

COI-PharmaSuite 2.1

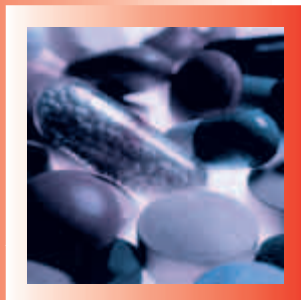


GxP-Dokumentation The Benefit

■ The Challenges posed by legal and official Requirements

In the field of GxP, today the life science industry is confronted with constantly increasing numbers of official requirements with regard to documentation. The market is additionally demanding shorter reaction times whilst retaining high quality standards.

The European Union and the competent authority in the USA, the FDA, have passed further guidelines and laws, compliance with it will be monitored more closely. Violations of these requirements are now avenged with more severe measures.

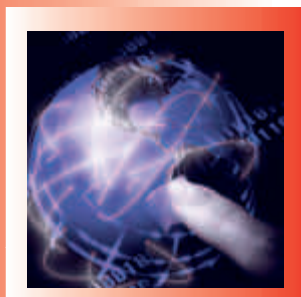


■ The Solution

In collaboration with pharmaceuticals companies COI GmbH has developed the COI-PharmaSuite product line. It is specially tailored to the requirements of the pharmaceuticals industry. COI-PharmaSuite complies with many international standards such as 21 CFR Part 11, EU GMP Vol. 3 and 4 Annex 11, ISO 9001 and WHO.

COI-PharmaSuite enables

- Document creation
- Document review
- Document approval
- Document security
- Company-wide access to documents



With COI-PharmaSuite, information is available to every employee at any time. The only restriction is the user right to the information: only those with entitlement can display or edit a document.

The component based design of COI-PharmaSuite supports the gradual implementation into a global system.

■ GxP-Documentation – Simple & easy!

Quality of documentation in the field of GxP and related costs can be effectively reduced by utilizing an electronic document management system (eDMS). The system enables more efficient preparation, handling and archiving of extensive volumes of documents. Complete life cycles and workflows for approval documents, SOPs, quality and management manuals and officially required manufacturing documentation are contained in the eDMS.

The COI-PharmaSuite module GxP-Documentation supports you in the composition, structuring and implementation of the required documentation. It is a tool for keeping relevant documents updated and providing them to employees.

■ Reliability through Master Templates

For optimal support, COI-PharmaSuite already contains the most important master templates and by request further automatism for the composition and life cycle management of GxP-compatible documentation.

COI-PharmaSuite

- Simplifies the control and monitoring of processes
- Supervise all workflow tasks restrictively and continuously
- Adapts to the individual requirements
- Is the tool for modern and flexible document management in the regulatory field

Module Overview

The flexible composition of COI-PharmaSuite is reflected in the GxP-Documentation module. You have the possibility to utilize individual modules one by one, in combination or individually.

Therefore, you only utilize what you really require or you really want to start with!

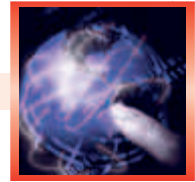


■ Base-Module

Quality data management documentation is one of the core elements of GxP-compatible documentation. The GxP-Documentation base module forms the fundament for the other modules: GMP (Good Manufacturing Practice), GLP (Good Laboratory Practice) and GCP (Good Clinical Practice). These can be interlinked according to requirements or project planning.

The following hierarchical structures can significantly disburden your future work

- Quality and environment management manual
- Standard work instructions
- Standard procedural instructions
- Standard operating instructions
- Validation and qualification documentation
- Training documentation
- Audit documentation
- Tests (not GLP)
- Approval documents
- Drawings



■ GMP-Module

Compliance with the applicable guideline on Good Manufacturing Practice (GMP) is a minimum standard from the perspective of the authorities.

This requirement has to be evidenced by written documentation of procedures and methods. If the documents are inadequately, incomplete or do not correspond to daily practice, the preparation will be nullified, despite outstanding quality.

The following standards are included in the GMP-Module

- Standard Operation Procedures SOPs
- Specification
- Manufacturing regulations
- Processing regulations
- Packaging regulations
- Procedural specifications
- Protocols
- Stabilities
- Batch documentation
- Failure Investigation FI
- Change Control CC
- Out of Specifications OOS
- Manufacturing instructions
- Batch Record Review BRR
- Sampling plans
- Raw data sheets
- Test instructions
- Audit trail

■ GLP-Module

The requirement of seamless tracking of GLP tests according to the motto "not written, not done" obliges full documentation and archiving of trials. However, implementation of these principle legal stipulations frequently fraught with problems in practice.

The combination of our base module and the GLP-module enables plain, structured and documented planning, execution and reporting of GLP tests.

The following issues are already taken into consideration in the GLP module

- SOPs
- Organization and personnel of testing facility
- Quality assurance program
- Rooms and facilities
- Devices, materials and reagents
- Testing systems
- Test and reference items
- Tests
- Measuring equipment
- Samples



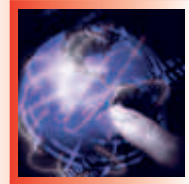


■ GCP-Module

Carrying out clinical trials is a particularly sensitive phase of product development or life cycle management. It ranks among the most costly and normally most time-consuming phases. Successful completion is decisive for approval or indication extension in the case of, e.g. medicines and therefore for the success of all previous development phases.



Even insignificant failures in the planning, execution and evaluation of clinical trials can have dramatic consequences. For example, inconclusive results can lead to the delay of a market launch or even a project halt.



In order to prevent this type of situation, use our GCP-module for the planning and execution of clinical trials with structured documentation on the basis of ICH E6. At the same time you keep up with the requirements specified in GCP-guidelines.

- SOPs
- Trial Master File
- Trial Center File
- Trial Investigator File
- Add-on Study Reports according to ICH Study Trapping File

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