



# Regulatory Services Group

## PROFESSIONAL GUIDANCE THROUGH THE eSUBMISSIONS MAZE

Datafarm's mission is to partner with clients to achieve mutual success, providing Global Regulatory Submission Services that support both:

- companies seeking the flexibility of leveraging an outsourced partner to address their eSubmission and paper publishing needs and
- companies with established eSubmission capabilities looking for additional resource support to address peak workloads or other specific eSubmission or paper publishing goals.

The Datafarm Regulatory Services Group (RSG) experts are available to work with client teams to create the optimum solution for every unique situation. As industry experts in regulatory submissions (both electronic and paper), Datafarm's RSG provides technical competency with its industry recognized solutions together with extensive experience working with large and small life sciences companies.

## DATAFARM REGULATORY SERVICES

In addition to providing software solutions for facilitating eSubmissions, Datafarm offers three types of services to support regulatory submissions worldwide: eSUB Outsourcing, eSUB Enabling and eSUB In-Sourcing.

### eSUB OUTSOURCING

The experienced eSUB Outsourcing team combines skills and technology to transform paper-based submissions into fully compliant eSubmissions. Whether companies require help transforming legacy data into an eSubmission or assistance in compiling an eSubmission, the Datafarm eSUB Outsourcing team is a very capable and efficient option.

eSUB Outsourcing services can be placed into three service categories:

- **Submission Component Preparation**
  - Scanning Services
  - MS-word Source Document Rendering
  - MS-word Source Document Formatting
  - PDF Publishing
  - Document Quality Control Activities
  - SPL & PLR Labeling Conversion Services
  - PIM Labeling Services
  - FDA Submission Data (CRT) Preparation Services
  - CDISC/FDA Submission Data Conversion Services
- **Submission Assembly & Paper Publishing**
  - Submission Quality Control Activities
  - eCTD Compilation
  - XML Validation Services
  - Lifecycle Management
  - Paper Dossier Services
  - Work Practices Kit
  - eCTD Submission Tracking Checklist
- **Consultation, Training & Education**
  - eCTD Guidance Consultation
  - Regional Regulatory Guidance Consultation
  - Submission Readiness Assessment
  - Submission Component Templates (S3)
  - eCTD Infrastructure Readiness Gap Analysis
  - Submission Inventory Services
  - Strategic eSubmission/eCTD Assessment Service

eSUB Outsourcing is ideal for clients who need to file electronic submissions but currently lack the infrastructure or resources to fully support the activity. It is also an excellent option for peak workloads, urgent requirements such as filing an expedited or fast-track submission and handling unfamiliar submission formats.

**Why Put Submissions At Risk When Datafarm RSG Experts Can Help?**



## eSUB ENABLING

eSUB Enabling allows companies to develop the infrastructure and in-house capabilities necessary for producing electronic submissions with the end-goal of self-sufficiency.

As part of this collaboration, RSG provides the necessary resources to assist companies in publishing and compiling an eCTD and, at the same time, provide expert on-the-job training. eSUB Enabling services include, but are not limited to:

- eCTD infrastructure development (coordinated by the Datafarm Technical Services Group)
- Software installation/validation & End-user training
- Collaboration on standard operating procedures
- Authoring, Publishing, Legacy document conversion & Quality checking
- Knowledge transfer for best practices
- On-the-job training

Combining Datafarm's technology and regulatory expertise provides the latest compliant software and superior regulatory support to guide clients through submissions.

## eSUB IN-SOURCING

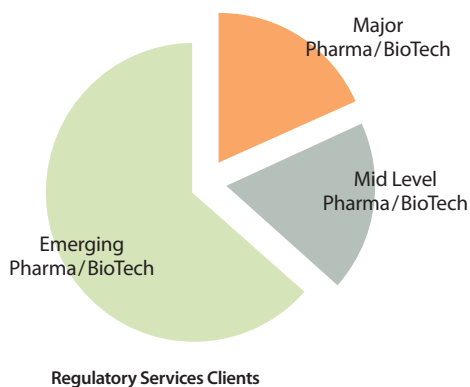
Combining aspects of eSUB Outsourcing and eSUB Enabling, the eSUB In-Sourcing approach supplements a company's internal resources with Datafarm experts in a collaborative effort. In-Sourcing focuses on achieving a compliant eSubmission rather than on knowledge transfer and, as such, does not offer "on-the-job-training." However, client regulatory personnel can anticipate an increased understanding of the eCTD submission process by project completion.

## THE TRACK RECORD SPEAKS FOR ITSELF

Datafarm's RSG has already produced and assisted with the assembly of hundreds of electronic submissions worldwide. Datafarm possesses experience with all US submission types

(NDA, BLA, ANDA, IND, DMF, etc.), all EU procedures (Centralized, Decentralized, Mutual Recognition, and National) and EU submission types (Original, Variations, FUM, PSUR, etc.), all Health Canada submission types (NDS, sNDS, Clarifaxes, etc.) and Japanese MHLW submission types delivered in eCTD format.

Datafarm's RSG has provided services for over 100 client companies. Clients include Top Tier Pharma/BioTech, Mid-Level Pharma/BioTech and Emerging Pharma/BioTech companies.



## CREATING PARTNERSHIP FOR SUCCESSFUL eSUBMISSIONS

Whether Datafarm simply supplements existing resources at peak times, helps personnel acquire knowledge or provides complete electronic submissions, RSG can help increase efficiency, reduce the cost of developing an infrastructure and system architecture, and minimize overhead.

In a stringent and exacting regulatory environment, Datafarm offers access to recognized industry specialists that, when combined with proven software solutions, delivers compliant, timely and effective electronic submissions. Datafarm's RSG has helped many companies create and maintain the eCTD lifecycle for their electronic dossiers.

## ABOUT DATAFARM

Established in 1997, Datafarm is a world leader in high performance electronic regulatory submission solutions for the Life Sciences industry. Datafarm's open, modular technologies and professional services experts enable Life Sciences companies to meet the strict standards of regulatory authorities across the world, helping them achieve quality, accuracy, and compliance to efficiently deliver regulatory reports and submissions. Datafarm has helped hundreds of sponsor companies compress the regulatory submissions approval process, improving speed to market, cost control and productivity in order to achieve their ultimate goal of ensuring patients' and physicians' timely access to new drugs.

As a total solutions provider, Datafarm employs some of the industry's pioneers in document-based software development as well as world renowned life sciences regulatory specialists who proactively work with customers and business partners to drive new initiatives and maintain a market lead approach to development and services.

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