Scilife Competitive Advantages in Medical Devices ISO 13485

Introduction

In order to ensure the quality, safety, and performance of medical devices and to comply with regulatory requirements, a robust quality management system is essential.

In the EU, this requirement is outlined in the Medical Device Regulation (MDR) as well as the In-Vitro Diagnostic Medical Device Regulation (IVDR). In the US, this requirement is addressed in the 21 CFR 820 or Quality Management System Regulation (QMSR) (effective 2 Feb 2026), which incorporates ISO 13485:2016 by reference and adds FDA-specific requirements.

Section 9 in article 10 of the MDR, *General obligations of manufacturers*, clearly stipulates that manufacturers of devices shall *establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device*.

On the other hand, ISO 13485:2016 is the international standard that outlines the requirements for a Quality Management System (QMS) in the medical device industry. This standard can also be used by an organization involved in one or more stages of the lifecycle of a medical device, including design and development, production, storage and distribution, installation, servicing, and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities.

Implementing an electronic Quality Management System like Scilife provides numerous competitive advantages for your organization. This document outlines the **key benefits** of Scilife with a focus on medical device compliance according to ISO 13485:2016, **addressing the potential challenges** posed by other electronic quality management systems in the market.

What does Scilife offer to medical devices?

Scilife offers an electronic Quality Management System (eQMS) for medical devices and In Vitro Diagnostic (IVD) products, providing various benefits such as digitizing processes, managing design and development, automating document control and record management, automating training, navigating audits, managing quality events, and hitting key performance indicators.

The eQMS also includes some features, such as automated notifications, reminders, and user rights management to support audit readiness and inspection preparedness through controlled workflows, traceability, and reporting.

Scilife is designed to address the challenges posed by paper-based QMS by offering advantages such as continuous learning, gamification strategies, and advanced data analytics.

By implementing Scilife, your organization can improve quality traceability, streamline quality workflows, and achieve compliance with ISO 13485:2016.

1. Compliance with ISO 13485:2016

- Scilife is designed to support alignment with ISO 13485:2016 requirements; compliance ultimately depends on your organization's implementation, configuration, and use.
- We incorporate appropriate risk management principles to ensure that our products meet the intended use and are compliant with ISO 13485:2016.
- Our solutions support electronic records and electronic signatures with audit trails and validation deliverables. Customers can apply controls to meet applicable expectations (e.g., 21 CFR Part 11, where applicable, and EU computerized system expectations where relevant). Our validation approach aligns with GAMP 5 principles.
- We help your organization **avoid costly compliance violations, regulatory fines, and product recalls**.

2. Quality Management Systems (QMS)

- Scilife is a structured QMS that helps to ensure your business operates efficiently and effectively.

- ISO 13485:2016 requires organizations to establish a **quality manual**.
- The **quality manual** is the top-level document for the QMS and the starting point for accessing the Quality Management System (QMS). This document must outline the scope of the QMS, the structure of the documentation used in the QMS, and a description of the interaction between the processes of the QMS.
- ISO 13485:2016 also requires documented statements of a quality policy, quality objectives, documented procedures and records.
- Scilife's **Document Control** is the right place to manage and keep the quality manual.
- In addition to managing quality, Scilife promotes **collaboration**, **communication**, **consistency**, and **continuous improvement** throughout life sciences organizations.
- Taking quality beyond a 'cost-of-doing-business' perspective, Scilife challenges conventional quality standards. It **reduces errors and enhances quality**.
- Providing access to data and easy-to-use processes encourages everyone in your business to naturally integrate quality into their daily work.
- Scilife builds a culture of engagement, responsibility, and reduced compliance risk by empowering everyone to take ownership of quality.
- By **accelerating time to market by 30 percent**, your manufacturing and supply chain can be made more responsive and capable, and your total **quality assurance costs will be reduced by 50 percent**, eliminating compliance burdens and freeing up key business resources.

3. Documents and Records

The Scilife platform includes three tools for managing documents and records: **Documents**, **Records**, and **Print & Reconciliation**.

3.1 Documents

- According to ISO 13485, although your QMS must contain 31 documented procedures, they don't have to be 31 physical documents. They can be divided up and found in several documents or combined into one physical document.
- Scilife's **Documents Control module** can manage different types of documents in accordance with ISO 13485. Scilife electronic Quality Management System stores, classifies, and categorizes any type of document, such as:
    - Specifications
    - Standard Operating Procedures (SOPs)
    - Work Instructions (WI)
    - Medical Device File
    - Protocols
    - Reports

    - Technical Agreements

- The creation of Document Types allows corporate templates to be used and most settings to be predefined.
- **Documents can be edited with MS Office** (Word, Excel, and PowerPoint) within Scilife without having to download/upload documents, and no editing using forms. You can also use office functionalities like track changes and comments.
- Documents can be retrieved based on multiple criteria (folders, tags, prefixes, types, etc.).
- **Version control and a version history tab are fully automated**. Metadata is automatically inserted and updated in documents.
- With Scilife's platform, you can access all these documents, track changes, and make sure everyone has access to the right information. This will not only **simplify compliance with audit requirements** but also keep everything secure and current.
- You can **easily standardize and systemize the documentation lifecycle** with an approval cascade and customized user permissions.
- You can establish periodic revision of documents to keep them up-to-date with automatic notification of upcoming reviews.
- Any electronic record that you are generating and saving in a digital format in your QMS using electronic signatures must comply with **21 CFR Part 11.** In Scilife, documents are approved, signed and dated by appropriate and authorized persons. All electronic records indicate the printed name of the signer, date and time of the signature, and the meaning of the signature (edition, review, approval, etc.)

3.2 Records

- Forms are also recommended to aid in the implementation of a QMS for medical devices to ensure compliance and repeatability of critical processes.
- Forms can simplify the documentation of processes, making it easier to ensure that all employees consistently follow the same procedures, ultimately contributing to the effectiveness of the QMS.
- With our **Record Management** solution, you can implement ISO 13485:2016 with ready-made forms, checklists, and other documents. Electronic forms can be customized and used with appropriate controls to keep records intact. Using these records, you can demonstrate compliance with instructions, events, investigations, CAPAs, or change controls.

- According to the contemporaneous principle of ALCOA, a record of the activity is made or completed at the time of the activity in forms. As a result of making or completing records, the activity can be traced, enabling the user to view the original information. The reason for any changes is also recorded where applicable.
- Scilife's approval workflow functionality **allows approvers to sign off forms with their electronic signatures directly** within the Scilife platform.
- Records can be used in quality control for registering analytical activities or in manufacturing for registering any data.

3.3 Print & Reconciliation

Data integrity is a critical aspect of the medical device industry, ensuring that the data generated by manufacturers is complete, consistent, accurate, and reliable.

There are still some manufacturers using paper-based systems, which can pose a greater risk of data integrity issues due to a lack of controls.

The use of blank forms for manual recording of data should be controlled to prevent unauthorized re-creation, and any blank forms used in operations must be controlled forms, reviewed and approved appropriately, and issued with a unique identifier to guarantee data integrity.

In addition, poor data integrity practices can lead to serious findings and negative consequences for the quality of materials and medical devices. Here's how Scilife can help you in averting such potential problems:

- With the **Print & Reconciliation** solution, you will not only be able to **track who has access to electronic forms** (and who printed them), but you will also be able to **gather and reconcile each printed document efficiently**.
- The Scilife Print & Reconciliation solution generates tracking barcodes for each document page. These unique barcodes **ensure traceability every time a document is printed**.
- As well as enabling traceability, essential for compliance, these unique barcodes are useful in tracking down and reconciling documents. **Every reconciliation action is also conveniently recorded in the audit trail** of the application.
- A reprint of the same Unique ID document number receives a unique barcode. After entering the reason for the reprinting, you will be asked to write down why you are reprinting the document. The action will be recorded in the audit trail after the reason is entered.

- While you and your team focus on value-adding activities, Scilife Document Control, Records, and Print & Reconciliation solutions will efficiently manage your document workflow.

3.4 Periodic review of documents

Keeping documentation up to date is an important part of document control in the medical device industry. In ISO 13485:2016, there is no specified period for periodic reviews, but you must ensure that data is accurate and compliant with applicable regulations and standards.

In order to ensure that documents remain relevant and effective, the **periodic review feature** in Scilife is conducted at predefined regular intervals. Scilife allows you to specify the periodic review for each document or record on an individual basis. Depending on the type and importance of documents and records, the legal and regulatory compliance team in your organization can set different periodic reviews.

4. Knowledge: Training and competence management

ISO 13485:2016 requires that personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills, and experience.

Organizations must establish the necessary competence for personnel, maintain a formal training program, and keep training and competence records.

Here's how Scilife makes the process of managing employee training and competence records a breeze:

- Document Control Solution enables you to create, review, approve, and distribute job descriptions for positions that directly impact product quality.
- **Scilife streamlines the management of training and competence**. By tracking employee training, certifications, and competencies, organizations can ensure their staff are qualified and comply with cGMP regulations.
- Training is based on roles, not just individual people.

- With Scilife's competence matrix and CV management tool, you will be able to **maintain personnel CVs up-to-date automatically** and keep their skills updated.
- Scilife manages employee certificates.
- Employees can also share their unique skills by setting levels for each competence.
- Training and Competence solutions **help you plan and adapt your personnel's initial and ongoing training**.
- Periodic retraining can be planned.
- When a new version of a document is approved, re-training notifications are automatically sent.
- **Automatic reminders and notifications** about pending training are sent and escalated.
- In addition to documents, training can also include external materials, online courses, presentations, videos, on-site and off-site training, effectiveness checks, and automatically corrected assessments.

5. Process management with predefined workflows

Predefined workflows make the Scilife platform easy to implement. As a result of their flexibility and consistency, predefined workflows can help to **ensure that quality processes are consistent, efficient, and compliant with GMP regulations and standards**. They can help to improve productivity, reduce the risk of errors and delays, and ensure that employees follow SOPs relevant to them.

Scilife has several predefined workflows off-the-shelf:

5.1 Quality events

Quality events refer to nonconformities, deviations, complaints, or failures. In order to avoid future complaints, events must be identified, documented, investigated, and addressed in a timely and compliant manner.

- Scilife allows users to **create events instantly on any device, including smartphones and tablets**, reducing the risk of forgetting or missing an

important quality event. This ensures data is recorded contemporaneously.
- Scilife **captures and manages any type of quality event**: deviations, nonconformities, complaints, out-of-specifications, incidents, near-misses, etc.
- By tagging each event with the responsible party, you can also ensure accountability in your organization.
- The event registration form and investigation form can be customized to capture the required information at every stage.
- If you are performing root cause analysis and impact assessment during the event investigation phase, you can upload (multiple) files as proof anywhere during the event workflow.
- The root cause analysis (RCA) allows you to determine what caused a quality event. Using Scilife, you can upload all the information related to the analysis and perform a quality risk assessment.
- Link the investigation to Risk Assessment or create one on your own.
- Scilife provides **configurable reports generated in a single click** with all the metadata filled in automatically.

5.2 Corrective and Preventive Actions (CAPAs)

The findings of investigations should be used to identify and implement appropriate corrective and preventative actions (CAPAs). As part of Quality Risk Management, such actions should be monitored and assessed for effectiveness. Here's how we facilitate these processes with our solution:

- Scilife offers a workflow for implementing CAPAs resulting from quality events.
- You can create a CAPA plan with all the relevant information and roles.
- The Project Management tool for CAPA actions sends automated notifications to the responsible people and a warning for due dates.
- Open a CAPA straight from the event: a linked CAPA or a link to an existing CAPA from the Events module.
- The effectiveness check allows verification of the effectiveness of CAPAs to ensure that they are effective and do not adversely affect the product.
- Change control is integrated with CAPAs, enabling the implementation of change management processes.

5.3 Change Control

There is no doubt that changes have a significant impact on medical device organizations, including internal processes and the products that they design, develop, manufacture, and distribute to the market.

ISO 13485:2016 requires control of design and development changes (7.3.9) and control of changes to QMS processes (4.1.4). In order to ensure everything is accounted for in your QMS, documentation, and records, you will need to properly manage any changes as they occur.

Change control is a process where qualified representatives review proposed or actual changes that might affect the quality management system, the medical devices produced, the validated status of facilities, systems, equipment, or processes. The intent is to determine the need for action to ensure and document that the system is maintained in a validated state. These are the steps that you should follow:

- Define the reason for a change request.
- Do your risk & impact assessment. You can also link it to the Risk Assessment solution.
- Link the change request to other modules (e.g., equipment) so you can add a cost estimate.
- The Project Management tool for Change Control tasks sends automated notifications to the responsible people and a warning for due dates.

5.4 Design and Development

Developing and bringing a medical device to market can be challenging. One of the key processes is design and development.

There are multiple stages of design and development to navigate before obtaining regulatory approval. And when human errors occur or documents go missing, this causes significant delays.

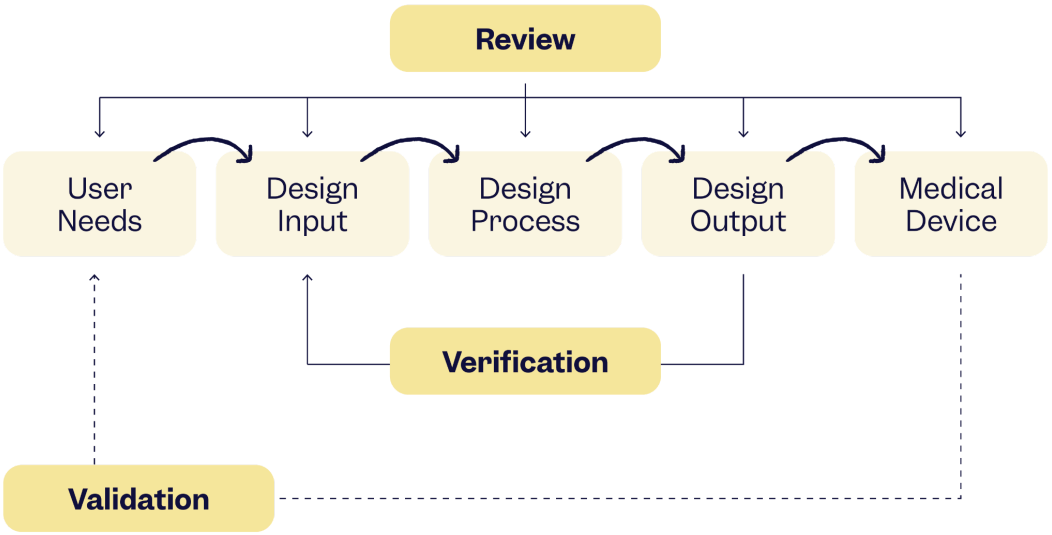
Every step of the process requires documentation and permissions. Getting organized early, using the right tools, and being proactive about the requirements will make the process easier.

These phases typically include:

- Design and Development planning
- Design inputs
- Design outputs

- Design review
- Design verification
- Design validation
- Design transfer
- Design history file
- Commercialization
- Post-market and design changes

The product development process must include all necessary reviews and checks to ensure that all requirements are accounted for logically and that the final product is unaltered and fully traceable.



FDA Design Controls Waterfall Diagram

Scilife supports design and development planning, documentation, review, and traceability across the lifecycle.

Here's how Scilife facilitates the design and development process:

- **Streamlined and automated** - Manage the entire process with a clear workflow. It tracks all aspects of the medical device design control. Scilife guides you through a clear, visual workflow.
- **Interactive traceability matrix** – Add, update, or delete design controls and test runs *right inside the matrix view*. Version comparison and audit trail allow you to compare product versions and keep track of changes.

- **Personalize your display**– Choose between sidebar or dialog view — whatever keeps your flow going.
- **Reports in a few clicks** – Create and export ready-to-share reports with industry best practice templates in just a few clicks.
- **Collaborative** - As a result of its audit trail and traceability matrix, version control, automated notifications, and compliant electronic signatures, quality and engineering teams can maintain constant collaboration and communication.
- **Export project data in multiple formats** – XLSX, CSV, DOCX, PDF… take your pick and share instantly.

The benefits are:

- Guaranteed regulatory compliance
- Errors and delays in product development are avoided thanks to the automated documentation system
- The time-to-market process is reduced by up to 50% through a simplified approval cascade
- Traceability is ensured for maximum oversight and control
- Collaboration is promoted between team members
- Silos of data are eliminated
- Project changes are traced seamlessly

5.5 Risk Assessment

ISO 13485:2016 requires that organizations shall apply a risk-based approach to the control of QMS processes, including product design and development, product realization, supplier selection, software use, CAPAs, etc., in order to avoid unintended consequences.

- Eliminate Excel files. Scilfe manages the entire risk assessment process through a predefined workflow. **Risk assessments are seamlessly moved through mitigation, review, and approval phases**.
- It has an in-built FMEA methodology.
- Scilife's risk assessments can be linked to deviations, non-conformities, CAPAs, or audits in other modules, **ensuring complete data integrity**.
- Following implementation, you can easily configure recurring reviews of risk assessments to ensure effectiveness.

5.6 Supplier Management

As part of ISO 13485:2016 and MDR 2017/75, organizations are required to establish criteria for the evaluation, selection, and control of suppliers based on the supplier's ability to provide products that meet the requirements and their performance.

Monitoring and re-evaluating suppliers is another important part of supplier management. Scilife's Supplier Management module helps you to stay compliant with these requirements. It provides a comprehensive view of the supplier's performance, allowing you to make informed decisions.

An important part of the supplier's quality control is the inclusion of written quality agreements. The manufacturer must discuss and agree with the suppliers on the quality requirements. A formal quality agreement or specification should document all required aspects of production, testing, and control, such as handling, labeling, packaging, and distribution. Here's how we can offer your organization a helping hand:

- Scilife allows you to oversee supplier qualifications and decide whether an audit is needed. With the Audits module, you can **keep track of suppliers, qualifications, and audits in real-time**.
- Qualify or reject your suppliers following **a simple and compliant workflow** according to best cGMP practices.
- Report the most important data of each supplier.
- Execute the Risk Assessment for the Qualification.
- Send a questionnaire to the supplier, collect answers, and certificates.

5.7 Audits

The EU requires that medical devices undergo a conformity assessment, which may include an audit of the manufacturer's Quality Management System (QMS). This assessment usually involves an audit of the manufacturer's QMS and, depending on the type of device, a review of technical documentation on the safety and performance of the device to demonstrate that it is safe and performs as intended.

ISO 13485:2016 requires organizations to conduct internal audits at planned intervals to evaluate the effectiveness of the QMS. Organizations must also take corrective actions to address any identified nonconformities. Finally, organizations must document the results of their internal audits.

With Scilife's Audit solution, **auditing becomes simpler and more efficient**.

- You can quickly identify areas of non-compliance and take corrective action. You can also track the history of previous audits and the status of CAPAs. Gathering all of the necessary information, documentation, and haphazard reports becomes easier and saves you time.
- Manage incoming, outgoing, internal and external audits.
- Define lead auditor, additional auditors, and hosts, even if they don't have a user license in Scilife.
- Generate an audit calendar.
- Configurable finding types are based on criticality. Define if it is mandatory to link them to new or existing CAPAs and Events, or if a Risk Assessment is required.
- Audit's solution integrates seamlessly with events, CAPAs and change Control modules so all the relevant information is linked and easily accessible.

5.8 Measuring Equipment

ISO 13485:2016 requires organizations to have documented procedures for ensuring measuring equipment is qualified, calibrated, and/or verified at specified intervals. If needed, this equipment will need to be adjusted or readjusted, and the actions recorded and maintained.

With Scilife's Equipment solution, you can:

- Keep track of all your qualification, maintenance, and calibration tasks in the same place.
- Ensure that the equipment is ready for inspection and that maintenance and calibration tasks are planned, assigned, and approved consistently.
- Link events to equipment elements to track non-conformities or deviations. The connected event can be created directly from the Equipment Module and full traceability can be maintained.

6. Process Management with configurable workflows

6.1 Configurable Workflow Designer

Quality workflows ensure that organizational processes produce safe, pure, effective, traceable, and reproducible products and services. They prioritize quality and integrate it into manufacturing processes.

With the Scilife Quality Process Designer, you can:

- Customize your quality processes to meet the needs of your organization or specific medical device compliance requirements.
- Create workflows in minutes, with statuses, roles, and permissions defined. You can also create sub-workflows, produce multiple types of fields based on when data is entered, and easily integrate it with other Scilife solutions.
- Benefit from unlimited configurability. This allows users to **quickly adjust to changing regulations and ensure their data is up to date**. It also ensures that the system is always tailored to the user's specific needs.

7. Management

The ISO 13485:2016 standard requires medical device companies to monitor and measure their quality management processes.

To ensure the success of quality management, key performance indicators (KPIs) are essential. These measurable values, which must be specific, measurable, achievable, realistic, and time-based, can be used to track progress towards specific goals and objectives.

7.1 Key Performance Indicators (KPIs)

- Scilife includes KPIs monitoring and reporting capabilities, providing **real-time insights into quality and compliance metrics**.
- This will empower your organization to **proactively identify and address potential issues** before they impact cGMP compliance.
- Equipped with real-time data and insights, your organization can shift its attention from uninspiring, repetitive, and reactionary tasks to high-value work leading to product innovation and impactful improvements.

Other benefits of Scilife over other solutions

Smart Quality

- Scilife Academy offers **free training** on quality trends, regulations, and best practices.
- Through augmented learning methods, **everyone is engaged and inspired to take action**, fueling continuous improvement.
- Smarty is a **Medical Device chatbot** powered by AI that can answer user questions and provide assistance related to this industry.
- With advanced analytics, custom reports, trend analysis, and benchmarking, you will be able to **make the right decisions and improve your performance**.
- Gamification elements built in will dramatically **increase employee engagement** in quality, improving your organization's quality culture.

Validation

In accordance with ISO 13485:2016, applications of computer software must be validated prior to initial use, and as appropriate, after changes.

Validation and data integrity controls must be justified and documented according to the risk assessment of the computer system.

The goal of validation is to ensure that applications, systems, solutions, and/or environments meet intended functionality consistently and reliably.

Scilife uses a **GAMP5 validation** approach for validating the system on the Amazon Web Services (AWS) platform. As part of the validation phase, the Scilife platform is validated for, e.g., standard functionality and workflows in an environment independent of customers. This validated environment for standard functionalities and workflows can be used by your organization if your business process is aligned with the Scilife platform default workflow. A full package of validation deliverables is made available as a validation package with all documents listed **here.**

Doubts?

Let’s talk