



Challenges

- › To build 2 eCTD submissions at latest 6 weeks after system installation
- › Integration of Documentum used by Pierre Fabre since 1995

Solution and Results

- › 4 weeks after the implementation of eCTDmanager, 2 submissions have been successfully forwarded to the authorities
- › As of today 15 submissions have been successfully produced
- › EXTEDO's EURS is Yours solution created additional synergies and benefits for Pierre Fabre



Case Study

eCTDmanager



Pierre Fabre Laboratory is the 2nd largest independent French pharmaceutical laboratory. Two main branches characterize the company: "Pierre Fabre Medicament" and "Pierre Fabre Dermo-Cosmetics". Pierre Fabre Medicament orients its development on specifically targeted therapeutic lines. Its focus areas lie on Oncology, Cardiovascular/Metabolism, Central Nervous System and Dermatology.

Challenge

Integrating Documentum® and building eCTD submissions shortly after system installation

Pierre Fabre has used a publishing tool in combination with Documentum® for years and submitted dossiers to agencies worldwide since 1995.

In the context of eCTD requirements, Pierre Fabre decided to search for a new system suitable to their eCTD submission needs. Pierre Fabre set up a project plan for in-

vestigation, proof of concept, decision making, purchasing and implementation. The time window for this project has been defined on purpose challenging. The target was to build 2 eCTD submissions at latest 6 weeks after system installation including the qualifications and training phase. The system should be installed with an integration to Documentum®.

Solution and Results

More time and cost efficiency through optimized process of publishing

EXTEDO's eCTDmanager was Pierre Fabre's first choice based on these requirements.

EXTEDO's suite of e-Regulatory solutions can be used as a comprehensive solution or as 'building blocks'. eCTDmanager is a scalable, 'all-in-one' electronic submission management system for eCTD and other electronic and paper submissions.

eCTDmanager offers flexibility and security in building, viewing, validating, publishing and compiling electronic and paper submissions.

The conjunct team (Pierre Fabre and EXTEDO) achieved the given challenges. Four weeks after the implementation of eCTDmanager, including data migration from

"The eCTDmanager, EXTEDO's proprietary solution for the complete preparation of eCTD and paper submissions, creates also the opportunity to optimize the process for publishing with a real benefit on time, cost and life cycle management of the dossier,"

explains PF publishing team manager.



Registration Management



Submission Management



Labeling Management



Pharmacovigilance Management



Document Management



Project Management

the existing publishing tool, 2 submissions have been successfully forwarded to the authorities. As of today fifteen submissions have been successfully produced.

EXTEDO's EURS is Yours solution created additional synergies and benefits for Pierre Fabre. EURS is Yours, a multifunctional software solution that serves as an overall eCTD validation, retrieval, view and review software, saves time as it provides a detailed report on whether a submitted eCTD-based application conforms with the official interpretation of the eCTD format.

"For Pierre Fabre this is a real advantage to have the same view as the authorities, which is key for agency communication procedures,"

adds PF publishing team manager.

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 Pierre Fabre



> **eCTDmanager**
is a scalable, 'all-in-one' electronic submission management system for eCTD and other electronic and paper submissions.



> **EURS is Yours**
is a multifunctional software solution that serves as an overall eCTD validation, retrieval, view and review software and is meeting the requirements of the EMA and National Competent Agencies.

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