INFOTEHNA Beyond Compliance.

SubmissionExpert™

INFOTEHNA **myPharma**Expert™ Suite solution

EFFICIENT DRUG REGISTRATION PROCESS BASED ON DOCUMENT MANAGEMENT

In today's extremely complicated regulatory environment, which is becoming even more complicated by the hour, it is no longer possible to meet challenges of tomorrow with yesterday's tools. Mountains of paper, the brand of every regulatory affairs department for so long, are bound to disappear. In the new, mostly electronic environment, the quality of a software solution will increasingly become the comparative advantage on the journey for a new drug , from the initial idea to eventual release into the market.

Although Electronic Document Management System (EDMS) is implicitly more suited to registration activities than any paper system, there are few requirements that each system implemented in the pharmaceutical environment has to fulfil. Most of them are based on GxP regulations, but there are some that are connected with underplaying technology, the most well known being the FDA 21CFR11 regulation of electronic records and electronic signatures. In order to be successfully employed in the pharmaceutical environment, any EDMS has to fulfil all of those requirements. **Submission**Expert™ is one of the few that is fully compliant with all the requirements.

SubmissionExpert™ is part of INFOTEHNA **myPharma**Expert™ Suite developed for Regulatory Affairs and features:

TRANSPARENCY

of the whole process of creation and document management with the ability of handling only the current and valid versions of documents and dossiers on one hand, and on the other, access to the history of every document and dossier in the system.

COOPERATION

among departments is fully supported. **Submission**Expert™ enables RA to create, manage and publish dossiers comprising of documents from different departments, locations and countries.

AVAILABILITY AND ACCESS CONTROL

to all users of the company information system using standard web browser interface and providing full security.

DOCUMENT CONTROL

is implemented and document lifecycle is available for all documents comprised in the dossier with automatic prompting and reporting. The lifecycle management of the submission means an ability to incorporate different submissions of regulatory information during the lifecycle of a drug (like new application, supplementation after questions, variations, etc.) into a single accessible system.

FEATURES

- Comprehensive Submission Lifecycle Management
- Integrated Content Management
- Scan/Input Capture & Imaging
- Implementation of Formal Document Lifecycles
- Build-in support for National, Centralized, Decentralized and Mutual Recognition Procedures
- Preconfigured Registration Dossier Templates for CTD, NDA, IND and other Country Specific Structures
- Assembly & Submission Publishing in PDF and eCTD Format
- CTD (PDF) and eCTD Publishing from the Same Structure

BENEFITS

- Totaly Integrated Solution for R&D Operations
- Lower Total Cost of Ownership
- Improved Efficiency
- Increased Collaboration
- Validation Ready

INFOTEHNA GmbH
T: +49 89 54 84 2920

INFOTEHNA Group LLC
T: +386 7 393 06 00 / sales@infotehna.com

INFOTEHNA Inc.
T: +1 312 321 6400

INFOTEHNA RO
T: +34 91 372 83 99 / 84 00

INFOTEHNA RO
T: +90 312 286 14 09

INFOTEHNA RO
T: +91 22 217 211 36

WWW.INFOTEHNA.COM

ROLE DEFINITIONS

with work task distribution and workflows are implemented. **Submission**Expert™ accommodates the ability to allocate different roles to the people who work within a team. Among other things, it can be decided who is the coordinator of the dossier compilation, who is the creator of any of the needed documents, who has the privilege to see every single document in every dossier etc.

DOCUMENT DISTRIBUTION

covers delivering documents to all participants in the process and to other users of corporate information system (Packaging, Labeling, Package information leaflet, SmPC, etc.). **Submission**Expert™ opens the system to other contributors of documents in the company enabling them to deliver documents online.

CHANGE MANAGEMENT AND CHANGE CONTROL

are facilitated. **Submission**Expert™ covers streamlining, auditing, reporting, tracking business processes and status of the document in connection with work tasks that have been conducted.

RE-USE OF DOCUMENTS

is extended to the compilation of a new dossier in the chosen format in the shortest possible time. **Submission**Expert™ provides an audit trail with the overview of different versions of any single document and variations of dossiers.

SubmissionExpert™ is a solution specially designed for the needs of Regulatory Affairs in the pharmaceutical industry. In addition to taking care of each individual document lifecycle, registration dossiers are prepared as virtual documents, ready to be published in either CTD, eCTD format or other country specific submission formats (CIS region, ASEAN countries, etc.). Registration dossiers are themselves also subjected to lifecycle management and allow customizable reports to be extracted from the stored attribute information. **Submission**Expert™ allows attributes from other source documents and applications to be imported into the dossier while still working with the original documents.

SubmissionExpert™ is based on INFOTEHNA's proprietary application **myProcess**™, which ensures the compliance with all regulatory requirements, including 21CFR11. In addition, **myProcess**™ is common to all of the other INFOTEHNA Expert Solutions ensuring 100% cross-solution compatibility and integration. In this way, documents originating from one solution can be reused seamlessly in an other and thus all cross-departmental company information contained in the system can be used as the basis for departmental or even CxO level corporate reporting.

SubmissionExpert™ is part of **myPharma**Expert™ Suite, **ALL-IN-ONE** software that contains **INTEGRATED SOLUTIONS** for:

- **RESEARCH & DEVELOPMENT** (**R&D**Expert™)
- **QUALITY ASSURANCE & QUALITY CONTROL** (**Quality**Expert™)
- **REGULATORY AFFAIRS** (**Submission**Expert™)
- **PHARMACOVIGILANCE** (**PhV**Expert™)
- **MANUFACTURING** (**Manufacturing**Expert™)

INFOTEHNA Beyond Compliance.

SOME OF OUR USERS

ratiopharm (TEVA)

Pliva (TEVA)

Krka

Lek (SANDOZ)

Hemofarm Group (STADA)

Richter Gedeon

Torrent Pharmaceuticals

Paddock Laboratories Inc

Egis (SERVIER)

Hospira

Belupo

Veropharm

Adamed

BioPhausia AB

G.L. Pharma

Bosnalijek

Grindex

JGL

Jelfa

Alkaloid

Maneesh Pharmaceuticals

Sanitas

Genera

Farmak

Antibiotic(Balkanpharma)

Ziaja

and many more...

OUR PARTNERS

EMC² where information lives®

Microsoft®

ORACLE®

adlibsoftware®

WWW.INFOTEHNA.COM