Scilife Competitive Advantages in current Good Manufacturing Practices (cGMP)

www.scilife.io

Scilife

Supporting science. Improving life.

Introduction

Scilife offers three products, plus a range of features described in this document. In the highly regulated Life Sciences industry, compliance with **current Good Manufacturing Practices (cGMP)** is essential for ensuring product quality, safety, and efficacy in pharmaceuticals, biotechnology, and medical devices.

Implementing a Smart Quality Management Platform like Scilife can provide numerous competitive advantages for your organization. This document outlines the **key benefits** of Scilife with a focus on cGMP compliance, **addressing the potential challenges** posed by other electronic quality management systems in the market.

What does Scilife offer to current Good Manufacturing Practices (cGMP)?

1. Compliance with cGMP Standards

- Scilife is designed to align seamlessly with cGMP requirements, ensuring that all quality management processes are in line with regulatory guidelines.
- We incorporate appropriate risk management principles to ensure that our products meet the intended use and are compliant with GMP standards.
- Our solutions comply with electronic records, electronic signatures, and audit trail requirements according to **21 CFR Part 11, EU GMP Annex 11,** and **GAMP 5** validation**.**
- We will 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.
- In addition to managing quality, our platform 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

- The **Documents solution** can manage any type of document in accordance with Good Documentation Practices. It stores, classifies, and categorizes any type of document such as:
    - Specifications
    - Standard Operating Procedures (SOPs)
    - Work Instructions (WI)
    - Manufacturing Formulae, Processing, Packaging and Testing Instructions
    - 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, nor 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.
- Documents are approved, signed and dated by appropriate and authorizedd persons. Electronic records, electronic signatures, and audit trail are performed in accordance with **21 CFR Part 11** and **EU GMP Annex 11**.

3.2 Records

- With Scilife's **Records** solution you can create customizable electronic forms that are used with appropriate controls to **ensure the integrity of the record throughout the retention period**. These records provide evidence of actions that will demonstrate compliance with instructions, events, investigations, analysis or manufactured batches, etc.
- A record of the activity is made or completed at the time of the activity, which complies with contemporaneously principle from ALCOA.
- At the time of the activity, records are made or completed and this allows the activity to be traced, allowing the user to read the original information. Where appropriate, the reason for the alteration is recorded.
- 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

Losing one sheet of blank form, such as a worksheet, laboratory analytical record or laboratory notebooks, etc, can have implications for data integrity.
Blank form is a pre-designed document or template that is used for recording, documenting, and managing various types of information and data related to quality, compliance, and processes.

Guidelines recommend Quality units or other document control methods to be used to ensure blank forms are controlled, thus guaranteeing product quality. Without proper control of blank forms, there is a risk of loss, misplacement, or intentional alteration, which can compromise the integrity of data.

In addition, poor data integrity practices can lead to serious cGMP findings and negative consequences for the quality of materials and finished products. Here's how we 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 the tracking down and reconciliation of 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

The periodic review for documents and records can be customized. The platform 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

In GMP-compliant environments, maintaining employee training and competence records is not a choice but a mandate. Manufacturers must establish and maintain a formal training program. This program should ensure that all personnel involved in activities that could affect the quality of the product are trained appropriately.

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

- Our 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 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 Events

Events refer to nonconformities, deviations, complaints, or failures. In order to avoid future deviations, 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 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.
- 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 an 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 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 warning to 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

The control of change is an important part in GMPs and needs to be handled appropriately. Change control is a process where qualified representatives review proposed or actual changes that might affect 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 the Equipment solution so you can add a cost estimate.
- The Project Management tool for Change Control tasks sends automated notifications to the responsible people and warning to due dates.

5.4 Risk Assessment

It is important to identify potential impacts on product quality, pharmaceutical quality systems, documentation, validation, regulatory status, calibration, maintenance, and any other system when evaluating planned changes in order to avoid unintended consequences and plan for validation, verification, and requalification.

- Get rid of 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 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 effectivity.

5.5 Supplier Management

As part of the pharmaceutical quality system, suppliers of starting materials should be selected, qualified, approved, and maintained. Supervisory levels should be proportionate to the risks posed by the materials, taking into consideration their source, manufacturing process, supply chain complexity, and intended use in the medicinal product.

As part of the process of setting quality requirements for the starting materials, 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 cGMPs 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.

5.6 Audits

To confirm compliance with good manufacturing practice and good distribution practice, audits should be conducted at active substance manufacturers and distributors. It is the responsibility of the holder of the manufacturing authorisation to confirm that compliance is being met either directly or through an entity acting on his behalf under a contract.

With Scilife's Audit's 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 audits and the status of suppliers. Gathering all of the necessary information, documentation, and haphazard reports becomes easier and saves you time.
- Manage incoming, outgoing, internal and external audits.
- Define the audit as internal, scheduled, or for cause.
- 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.

5.7 Equipment

Equipment used in manufacturing and Quality Control must be designed, located, and maintained to fulfill its intended purpose. Repair and maintenance operations shouldn't compromise the quality of products.Measurement, weighing, recording, and control equipment should be calibrated and checked at defined intervals. Adequate records should be 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 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 cGMP 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

cGMP demands that Key Performance Indicators (KPIs) align with a company's goals, and are well defined and quantifiable. The KPIs should be specific, measurable,

achievable, realistic, and time-based. Manufacturing companies should use KPIs to improve quality, customer satisfaction, productivity, and lower costs. Moreover, KPIs should be regularly monitored and updated to ensure they remain relevant and efficient.

7.1 Key Performance Indicators (KPIs)

- Scilife includes KPI 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 organizations can shift your attention from uninspiring, repetitive, and reactionary tasks to high-value work leading to product innovation and impactful improvements.
- **Implementation of AI** within the KPI analytics to predict based on your historic data and performance within your QMS, helping you **prevent** things before they happen.

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 inbuilt will dramatically **increase employee engagement** in Quality improving your organization's Quality Culture.

Validation

In accordance with GMP, applications must be validated according to the Computer System Validation (CSV) activity. 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 :)