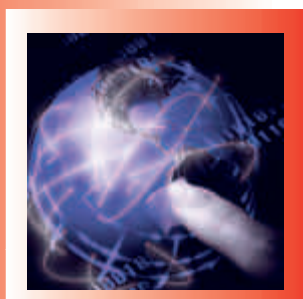


COI-PharmaSuite 2.1



Regulatory Affairs The Benefit

COI-PharmaSuite enables pharmaceutical companies to handle complex documentation and workflow in the process of managing Regulatory Affairs and all GxP-related documentation (specifications, instructions, records) which are produced and kept in different departments, including Regulatory Affairs, QA, QC, R&D or production.

■ Efficiency benefit in

- Workflow
- Economic efficiency
- Reliability of documents
- Archiving capacity
- Scalability

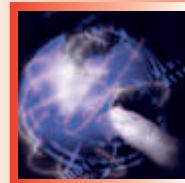
■ Return On Investment

- Cost reduction by the administration of organization-internal knowledge (mental property).
- Cost reduction by the care of the integrity of contents.
- Reduction of the actual time-to-market by optimization of business processes.
- Competitive advantage of simple and extended access to knowledge and information within the enterprise
- Consolidation of documentation in the context of product liability connected with the quality guidelines ISO 9000/2001 as well as GxP-Guidelines
- COI-PharmaSuite clearly simplifies validation and reduces costs – one validation for integrated archive, document and workflow management as well as publishing
- Increase fair market value

■ e-Submissions

COI-PharmaSuite is a software which supports the management, assembly and publishing of the electronic Common Technical Document (eCTD) for fast, reliable and compliant e-submissions.

- Choosing the right (electronic) submission solution is a critical success factor in managing the product pipeline
- Reducing submission “hiccups” leads to faster approval by the regulating authorities, maximizing the life of a drug and leading to enhanced profitability
- COI-PharmaSuite streamlines the approval processes, reducing time-to-market even further



■ International Compliance with

- Council Decision 90/683/EEC
- Directive 91/356/EEC
- GxP-Guidelines
- German drug law (AMG)
- German product liability law
- Requirements for complete traceable proof lifecycle management of documents

■ Revision secure long-term Archive

■ Managing critical Information and enterprise-wide Documents

Complete lifecycle management for regulatory documents and processes such as policies, standard operating procedures, corrective and preventive actions, and work instructions. All documents, regardless of document type, are handled from collaboration to document approval through archiving.

COI-PharmaSuite provides complete change control while automating document routing, approval and distribution is done over the corporate intranet so that users always have the right documents at their fingertips.

■ Collaboration

The ability to collaborate with individuals and departments enterprise-wide is crucial to increase efficiency and improve operating costs. Users are able to add, collect, revise, annotate and automatically compare document changes as they flow through the collaboration progression. Processes are automated and streamlined such as corrective and preventive action, engineering change, failure analysis and work instructions.

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