



SUBMISSION CENTERED SOLUTIONS

Regulatory Submissions by Apyx Incorporated Hosted by Distributed Compliance Solutions

Apyx offers a full range of Solutions and Services:

Document Management

Our combined SOP best practices with specific strategies help us manage submission documents and data efficiently. And help you with:

- ◇ System selection and implementation
- ◇ Outsourcing electronic archiving
- ◇ Document lifecycle review and assessment
- ◇ Technology evaluation
- ◇ Publishing-Document Management system integration

Regulatory Publishing

We listen to your needs and create a submission management solution tailored to meet your projects unique requirements.

SPL Conversion

The SPL R4 release of SPL Manager creates all SPL output required by FDA: Product Label including the updated drug listing section as well as Drug Establishment Registration and NDC Labeler Code Request submissions.

Regulatory Affairs

As part of the overall submission management process:

- ◇ Regulatory Strategy
- ◇ Regulatory Liaison
- ◇ Writing and Review
- ◇ Submission Project Management
- ◇ Post-submission activities

Why Apyx?

At Apyx, we realize there are a number of submission service providers available; we stand apart from all others in our dedication to our clients and our partnering approach. We believe that good people, efficient processes and well controlled systems produce consistent positive results. We strive to create the highest quality regulatory documents and submissions in the industry while empowering our clients and controlling cost through expertise and efficient processes.

Apyx business model is exclusively focused on our core competencies: regulatory submission, document management services and technologies, and essential safe management of client's critical documents within a secure platform.

We care about your submission as much as you do.

Apyx strives to continually provide worldwide clients superior services by identifying and developing new and innovative ways to improve business value of the document lifecycle within the life sciences industry. Documents and data are the lifeblood of an organization. We know how to leverage document management solutions to increase the efficiency of submission publishing

Distributed Compliance Solutions hosts servers and software already configured with best practices business process from Apyx best practices business process. After a Configuration Workshop you will be ready to work with Apyx Services Team in our secure collaborative environment.



DCS Hosting

Through 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, protecting IP and leveraging the process to streamline submission publishing activities.



DCS provides the solution with a price structure that reduces IT costs dramatically over purchasing and maintaining the necessary IT structure in-house.



Apyx Tools and Services:

- ◇ eSub expertise: eCTD and NeeS
- ◇ Electronic and paper submission management and publishing
- ◇ Regulatory strategy, project management, writing and review
- ◇ Regulatory document management
- ◇ Preparation of the submission data package
- ◇ CTD authoring and labeling templates
- ◇ SPL conversion

We support our client's efforts to bring new therapies to market quickly and cost effectively by providing tools and services specifically designed to streamline the submission process and reduce associated expenses. We continually strive to exceed our client's needs and expedite document turnaround via our strong client focus, experienced staff, and tight processes.

DCS and our Hosting Site

Our hosting partner, Peak 10, provides 'state of the art' facilities. Each site provides highly skilled technical personnel, 24x7x365 and are engineered with multiple levels of security, uninterruptible 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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