

Regulatory Services Group



RSG - Your Partner for Successful eSubmissions Hosted by Distributed Compliance Solutions

The Datafarm Services include but are not limited to:

eSUB Outsourcing

- Regional eCTD guidance consultation
- eCTD publishing training and educational services
- Scanning services
- PDF publishing
- Document and submission quality control activities
- eCTD compilation
- Case Report Tabulation (CRT) - clinical data
- submission to the Regulatory authority
- eCTD XML backbone validation services
- SPL and PLR labeling conversion
- Gap analysis (systems and processes)
- Paper dossier services
- Submission preparation evaluation service
- Work Practices Kit
- eCTD checklist

eSUB Enabling

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

Professional Guidance Through the eSubmission Maze

With eCTD and eSubmissions here to stay, the choice of software solutions to help you comply with all of the new requirements is becoming increasingly varied and confusing.

Outourcing 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 a good option for urgent requirements, such as filing an expedited or fast-track submission.

At Datafarm, we offer you something distinctive and unique. We not only sell our software and support services, we partner with our clients to achieve mutual success. Our Regulatory Services Group experts are available to work with you to create the optimum solution for your specific situation. As an industry expert in regulatory submissions (both electronic and paper), Datafarm provides technical competency with industry recognized solutions, and extensive experience with large and small Life Sciences companies.

Distributed Compliance Solutions host servers and software already configured with Datafarm's RSG best practices business process. After a Configuration Workshop you will be ready to work with Datafarm's products and RSG Team in our secure collaborative environment.



Why DCS?

In the initial stages of drug development, life science and biotechnology companies need to focus their talents, time and financial resources on research and development. And yet, there is an obvious need for collaboration with outside vendors and partners while controlling content and protecting IP.

DCS provides the solution with a price structure that reduces IT costs dramatically

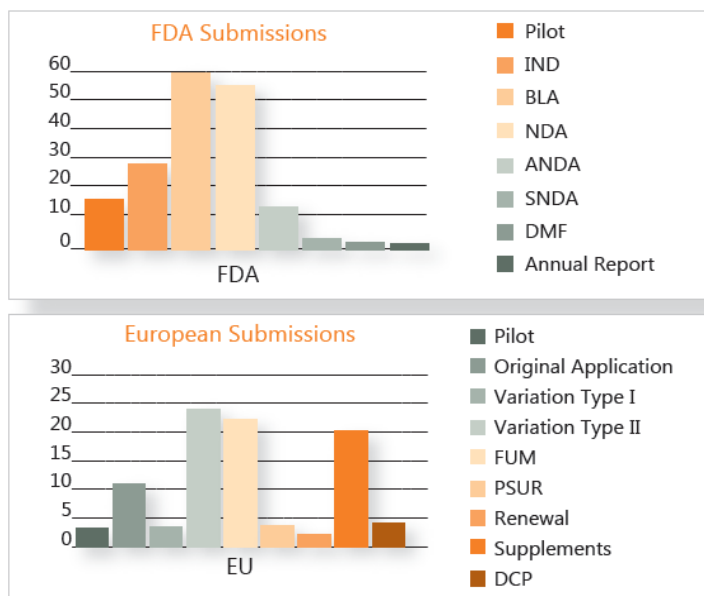


over purchasing and maintaining the necessary IT structure.

The Datafarm Difference:

Whether we simply supplement your existing resources at peak times, help your personnel acquire knowledge or provide you with complete electronic submissions, our Regulatory Services Group can help you increase efficiency, reduce the cost of developing your infrastructure and system architecture, and minimize your overhead.

Datafarm and eSUB are registered trademark of Datafarm Inc.



DCS and our Hosting Site

Our hosting partners provide 'state of the art' facilities. Each, provides highly skilled technical personnel, on site, 24x7x365 and are engineered with multiple levels of security, uninterrupted power, redundant HVAC systems and fire suppression. Data backup solutions are included and disaster recovery services are available, including auto hot-site failover. All this, means around-the-clock monitoring and management of your critical content.

Regulatory Compliance

The sites are SAS70 Type II compliant. SAS 70, is an auditing statement issued by the Auditing Standards Board of the American Institute of Certified Public Accountants (AICPA). SAS 70 defines the professional standards used by a service auditor to assess the internal controls of a service organization and issue a service auditor's report. A Type II service auditor's report includes the service auditor's opinion on the fairness of the presentation of the service organization's description of controls that have been placed in operation and the suitability of the design of the controls along with the auditor's opinion on whether the specific controls were operating effectively during the period under review.

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