

Successful global rollout of eCTDmanager helped streamline many processes



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 generic I.V. drugs. Therapy and care of chronically and critically ill patients, both inside and outside the hospital, is a key focus of the company. Dedicated to improving patients' quality of life, the company embodies its philosophy of "Caring for Life".

The Challenge: Creating synergies within a worldwide network

After the implementation of the eCTD 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 the desired specifications and was subsequently purchased by the company in October 2007. After immediate installation by EXTEDO, the tool was ready for Fresenius Kabi use.

Solution & Results: Successful global rollout of eCTDmanager helped streamline many processes

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

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

Customer Benefits

Challenges

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



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.

Anthony Agitodan,
Fresenius Kabi Manager of Regulatory Affairs



DOCvalidator, configured to each company's specific documentation standards, enables compliance verification of both legacy documents and externally created documents. This ensures the consistency and reliability of the documentation process.



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

Anthony Agitodan,
Fresenius Kabi Manager of
Regulatory Affairs



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

Anthony Agitodan,
Fresenius Kabi Manager of
Regulatory Affairs

EXTEDO products used by Fresenius Kabi

eCTDmanager

enables you to readily build, view, validate and publish compliant submissions based on CTD, eCTD, NeeS, eCopy, IMPD, CTA, VNeS, DMF, ASMF and other submission structures.

EURS

(EXTEDO Universal Review System) serves as a complete eCTD validation and reviewing solution used by over 35 authorities worldwide, including EMA. It evaluates whether any eCTD- or NeeS-based submission conforms to the mandated standards.

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