



Challenges

- › To create efficiencies and synergies across processes in a huge worldwide network involved
- › To validate the format of the company's templates and regulatory documents in order to prevent a refuse to file

Solution and Results

- › Significant time and money savings in meeting the requirements of the EMA and National Competent Agencies
- › Streamlining of many processes



Case Study

eCTDmanager



Fresenius Kabi, a subsidiary of Fresenius SE, is the European market leader in infusion therapy and clinical nutrition. The company also holds a leading market position in both the Asia Pacific region and Latin America. In the US market Fresenius Kabi is a leading supplier of I.V. generic drugs. Therapy and care of chronically and critically ill patients, both inside and outside hospital, is a key focus of the company. Dedicated to improving patients' quality of life, the company embodies its philosophy of "Caring for Life".

Challenge

Creating synergies within a worldwide network

After the implementation of the eCTD was agreed in the ICH region, Fresenius Kabi started looking for a suitable vendor that had developed a tool for eCTD regulatory submission publishing.

EXTEDO's eCTDmanager fulfilled all these requirements, and this tool was purchased by Fresenius Kabi in October 2007 and immediately installed.

Solution and Results

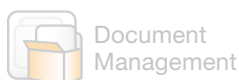
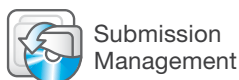
Successful global roll out of eCTDmanager — helped streamlining many processes

Fresenius Kabi employs a range of EXTEDO products and solutions to streamline its business and to improve efficiency.

The eCTDmanager, EXTEDO's scalable, 'all-in-one' electronic submission management system for eCTD, non-eCTD electronic and paper submissions, is used integrated with IBM Score and has enabled Fresenius Kabi to prepare new drug applications and variations.

"eCTDmanager is comparatively easy to use and EXTEDO's IT support was both fast and straightforward. This was one major benefit for the important roll out of eCTDmanager to our global organization [...] We also selected EXTEDO's DOCvalidator solution. This application reports formatting errors within both MS Word and PDF documents, and we successfully use it to validate the format of Fresenius Kabi templates and regulatory documents, thereby preventing a refuse to file."

**says Anthony Agidotan,
Manager Regulatory Affairs at
Fresenius Kabi.**



DOCvalidator, configured to your specific documentation standards, enables the compliance verification of both legacy documents and externally created documents thereby ensuring the consistency and reliability of your documentation process.

"The EURS is Yours product, EXTEDO's proprietary solution for eCTD validation and retrieval, helped us streamline many of our processes."

concludes Anthony Agidotan.

"The software, easily installed and fully compatible with our existing information system, saved us time and money in meeting the requirements of the EMEA and National Competent Agencies."

says Anthony Agidotan.

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 Fresenius Kabi



> eCTDmanager

is an easy to use submission tool with deep functionality which fulfills the requirements for paper, electronic (NEES) and eCTD submission publishing for all regions.



> EURS is Yours

saved time and money in meeting the requirements of the EMA and National Competent Agencies.



> DOCvalidator

is the successful implementation of a compliance check on format, layout and metadata of Fresenius Kabi ".doc" and ".pdf" documents.

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