

## **Lundbeck Achieves First eCTD Submission with Datafarm's eCTD Solution**

*When they were looking for a partner to help them achieve their first ever eCTD submission, scheduled for January 2007, H Lundbeck A/S needed a product to meet its technical and regulatory requirements and a vendor who had the expertise to help it install, train, validate and prepare the system.*

H. Lundbeck A/S, the international pharmaceutical company specialising in drugs for the treatment of psychiatric and neurological disorders, is one of the leading companies in its field. As such, it wanted to adopt the most modern and efficient methods for its regulatory submissions in advance of the statutory requirement due in 2009.

The company issued a Request for Proposal (RFP) in April 2006 for a complete electronic submission solution that would meet its exacting technical and regulatory requirements, enabling compilation/creation, management and viewing of eCTD submissions. The chosen system had to be fully capable of delivering an eCTD submission scheduled for completion in January 2007.

Lundbeck needed a vendor experienced in delivering eCTDs and with the expertise to help the company achieve a successful transition to eSubmissions. The vendor needed to be capable of supporting the system and to demonstrate strong client / vendor partnership attributes to sustain a long term relationship.

Having considered proposals from four suppliers in a thorough and lengthy process, Lundbeck chose to partner with Datafarm in late October 2006.

Combining its eCTDBuilder, eCTDViewer, Gatekeeper, pCTD, a-Pulse and Validation Kit modules into one integrated solution to deliver the eCTD, Datafarm was also tasked with implementation planning, implementation and integration services, training, SOP considerations and validation assistance for Lundbeck.

Project managed by Lundbeck, the Datafarm team integrated with the Lundbeck project team to provide technical and regulatory support.

They used the eCTDBuilder to build the XML backbone that constituted the electronic CTD without the need for Lundbeck users to understand XML and eCTD Document Type Definition (DTD). Its built-in intelligence made the creation of the electronic CTD submission seamless, reliable and accurate.

The Lundbeck team was able to view and comment on the contents of the application throughout its life cycle using Datafarm's eCTDViewer and Gatekeeper validation module. Gatekeeper verified the validity and integrity of the submission and, as an integral part of the eCTD review process, allowed Lundbeck to mimic the agency review environment for its own QA/QC process before the submission was shipped to the agency.

But just as important were the associated publishing requirements that supported and streamlined the actual eSubmission compilation process. The Lundbeck eSubmission

benefited from having compliant and submission-ready source content (PDF) provided by the a-Pulse automated PDF publishing solution.

A set of Adobe® Acrobat® plug-ins that focus on providing publishing automation combined with intuitive maintenance and task management functions for eSubmissions, a-Pulse provided Lundbeck with PDF publishing functionalities and navigational tools not available in Acrobat®, making the PDF publishing process easier, quicker and more accurate.

And finally, as some agencies still require paper as the official and archival format, Lundbeck used Datafarm's pCTD (paper CTD) module to create a paper dossier from the electronic CTD.

Datafarm helped Lundbeck go from purchase to production in less than 8 working weeks; the company's first eSubmission was made on time in January 2007.

According to Steen Otto Rugaard, Project Manager for Lundbeck, Datafarm was chosen because of the responsiveness of its people, from sales right through to support, "We were very impressed by Datafarm's positive, constructive interaction with our team, alongside its obvious knowledge, expertise and understanding of the eCTD", he explained. "Datafarm clearly understands our business needs as well as our technical requirements".

"Its regulatory understanding, attention to our needs, technical competence and communication skills have all contributed to an excellent achievement for our company".

"Without Datafarm's fast responses we would not have been able to achieve this goal".

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**H. Lundbeck A/S; [www.lundbeck.com](http://www.lundbeck.com)**

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#### **Editors' Note**

Established in 1997, Datafarm is a leading provider of Electronic Document Publishing solutions and Regulatory Submissions Services for the Life Sciences Industry. Datafarm augments the drug development process by providing custom and off-the-shelf solutions worldwide, producing high-quality, agency-compliant e-Submission-ready documents. Headquartered in Marlborough, Massachusetts, USA, Datafarm has regional offices in California, UK, France, India, Japan and Taiwan. To date, the company has assisted with over 150 eCTD submissions, submitted to the FDA, Health Canada, EMEA and Japanese regulatory authorities.

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