SIEMENS

CLOSED LOOP QUALITY AND COMPLIANCE

Closed Loop Quality and Compliance for Medical Devices

Improve patient safety with an enhanced quality approach and simplified regulatory management

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Challenges in assuring quality and compliance

Medical device manufacturers strive to generate products that meet the highest levels of quality to ensure the appropriate delivery of patient care. However, regulatory compliance can be a problem due to ever-changing guidelines, varying levels of employee engagement and the sheer volume of information needed for health authorities.

Quality and compliance can often feel at odds. You want high product quality via adapted and advanced processes, but limited resources and budgets can put a strain on efficiency. Compliance introduces necessary rigor to support better patient outcomes; however, these measures can lead to burdensome documentation and analysis paralysis.

So how can manufacturers efficiently act on product and process quality for patient safety while ensuring continuous, real-time compliance with regulations?

Siemens Closed Loop Quality and Compliance for Medical Devices tools enable companies to bring together the forces needed to keep quality and compliance efforts harmonious throughout the entire device lifecycle:

- An integrated and collaborative digital backbone for data and documents based on Product Lifecycle Management (PLM)
- A comprehensive quality management system (QMS) to oversee multiple regulatory requirements simultaneously
- An innovative and convenient Regulatory Information Management System (RIMS)

By adopting Closed Loop Quality and Compliance, manufacturers can achieve expertise and peace of mind. You gain access to comprehensive, up-to-date information for market submission and audits to ensure compliance, enhance interaction with authorities and better address product quality.

An integrated system to efficiently deliver safe devices

Regulations and standards exist to help manufacturers deliver devices that are safe and effective. In this way, the FDA QSR (Quality System Regulation) and ISO 13485 provide frameworks for companies to organize their Quality Management System (QMS).

To continuously master and monitor compliance with regulations and procedures, it's crucial to use digital tools that centralize quality data for all company departments.

Ensure the quality of your medical devices by respecting all regulations throughout the product lifecycle. It can be a challenge, but Siemens Closed Loop Quality & Compliance tools have the 3 must-haves for an efficient, integrated process.

1. Establish a digital quality and compliance framework

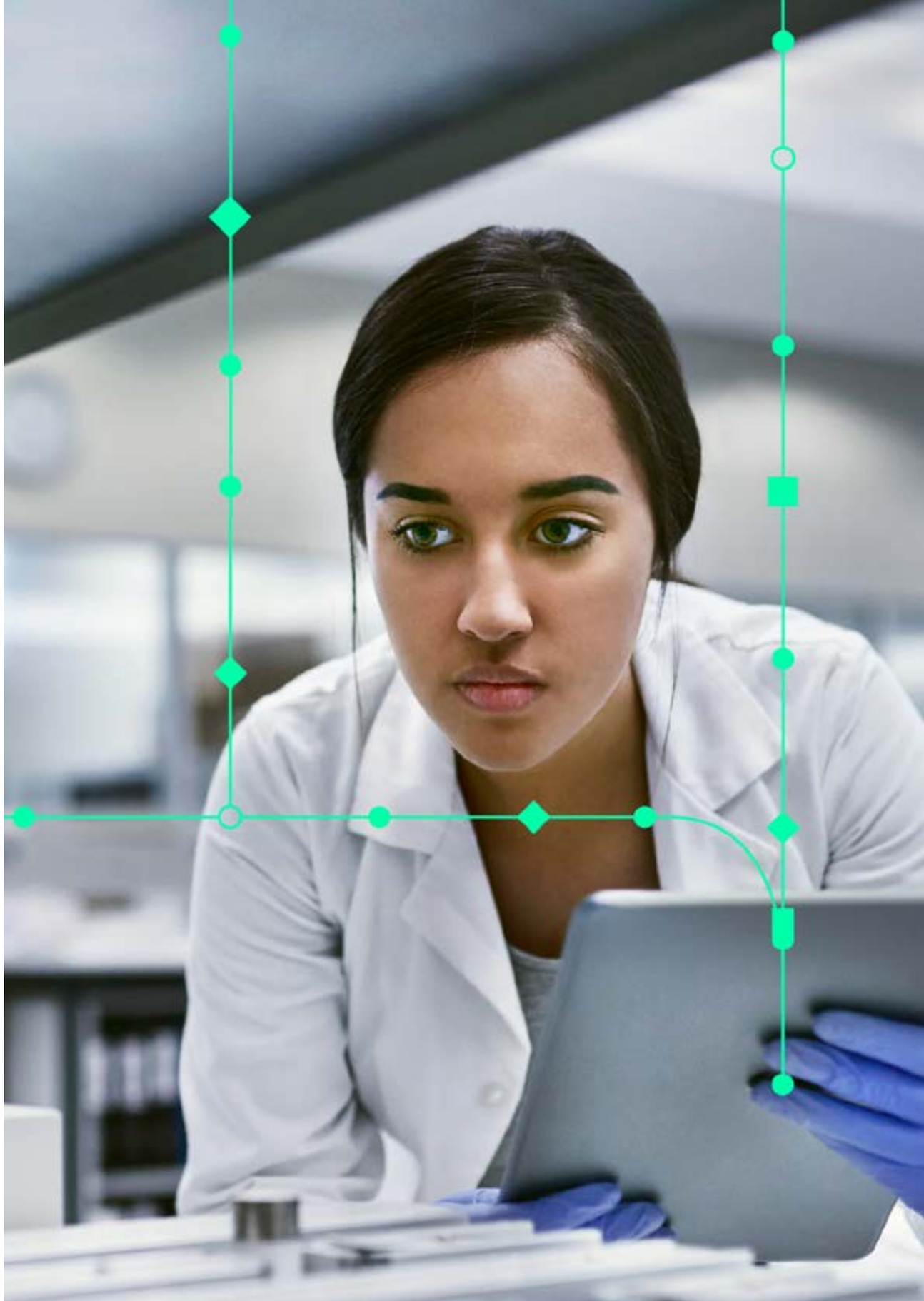
Many new regulatory changes have been implemented over the last few years, such as EU medical device regulation (MDR/IVDR), application of Unique Device Identifier (UDI) and the Medical Device Single Audit Program (MDSAP).

To ensure compliance, manufacturers should implement an integrated and collaborative digital quality and compliance framework for processes and products.

Having a product lifecycle management and application lifecycle management (PLM/ALM) tool in place helps ensure that all activities related to design, development, manufacturing and post-market surveillance are planned, controlled and monitored.

It automates the flow of documents and data to provide a variety of features not possible with traditional paper processes including:

- International access
- Support for electronic signatures
- Built-in compliance approval workflows
- The ability to establish KPIs, efficacy metrics and performance tracking



Siemens integrated Closed Loop Quality & Compliance tools help manufacturers better integrate and control:

- CAPA & Quality Issue Management
- Non-conformances management
- Change control
- Document management
- Training & qualification
- Regulatory information management

2. Ensure quality process efficiency

Medical device manufacturers must comply with a wide variety of standards and regulatory requirements. Mastering and monitoring quality processes is key to compliance validation.

Siemens QMS tools ensure full traceability of design development phases for a complete Design History File/Device Manufacturing Record (DHF/DMR) and seamless design transfer to production. They help make it possible to respond promptly to issues that arise during the product lifecycle or in the field, determine the root cause, and implement quick measures to prevent its recurrence.

Our integrated QMS enables manufacturers to support the continuous improvement process through:

- Risk & Requirements management
- Failure Modes and Effects Analysis (FMEA)
- Quality planning
- Non-conformances management
- Corrective and Preventive Actions (CAPA)
- Change management
- Employee training

3. Establish information transparency

Manufacturers must be able to clearly view context and regulatory compliance throughout the product and market lifecycle. Our unique Regulatory Information Management System (RIMS) can be fully customized to your compliance specifications.

Based on low-code apps, our RIMS facilitates collaboration between the different teams involved in regulatory affairs by providing easy access to all information in a single repository to improve communication with health authorities. It's true integrated data management, not another standalone system.

RIMS connects with existing systems and aligns with evolving company business processes to collect inputs from all lifecycle phases including:

- Design control
- Design transfer
- Production and process control
- Post-market surveillance

Develop a quality-based culture within your organization

Quality must be considered by every person in the company, not just the Quality department. All employees need to feel part of a complex ecosystem, where quality is a structured way of working that affects every step of product life.

Being focused on compliance leads to product quality enhancement through prioritization of better solutions, information and processes, especially for new and innovative medical technologies that can carry patient risk.

Establish full traceability

An integrated and collaborative digital backbone for data ensures that siloed teams will be more coordinated on quality activities. Data and trace transparency will be established to keep track of standards and regulatory workflows, timelines and market differences.

Reinforce process efficiency

A comprehensive QMS enables you to respond promptly to issues, determine the root cause, and implement quick measures to prevent recurrence. Implementation can verify and confirm that employees are cyclically trained and certified according to requirements.

Facilitate transparency to internal and external stakeholders

An efficient RIMS ensures that communication with regulators will be facilitated and compliance for pre-market submissions, post-market reporting, UDI databases, audits, device registrations and complaints management will be accelerated.

Benefits of Siemens Closed Loop Quality and Compliance tools:

- **Peace of mind.** You gain access to comprehensive up-to-date information for market submission and audits.
- **Expertise.** Your device quality will be continuously monitored and improved for patient safety.

Siemens Closed Loop Quality and Compliance enhances organizational compliance and continuously acts on medical device quality. Let us show you how it can help your organization.

About Siemens Connected Care:

Closed Loop Quality and Compliance for Medical Devices is Siemens' digital solution that supporting to be compliant with industry regulations while enhancing quality approach for products.

It tracks required data with an integrated digital backbone, continuously addresses quality processes efficiency and improves your interactions with health authorities.

For more information on Siemens Closed Loop Quality and Compliance for Medical Devices, visit siemens.com/CLQC or follow us on LinkedIn and Twitter.

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