



Challenges

- › To profit by eCTD as soon as possible
- › To extend the advantage from early EDMS use
- › To benefit regarding submission management and archiving issues

Solution and Results

- › eCTDmanager: Significant improvement concerning regulatory control and transparency of product lifecycle plus Better co-operation with affiliates and more efficiency in DCP and MRP submissions
- › RLPmanager: integration of RLPmanager results in highest level of efficiency
- › EURS is Yours: Very efficient validation process for eCTD dossiers and most efficient protection from technical rejection



Case Study

eCTDmanager



Meda Pharma GmbH & Co. KG, the German subsidiary of the leading Swedish pharmaceutical company Meda, provides a large spectrum of both prescription and over the counter drugs to the German market. Its focus areas for the German market lie on therapies for respiratory and dermatological diseases, on the cardio-vascular and central nervous system plus pain.

Challenge

Benefitting regarding submission management and archiving issues

"As already 1995 the company has started to administer all regulatory documents using an EDMS (Documentum®) it was quite logical that based on our document repository we tried to profit by the regulatory innovation called eCTD as soon as possible.

The strategy was to extend our advantage resulting from the early EDMS use via electronic dossier creation. We were sure to benefit regarding submission transparen-

cy and archiving issues, aspects which in the long run have an impact on resources," explains Jaroslava Paraskevova, Head of Documentation & Information Services of Meda Pharma.

"2005 after a careful market examination and a subsequent pilot project including test installations of 2 eCTD tools we selected eCTDmanager. The system convinced by high score superiority in the testing and the best fitting to our needs."

Solution and Results

Significant improvement concerning regulatory control and transparency of product lifecycle



Registration Management



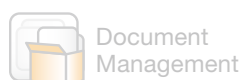
Submission Management



Labeling Management



Pharmacovigilance Management



Document Management



Project Management

EXTEDO's suite of e-Regulatory solutions can be used as a comprehensive solution or as 'building blocks'. eCTDmanager, EXTEDO's scalable, 'all-in-one' electronic submission management system for both eCTD and other electronic and paper submissions, is used as a key building block in many pharmaceutical companies such as Meda Pharma. The tool offers both flexibility and security in building, viewing, validating, publishing and compiling electronic and paper submissions. With products sold in approximately 120 countries this software offers Meda Pharma concrete advantages, creating benefits such as time and cost savings.

In addition a very important aspect is a significant improvement concerning the

regulatory control and transparency of product lifecycle. Beyond that a local eCTDmanager use (several EU countries) facilitates a better co-operation with affiliates and more efficiency in DCP and MRP submissions.

Dedicated to increasing efficiency, MedaPharma decided to also employ the eCTDmanager Suite option RLPmanager. RLPmanager primarily supports clinical departments for pre-publishing work such as studies or reports. Using eCTDmanager and RLPmanager in an integrated environment enables the highest level of efficiency.

Available reports or studies including inter- and intra document hyperlinks can easily

"Particularly valuable is also the EURS is Yours solution which enabled us to establish a very efficient validation process for our eCTD dossiers prior to submission to the authorities. A speedy powerful control using an assessor-like review is extremely helpful during the short timeframe between the dossier finalization and the official submission date. Such final check is rather important as it prevents from technical rejection and this saves time and money."

"All things considered eCTDmanager proves to be the key tool regarding our cross-national regulatory co-operation in Europe. Corresponding to the long-run strategy of Meda Pharma to involve all local affiliates in a centralized eCTDmanager use we expect further substantial benefits,"
underlines Jaroslava Paraskevova.

be 'dragged and dropped' from RLPmanager into eCTDmanager and reused for different purposes. Using the integrated check for the new reports/studies easily facilitates changes to the reports or studies during the lifecycle.

EXTEDO's EURS is Yours solution created additional synergies and benefits for Meda Pharma. EURS is Yours, a multi-functional software solution that serves as an overall eCTD validation, retrieval, view and review software, saves time as it pro-

vides a detailed report on whether a submitted eCTD-based application conforms with the official interpretation of the eCTD format.

Specifically designed for the validation, acceptance, import, view, review and maintenance requirements of the EMA and associated national competent authorities, EURS is Yours is today used from the industry as well. Especially to have the same view as the authorities is key for agency communication procedures.

About us

EXTEDO is the key solutions and services provider in the field of eRegulatory Affairs. The complete EXTEDOsuite is unique in all that it covers:

- Product Registration Planning & Tracking
- Submission Management (eCTD, CTD; NeeS, CADDY, ePRISM, eIndex, eNTA, vNeeS)
- Pharmacovigilance Management (SUSAR, ICSR, PSUR, E2B)
- Label Management (PIM, SPL) and
- Document Management

We provide configurable off-the-shelf products, as well as customized and integrated solutions. EXTEDO also provides EURS is Yours, the validation, review and approval system for the EMA and more than 25 Regulatory Authorities worldwide.

Today we serve more than 700 customers in 57 countries ranging from small companies with less than 25 employees to large multi-national organizations. EXTEDO operates in the following markets for human, veterinary and crop protection:

- Life sciences, including pharmaceutical, biotech and biopharma, generics, homeopathics and medical devices
- Healthcare and public sector

EXTEDO is recognized as the worldwide leader in each of our areas of operation.

Additional EXTEDO products used by MEDAPharm



> **eCTDmanager**
facilitates a better co-operation with affiliates and more efficiency in DCP and MRP submissions.



> **EURS is Yours**
enabled us to establish a very efficient validation process for our eCTD dossiers prior to submission to the authorities.



> **RLPmanager**
primarily supports the clinical departments for pre-publishing work such as studies or reports. Using eCTDmanager and RLPmanager in an integrated environment enables the highest level of efficiency.

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