Scilife Competitive Advantages in Good Distribution Practices (GDP)

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Introduction

According to the European Medicines Agency (EMA), Good Distribution Practice (GDP) describes the minimum standards that a wholesale distributor must meet to ensure the quality and integrity of active substances and medicinal products are maintained throughout the supply chain: storage, transportation, and handling of medicinal products.

GDP compliance ensures that:

- Medicines in the supply chain are authorized in line with European Union (EU) legislation.
- Medicines are maintained in the right conditions at all times, including during transportation, during which contamination by or of other products is avoided.
- There is an adequate turnover of stored medicines.
- The right products reach the right recipient within a satisfactory period.

Implementing a Smart Quality Management System like Scilife can provide numerous competitive advantages for your organization, addressing safety, security, and customer service, efficient management of processes and documentation, compliance with regulatory requirements, and streamlined workflows.

This document outlines the **key benefits** of Scilife with a focus on Good Distribution Practices according to:

- EU Directives 2001/83/EC and 2001/82/EC,
- Guidelines on GDP of medicinal products for human use (2013/C 343/01),
- Guidelines on principles for active substances for medicinal products for human use (2015/C 95/01),
- Directive 2011/62/EU amending directive 2001/83/EC regarding the prevention of the entry into the legal supply chain of falsified medicinal products

Scilife can help ensure the quality of medicinal products at all levels of the supply chain, facilitate compliance with GDP guidelines, and enable the implementation of quality risk management and corrective and preventive actions.

Additionally, Scilife can provide benefits such as time and cost savings, especially when it comes to data integrity, compliance, and streamlined workflows.

Guideline on GDP of medicinal products for human use (2013/C 343/01)

Taking a closer look at the EU's ten 'chapters' of GDP compliance is the best way to figure out the key principles of GDP.

Chapter 1: Quality Management

Wholesale distributors must establish and maintain a robust, well-documented quality management system to ensure continuous compliance with GDP requirements.

Key requirements:

- The quality system and its activities should be fully **documented** and its **effectiveness monitored** (chapter 1.2 2013/C 343/01).
- A **change control system** should be in place. It should incorporate quality risk management principles, and be proportionate and effective (chapter 1.2 2013/C 343/01).
- **Records** must be made contemporaneously (chapter 1.2 2013/C 343/01).
- **Deviations** from established procedures must be documented and investigated.
- **Corrective and Preventive Actions (CAPAs)** must correct deviations and prevent them in line with the principles of quality risk management.
- The quality system should extend to the control and review of any **outsourced activities** related to the procurement, holding, supply, or export of medicinal products (chapter 1.3 2013/C 343/01).
- There must be a formal **process for reviewing the quality system** periodically (chapter 1.4 2013/C 343/01).
- **Quality risk management** should be applied to the evaluation of the risk to quality, using ICH Q9 (chapter 1.5 2013/C 343/01).

Scilife solution to quality management requirements:

- Scilife is a structured eQMS that helps to ensure your business operates efficiently and effectively.
- GDP requires organizations to establish a **robust, well-documented QMS** that outlines the processes, procedures, and responsibilities related to good distribution practice. Your quality policies, quality manual, quality

objectives, documented procedures, and records can be described and maintained in our **Document Control solution**.

- Scilife allows users to **create any quality event instantly on any device, including smartphones and tablets**, reducing the risk of forgetting or missing an important quality event. This ensures that 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 a root cause analysis and impact assessment during the event investigation phase, you can upload (multiple) files as proof anywhere during the event workflow.
- 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.

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 Scilife facilitates these processes:

- Scilife offers a workflow for implementing CAPAs resulting from complaints and other 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 warnings about 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.

GDP requires that organizations apply a **risk-based approach** to the control of QMS processes, including product design and development, product realization, supplier selection, software use, CAPAs, etc., to avoid unintended consequences.

- Eliminate Excel files. Scilife 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.

There is no doubt that **changes** have a significant impact on GDP, including internal processes and changes to avoid complaints and repeated quality events.

GDP requires procedures for **change control**. 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 distribution of products, and 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 with Scilife:

- 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 warnings about due dates.

Chapter 2: Personnel

Personnel of wholesale distributors should be competent to perform all tasks assigned to them. Therefore, it is necessary to train and qualify personnel to handle and distribute medicinal products safely and legally.

Key requirements:

- There must be a **responsible person** with the right qualifications to be continuously contactable (chapter 2.2 2013/C 343/01).
- There must be a **job description** of the responsible person defining their authority to make decisions about their responsibilities. Some of their responsibilities are implementing and maintaining (chapter 2.2 2013/C 343/01):
    - A quality management system;
    - Training programs;
    - Managing complaints recalls operations;
    - Approving suppliers, subcontracted activities, and customers;
    - Ensuring self-inspections are performed;
    - Keeping records of activities;
    - Deciding the disposition of returned, rejected, recalled, or falsified products
- All employees should have **job descriptions** that clearly define their responsibilities and roles (chapter 2.3 2013/C 343/01)
- All personnel involved in wholesale distribution activities should be trained on the requirements of GDP, receive training, and maintain their competence through **regular training** (chapter 2.4 2013/C 343/01).
- All **training** should be kept, and the **effectiveness of training** should be periodically assessed and documented (chapter 2.4 2013/C 343/01).

Scilife solution to personnel requirements:

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.

Chapter 3: Premises and Equipment

Wholesale distributors must establish standards for premises, storage installations, access control, and equipment for temperature and environmental control.

Key requirements:

- **Procedures** should be in place for all activities
- **Equipment should be maintained, and calibrated** at defined intervals based on a risk and reliability assessment (chapter 3.3 2013/C 343/01)
- Data should only be entered into the computerized system or amended by persons authorized to do so. Data should be secured, protected, and backed up against accidental or unauthorized modifications (chapter 3.3 2013/C 343/01)

Scilife solution to equipment requirements:

GDP requires organizations to have documented procedures for ensuring measuring equipment is qualified, calibrated, and/or verified at specified intervals. 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.

Chapter 4: Documentation

Key requirements (chapter 4.2 2013/C 343/01):

- Documentation (written procedures, instructions, contracts, records, and data) should be readily available/retrievable.
- Procedures should be approved, signed, and dated by the responsible person, and by appropriately authorized persons.
- Alterations to documentation should be signed, and dated, and the reason should be recorded.
- Each employee should have ready access to all necessary documentation for the tasks executed.
- Documents should be reviewed regularly and kept up-to-date. Version control should be applied to procedures.
- Superseded or obsolete procedures should be removed from workstations and archived.

Scilife solution to Documentation:
Scilife includes three tools for managing documentation: **Documents**, **Records**, and **Print & Reconciliation**.

Documents

- Scilife's **Documents Control module** can manage different types of documents. Scilife eQMS stores classifies, and categorizes any type of document such as:
    - Specifications
    - Standard Operating Procedures (SOPs)
    - Work Instructions (WI)
    - Protocols
    - Reports
    - Technical Agreements

- The creation of Document Types allows corporate templates to be used and most settings to be predefined.
- **MS Office live-edit:** Documents can be edited with MS Office (Word, Excel, and PowerPoint) within Scilife without having to download/upload documents. 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, the date and time of the signature, and the meaning of the signature (edition, review, approval, etc.)

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 GDP 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.
- Data or activities can be registered in electronic records throughout the supply chain lifecycle.

Print & Reconciliation

Data integrity is a critical aspect of the supply chain lifecycle, ensuring that the data generated is complete, consistent, accurate, and reliable.

There are still some organizations using manual 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 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.

Periodic Review of Documents

Keeping documentation up to date is an important part of document control. In GDP, there is no specified period for periodic reviews, but you must ensure that data is accurate and compliant with applicable regulations and standards.

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.

Chapter 5: Operations

Key requirements:

- Appropriate qualification and approval of suppliers should be performed before any procurement of medicinal products. This should be controlled by a procedure and the results documented and periodically rechecked (chapter 5.2 2013/C 343/01)
- For all supplies, a document (e.g. delivery note) must be enclosed stating (chapter 5.2 2013/C 343/01):
    - the date;
    - name and pharmaceutical form of the medicinal product;
    - batch number at least for products bearing the safety features;
    - quantity supplied;
    - name and address of the supplier:
    - name and delivery address of the consignee and applicable transport and storage conditions:
    - Records should be kept so that the actual location of the product can be known.

Scilife solution to Operations:

- Scilife's **Supplier Management solution** 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 GDP practices.
- Report the most important data of each supplier.

- Execute the Risk Assessment for the Qualification.
- Send a questionnaire to the supplier, and collect answers and certificates.

Chapter 6: Complaints, returns, suspected falsified medicinal products and medicinal product recalls

Key requirements:

- Complaints related to the quality of a medicinal product and those related to distribution should be recorded. Any complaint should be thoroughly investigated to identify the origin of or reason for the complaint. If necessary, appropriate CAPAs and follow-up actions should be taken after the investigation and evaluation of the complaint, including where required notification to the national competent authorities (chapter 6.2 2013/C 343/01).
- A procedure for informing competent authority about any falsified medicinal product or suspect to be falsified, and recalls, should be in place (chapter 6.4 2013/C 343/01).

Scilife solution to complaints:

Complaints are a type of quality event. Complaints and other quality events must be identified, documented, investigated, and addressed in a timely and compliant manner. See the solution we propose above for Chapt 1 Quality Management.

Chapter 7: Outsourced Activities

Key requirements:

There must be a written contract between the contract giver and the contract acceptor which establishes the duties of each party (chapter 7.1 2013/C 343/01).

Scilife solution to outsourced activities:

Scilife's **Documents Control module** can manage contracts and technical agreements with an approval cascade and customized user permissions.

Chapter 8: Self-inspections

Key requirements:

- A self-inspection program should be implemented covering all aspects of GDP and compliance with the regulations, guidelines, and procedures within a defined time frame. They may be divided into several individual self-inspections of limited scope (chapter 8.2 2013/C 343/01).
- All self-inspections should be recorded in reports. Corrective and preventive actions (CAPA) should be documented and followed up (chapter 8.2 2013/C 343/01).

Scilife solution to self-inspections:

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.
- With the same solution, you will 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.

Chapter 9: Transportation

Key requirements:

- A procedure should be in place for investigating and handling temperature excursions (chapter 9.1 2013/C 343/01).
- There should be written procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions (chapter 9.2 2013/C 343/01).

- Equipment used for temperature monitoring should be maintained and calibrated at regular intervals at least once a year (chapter 9.2 2013/C 343/01).

Scilife solution to transportation:

- Scilife's **Documents Control** module manages procedures for any operation and is readily accessible at the point of use.
- The **Equipments** module keeps track of all your qualification, maintenance, and calibration tasks in the same place. This ensures that the equipment is ready for inspection and that maintenance and calibration tasks are planned, assigned, and approved consistently.

Chapter 10: Specific provisions for brokers

Key requirements:

The quality system of a broker should be defined in writing, approved, and kept up-to-date (chapter 10.2 2013/C 343/01).

- The quality system should include an emergency plan for the effective recall of medicinal products from the market (chapter 10.2 2013/C 343/01).
- Any member of personnel involved in the brokering activities should be trained in the applicable EU and national legislation and the issues concerning falsified medicinal products (chapter 10.3 2013/C 343/01).

Scilife solution to specific provisions for brokers:

- The **Document Control module** can manage all documents your brokers need.
- The **training module** will track all training activities, evidence, and learning materials used to train your brokers.

What does Scilife offer to wholesale distributors?

Scilife offers a Smart Quality Management System (QMS) for wholesale distributors of active substances and medicinal products, providing various benefits such as digitizing processes, automating document control and record management, automating training, navigating audits, managing quality events, and hitting key performance indicators.

The QMS also has some features such as automated notifications, reminders, and user rights management to simplify regulatory compliance and pass audits and inspections quickly and easily.

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

In addition to managing quality, Scilife promotes **collaboration**, **communication**, **consistency**, and **continuous improvement**.

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.

Plus, there's more! By empowering everyone to take ownership of quality, Scilife builds a culture of engagement, and responsibility, and reduces compliance risk.

But that's not all! By **accelerating time to market by 30 percent**, your 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.

By implementing Scilife, your organization can improve quality traceability, streamline quality workflows, and achieve compliance with EU GDP Guideline 2013/C 343/01.

Compliance with EU GDP Guideline 2013/C 343/01

- Using Scilife, you can be assured that all quality management processes comply with EU GDP Guideline 2013/C 343/01 requirements.
- We incorporate appropriate risk management principles to ensure that our products meet the intended use and are compliant with EU GDP Guideline 2013/C 343/01 requirements.
- 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**.

Management

GDP requires a formal process for reviewing the quality system periodically.
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 toward specific goals and objectives.

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 organizations can shift your 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.
- 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 :)