions, SOPs, and templates according to the company's QMS. This enables an automatic roll-out of training plans and facilitates communication among the stakeholders within and between departments. This is particularly helpful in times of rapidly changing teams.

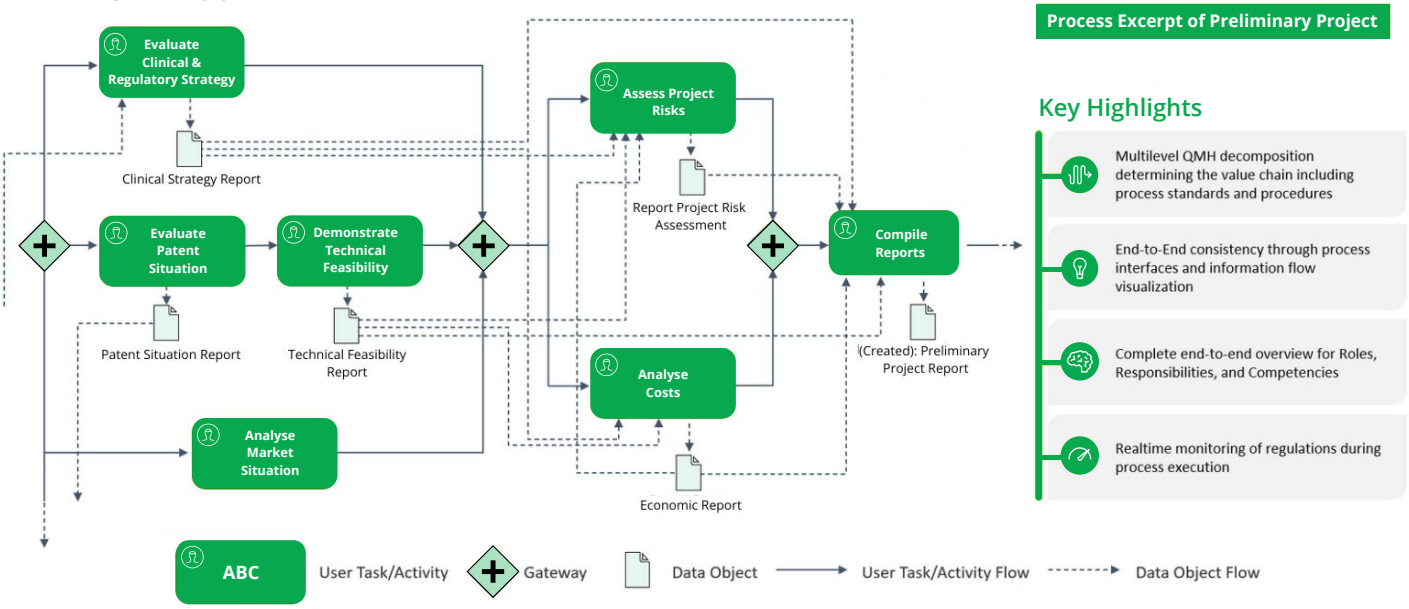
Full traceability to laws and standards

Deloitte's digital QMH enables traceability to the laws and standards relevant to your company. Each applicable article of the laws and standards is linked to the business processes, work instructions, SOPs, and templates of your QMS leading to full traceability during daily work and audits. The end-to-end transparency of the digital QMH and the automatic roll-out of training plans enable efficient implementation and adaptation of your QMS in the event of an update to legal requirements or the improvement of internal business processes.

Digital QMH as basis for eQMS implementation

Any gaps existing in the company´s QMS are closed, and redundancies removed prior to eQMS implementation. In addition, the holistic presentation of business processes, tasks, and artefacts with the associated responsibilities simplifies the introduction of the eQMS. The workflows in the eQMS are generated from BPMN models of the digital QMH. Deloitte can support MedTech companies in the implementation of the digital QMH and eQMS.

Figure 1—The excerpt from the design verification process shows the tasks that can be performed in parallel and those that can be sequentially performed



Process analytics and process mining

Based on the digital QMH you can simulate effort, throughput time and cost, and analyze process enhancements for standardized, highly repetitive processes prior to establishing changes. Deloitte provides GenAI integration to answer questions based on the process model as well as the QMH documents.

Expertise in establishing a state-of-the-art digital QMH

We have identified a standardized approach to establish a digital QMH according to our customer's requirements coupled with key understandings of industry best practices. After identifying the customer's needs, we offer three key steps to implement the digital QMH:

Plan

As a first step, we identify specific local regulations and quality management system requirements according to our client's target markets and conduct an "as-is" analysis of the established QM system(s) and business processes. Interactions between the business processes are identified and gaps are assessed.

Based on this analysis an action plan is developed to implement the digital QMH at the level required by our client.

Implement

Deloitte's experts and professionals work in close collaboration with the MedTech companies and assist them in the implementation of the digital QMH, according to Deloitte's blueprint or the client's existing QMS and best practices. This includes full-time support with regular proof of concept and performance checks for the digital QMH. Given our expertise in Process Analytics and Process Mining, this implies a high-quality implementation process, ensuring complete traceability of the digital QMH. Moreover, Deloitte's extensive global network of experts facilitates and supports multi-national companies to realize overseas programs for harmonization and implementation of the digital QMH.

Operate

An important dimension of the successful digital QMH implementation is its iterative improvement and keeping track of its performance indicators. Deloitte offers support in performing such activities, and also enables and empowers customers to operate, improve and adapt the digital QMH according to their needs and requirements.
The digital QMH solution by Deloitte is already in use in the automotive, aerospace, and pharmaceutical industries and has demonstrably led to cost savings.

It is an advanced tool that allows MedTech companies to strategically plan, manage, and execute processes and activities of the QMS. This will help companies to develop and maintain high-quality products, achieve regulatory compliance cost-effectively, reduce time to market, and keep pace with evolving challenges in the MedTech industry.

"Our digital QMH is useful for MedTech companies with an established QMS, start-ups introducing a new QMS, or associations of companies wishing to harmonize part or all of their QM systems."

Dr. Heike Fischer
Deloitte

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Clinical Research by Deloitte

Figure 2—Steps to establish a digital QMH

PLAN

- Identification of Quality Management System Requirements
- Mapping of Business Process Interactions and Corresponding Gaps
- Development of Client Specific Actionplan and Roadmap

IMPLEMENT

- Implementation of the Digital QMH based on Deloitte's Blueprint
- Ensuring complete Traceability within digital QMH
- Global Scaling Support for digital QMH through regular Proofs of Concept

OPERATE

- Iterative Improvement of digital QMH
- Regular 1st, 2nd, and 3rd level of Support based on Customer Requirements

Contact us

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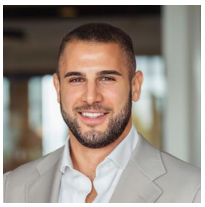

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Bibliography

1. Veronika Schweighart, Jan Brützel and Catherine Higginson: "EU-MDR Readiness Check 2020", Climedo Health, 2020.
2. Schiel C. 2023: More than 'license to operate' How quality and regulatory compliance in MedTech became a driver of financial performance.
3. Quality Management System Certification. Understanding Medical Device Quality Management System (QMS) certification (updated March 2016). Bsi.

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