

## **With Datafarm eSubmissions Software, Orbis Consumer Product Limited Cuts Submissions Preparation from Four Weeks to Four Hours**

### ***Customer's Challenge***

Orbis wanted to be able to prepare new drug submissions more quickly and with fewer errors. They also wanted to be positioned to make submissions in other countries.

### ***About Orbis***

Orbis is a 20-person producer of liquid state generic drugs located near London. Orbis sells a nonsteroidal anti-inflammatory drug (NSAID), Ibuprofen; a diabetes drug, Metformin; a thyroid drug, Thyroxine; and other generics to pharmaceutical wholesalers. Like other producers of generic drugs, Orbis must complete a rigorous submissions process for new drugs even though generic drugs contain the same active ingredients as licensed brand-name drugs.

For each new drug, Orbis must submit a number of documents to the UK's Medicines and Healthcare products Regulatory Agency (MHRA) in a set format. To be able to produce submissions more quickly, Orbis purchased Datafarm's eCTDBuilder<sup>®</sup> and a-Pulse<sup>®</sup> (a PDF utility for Life Sciences) eSubmissions solutions. In less than a year, Orbis has made six electronic submissions, compared with nine submissions completed between the founding of the company in 1998 and the purchase of Datafarm software.

### ***The Challenge— Produce Error-Free Submissions in Less Time***

Drug submissions require time, money, and meticulous attention to detail. Before the purchase of eCTDBuilder<sup>®</sup> and a-Pulse<sup>®</sup> in November, 2007, Orbis used Microsoft Word to prepare the entire submission. Ashmita Bhudia, the regulatory affairs (RA) manager, and three Orbis directors wrote reports and documents and checked whether they adhered to MHRA regulations. Next the team assembled, copied, hole-punched, and bound the 1,200-1,500 pages that went into each submission. During this four week period, they were too busy to do their "real jobs."

Switching from paper submissions to PDF based electronic submissions on compact discs in 2005 only compounded the problem. For each submission, the regulatory affairs (RA) department had to allocate 10-15 hours for manually creating and renaming approximately 200 PDF files. As MHRA has complex naming conventions, "there was a huge room for error," says Bhudia. To correct errors, they sometimes had to manually search all 200 files.

### ***The Solution--eCTDBuilder<sup>®</sup> and a-Pulse<sup>®</sup> Slash Orbis's Preparation Time***

Impressed with Datafarm's products and pricing, Orbis purchased eCTDBuilder<sup>®</sup> and a-Pulse<sup>®</sup> in November, 2007. The RA department continues to use Word to author documents and PDF Maker to render word documents to PDF for each submission. Then, they use a-Pulse's IntelliQC

module to check the PDF files for regulatory nonconformance, issue reports, and rectify problems.

Next, the RA department uses eCTDBuilder<sup>®</sup> to construct the XML backbone and subsequently drag and drop files into eCTDBuilder<sup>®</sup>. The RA department also uses eCTDBuilder<sup>®</sup> to scan the documents and “validate the submission.” Finally, they burn a compact disc and send it to the MHRA for processing. Orbis now completes submissions in four hours, not four weeks.

### ***Advantages of Investing in eCTDBuilder<sup>®</sup> and a-Pulse<sup>®</sup>***

Bhudia summarizes, “I think for us the main advantage [of using Datafarm’s products] has been the time saving. For a small company, where you are wearing many hats, there is nothing more valuable than the time taken to do things.”

Using Datafarm’s eCTDBuilder<sup>®</sup> and a-Pulse<sup>®</sup> provides Orbis with several advantages:

- eCTDBuilder<sup>®</sup> creates the XML backbone required by agencies without requiring XML expertise.
- eCTDBuilder<sup>®</sup> provides drag and drop capabilities for making changes or moving files into individual modules/sections.
- eCTDBuilder<sup>®</sup> automatically renames the PDF documents to match the recommended file naming convention and creates the required folder structure.
- a-Pulse<sup>®</sup> simplifies the preparation of PDF files and the creation of bookmarks within the PDF files.
- a-Pulse’s IntelliQC checks PDF files for publishing related problems, issues a report, and then facilitates corrective measures. Orbis does not need to open and correct individual files.
- a-Pulse<sup>®</sup> allows Orbis to split files and divide up tasks among staff.

Additionally, eCTDBuilder<sup>®</sup> and a-Pulse<sup>®</sup> have given Orbis the ability to:

- Access tools that eliminate file naming errors.
- Search multiple submissions documents simultaneously to find and correct errors or respond to requests for changes from the MHRA.
- Transmit submissions in a format that invites quicker review by regulatory agencies.

By eliminating the cost of printing, binding, delivering, and storing massive submissions documents, Orbis has realized other savings. Additionally, Orbis has also been able to shift some tasks from directors to more junior staff. Finally, Orbis has been able to complete submissions more quickly but without adding employees.

### **S-Cubed<sup>®</sup> Supports Regulatory Requirements in Different Countries**

In November, 2007 Datafarm introduced S-Cubed<sup>®</sup>, a new eCTD solution that also includes non-eCTD Electronic Submissions (NeES) capabilities. Orbis recently installed S-Cubed<sup>®</sup>. One feature Orbis especially likes is that S-Cubed<sup>®</sup> provides multi-user capabilities. This means that directors and quality control staff can view submission files on their own PCs while someone else is working on them. Additionally, submission files are more secure as they are housed on a server, not just a single laptop.

Using S-Cubed<sup>®</sup>, Orbis will eventually be able to make eCTD and non eCTD submissions in other countries. “You don’t have to use different programs just because you have decided to submit in Japan!” Bhudia concludes.

## Definitions

**a-Pulse<sup>®</sup>** (Automated PDF Utilities for Life Sciences) consists of Adobe<sup>®</sup> Acrobat<sup>®</sup> tools that automate the publishing and quality control of PDF documents for electronic submission to regulatory agencies.

**CTD** or Common Technical Document refers to a set of specifications for drug companies to follow when making submissions to drug regulatory agencies.

**eCTDBuilder<sup>®</sup>** is a solution that creates and manages electronic eCTD submissions throughout the life cycle of a pharmaceutical product. eCTDBuilder<sup>®</sup> creates an XML backbone and elements and leaves according to Common Technical Document (CTD) specifications. Users drop and drag files to an element, and eCTDBuilder<sup>®</sup> suggests appropriate file names and folder structure. Also, this application includes a Validation module which is critical to the submission process.

**MHRA** or Medicines and Healthcare products Regulatory Agency is the regulatory agency in the United Kingdom that is responsible for drug approvals.

**S-Cubed<sup>®</sup>** (Smart Submission Solutions) is an all-inclusive software system for creating eCTD NeES and paper submissions that meet regulatory requirements in the United States, European Union, Canada, Japan, and countries around the world that accept either eCTD or any other type of electronic submissions.

**NeES** or Non eCTD Electronic Submission refers to a format intended to assist pharmaceutical companies with the submission of regulatory information in electronic format to the National Competent Authorities (NCAs) and the European Medicines Agency (EMA).

---

Datafarm, Inc.: 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. Datafarm’s Regulatory Services Group has joined forces with sponsors to submit hundreds of eCTD dossiers to the FDA, Health Canada, EMA, and Japanese regulatory authorities.

To learn more about Datafarm’s products and services, please contact Maria Fabbo, +1 (508)624-6454, or email [info@datafarminc.com](mailto:info@datafarminc.com).

---