



In Partnership with Datafarm, KOWA Submits First eSubmission in eCTD Format

Customer's Challenge

KOWA wanted to prepare for eWorking and create their first eSubmission in eCTD format, by August 2008.

About KOWA

KOWA Research Europe, Ltd. (KRE), established in 1999 in the United Kingdom, manages European clinical trials for KOWA's strategic global pharmaceutical development. The primary therapeutic areas of focus are cardiovascular and related conditions (e.g. diabetes), anti-inflammatory conditions (R.A), dermatology and ophthalmology.

The Challenge - Find a Solutions Provider

KOWA began their vendor selection process in June 2007, searching for companies that could meet their criteria. KOWA required a partner with a combination of industry-leading software solutions and experienced regulatory consultants.

The Solution - Datafarm

After a lengthy evaluation process, KOWA chose to partner with Datafarm. Datafarm and KOWA joined forces to complete KOWA's first decentralised procedure (DCP) submission. The DCP included 8 eCTD applications with a combined total of 21 GB data. Each eCTD was 2.6 GB in size and contained 275,000 PDF links and bookmarks. The submission went to 16 countries accompanied by 520 volumes of paper. In total 1,100 CD-ROMs were created to meet multiple copy requirements at each agency. This complex submission incorporated the new EU Module 1 Specification/DTD Version 1.3, which was released in May 2008.

Industry-Leading Software Solutions Combined with Regulatory Process Expertise

Datafarm used its a-Pulse[®] PDF utility and experienced regulatory publishing consultants to ensure the documents were compliant, before compiling into the eCTD using Datafarm's eCTDBuilder[®] and S-Cubed[®] Publisher application to produce paper volumes.

- **a-Pulse:** Datafarm's a-Pulse (a PDF Utility for Life Sciences) provided the team with PDF publishing functionalities and navigational tools not available in Adobe[®] Acrobat[®], making the PDF publishing process easier, quicker and more accurate. Many of KOWA's source documents were scanned. Using a-Pulse ensured the scanned documents were transformed into compliant, submission-ready documents.
- **eCTDBuilder:** Datafarm's eCTDBuilder software let the team build the XML backbone that constitutes the electronic CTD, without the need for the users to understand XML and the eCTD Document Type

Definition (DTD). Built-in intelligence in eCTDBuilder made the creation of the electronic CTD submission seamless, reliable and accurate.

- **eCTDViewer:** Datafarm’s eCTDViewer software let KOWA reviewers view, and comment on the contents of the application throughout its publishing lifecycle.
- **S-Cubed Publisher:** As some agencies still require paper as the official and archival format, the team used Datafarm’s S-Cubed Publisher to create a paper dossier from the electronic CTD.

Datafarm led the project management of the DCP, using their global regulatory resources to integrate with the KOWA project team, providing both technical and regulatory support. Regular project update meetings were carried out to ensure that both teams worked together to achieve their August submission deadline.

According to Bryan Carter, Head of Regulatory Affairs, KOWA, “This was our first eCTD submission, and due to its size and complexity we needed a partner with an excellent combination of eSubmission products, strong regulatory expertise and a clear focus on the pharmaceutical industry. We wanted a partner that didn’t just sell us products, but was willing to work alongside us for mutual success. We found that in Datafarm.”

Jasbir Chohan, Associate Director Regulatory Services, said “It has been a pleasure to partner with KOWA on this project. It has been an exciting project to be involved in, not only due to its complex nature, but also because we were able to help KOWA successfully submit their first ever eCTD submission. Through the use of our global publishing resources, we provided 24 hour regulatory support and ensured that KOWA achieved success in their submission process.”

About Datafarm

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, and agency-compliant e-Submission-ready documents. Headquartered in Marlborough, Massachusetts, USA, Datafarm has regional offices in California, the UK, France, and India. To date, the company’s products have been utilized in compiling thousands of eSubmissions. Our Regulatory Services Group has joined forces with sponsors to submit hundreds of eCTD dossiers to the USA, Canada, European Union, and Japanese regulatory authorities. For more information, visit the company website at www.datafarminc.com

Contact Information:

USA	Maria Fabbo	maria.fabbo@datafarminc.com	Tel: +1 508-624-6454
Europe	Steven Mckinlay	steven.mckinlay@datafarminc.com	Tel: +44 (0) 870 774 4298
India	Veeresh Sondur	veeresh@datafarminc.com	Tel: +91 080 329 03619