

# COI-PharmaSuite 2.1



## RegulatoryAffairs Standard Solutions for Pharmaceutical Life Cycle Management

Year 2003 was a turning point in Regulatory Affairs in the Pharmaceutical Industry. Now the obligation is to provide submissions in CTD or eCTD format. Is your organization ready?

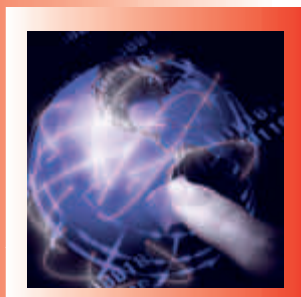
Are you currently looking for conclusive and vital information on how to carry through the migration to CTD, eCTD and e-Submissions? Are you looking for a convenient solution?

The module RegulatoryAffairs supports the collection, combination, assessment, assembly and preparation of documents in combination with dossier publishing according to the requirements of the regulatory authorities.



Usually each department, such as toxicology or pharmacology, prepares documents in its own way. Beside internal documents, there are a number of in-bound and out-bound documents such as ordinary mail, email and other important correspondence. The number of regulatory submission dossiers can expand to several thousand, whereas individual dossiers can comprise tens or even hundreds of thousands of individual documents.

Regulatory dossiers are undoubtedly the most complex documents in the pharmaceutical industry.



COI-PharmaSuite is an application specifically developed to meet the requirements of the pharmaceutical industry operating in a multi-cultural and multi-lingual environment and dealing with regulatory affairs management, including

- Support of multiple dossier templates including eCTD
- Provision for assembly and maintenance of dossiers
- Audit trail and traceability for submission procedures
- Audit trail and traceability for the lifecycle of documents comprised in the dossier
- Usage of XML definitions of document types
- Facilitation of change control and deficiency management
- Digital signatures
- Electronic submission of documents via integrated module
- Scanning/bulk import to the file server
- Full security and access control

COI-PharmaSuite is in line with the requirements of the FDA regulation 21 CFR Part 11 and GMP-Guidelines.

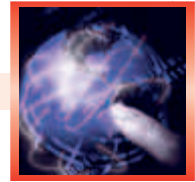
## ■ Marketing Authorisation – A complex Procedure

Pharmaceutical development – a lengthy and cost-intensive process – crucially long-winded for the success of each pharmaceutical company.



The average development time for a new medicine can last up to 10 years and the dossier can increase to up to 500.000 pages or more.

A central component of each approval is the documentation and archiving of all reports – from the first document to the most recent amendment.



COI offers with the module RegulatoryAffairs of its product COI-PharmaSuite a ready to run solution – independent of IT-environment (UNIX, LINUX or Windows) and according to the guidelines of quality management, i.e. GMP-Guidelines and 21 CFR Part 11.

This industry-specific software enables a simple, format-independent collection and administration of all documents, which are compiled in the course of the pharmaceutical permission process and all documents developed during the lifecycle of the pharmaceutical product. The consistent and central data collection as well as the avoidance of formal errors – one of the principal reasons for the refusal of acceptance or delay of many licence notices – not only leads to the reduction of costs and a rationalization of the internal operational sequence. Also it offers the option of a clearly reduced time-to-market for new products.



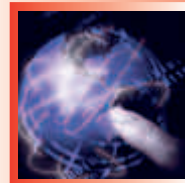
The solution includes all necessary national and international codes, e.g. to CTD, NtA and, with a new add-on module, is ready for electronic submission as required by the ICH eCTD specification.

At any time, country-specific variants can be generated and/or developed synchronistic. Besides version administration the module RegulatoryAffairs has a comprehensive right and role concept, ensuring data security during the entire administrative process. In addition interfaces for digital signature and encryption are integrated.

On legal grounds all applicants have to submit special parts of the documentation electronically to the BfArM (Federal Institut for Drugs and Medical Devices). With the add-on 'AMG-EV-Submission' COI offers a feature for a quick and easy compilation of the stated documents according to the Ordinance on Submission of Documents within Licensing and Renewal Procedures for Medicinal Products.

## ■ Publishing

The integrated publishing component provides hardcopy versions with the automatic production of XML structures in accordance with the ICH eCTD specification.



## ■ Integration

Due to its modular structure COI-PharmaSuite offers the option for subsequent extension to centralized archiving, document and workflow management. The system can fit into existing and future IT and organisational structures. For systems such as SAP® R/3® or mySAP.com® there are various optional interfaces available. As well as archiving of emails from Microsoft Outlook® and Lotus Notes® or of Microsoft Office® documents.

COI's lifecycle approach is outstanding. It corresponds to the requirements of the 21 CFR Part 11 guideline, clearly simplifying and reducing the cost of validation.

COI will come up with new standard solutions soon

- module for the production of leaflet
- module for the lifecycle of drug development and study documents – also compliant to the GxP-Guidelines
- module for E2C
- module for E2D

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