Infosys Life Sciences Regulatory Submission Platform

A comprehensive, cloud-based solution for the regulatory submissions life cycle

The tedious process of regulatory submissions often prevent organizations from realizing the benefits of investments in research and new markets, making it a critical function for biopharmaceutical organizations to manage. The need of the hour is thus to optimize regulatory submissions to accelerate time-to-market, reduce cycle times with regulators, save patients' lives, and maximize research investments and value. At the same time, biopharmaceutical organizations need to keep up with greater scrutiny by regulators and the dynamism of compliance. As a result, they are increasingly feeling the need to streamline related operations and smartly manage global, submissions' life cycles.

An end-to-end solution from Infosys

The Infosys Regulatory Submission platform accelerates and streamlines all aspects of regulatory submission — from planning, document creation, review and approval, tracking and submission. It resolves business challenges by providing:

Seamlessly integrated, end-to-end services

The platform offers comprehensive regulatory submissions capability in a collaborative business model. It includes:

- Submission planning
- Product Registration
- Document management, including approval workflows
- Document publishing and submissions
- Submissions tracking
- Search, dashboards, reports, and analytics

Best-in-class tools

The platform is integrated with industry-leading tools that provide:

- Centralized content authoring and dossier management
- Product Registration management
- Versatile publishing functionalities
- eCTD | NeeS assembly, review, and submission management
- Reporting in Extended EudraVigilance Medicinal Product Dictionary (xEVMPD) and Structured Product Labeling (SPL) formats
- An interface with an electronic gateway for submissions and reporting

Solution and technology

- Single source of truth, providing a fully integrated system for all regulatory submission needs
- Integrated processes and data with standard SOA factory architecture
- Fully secured solution delivered through the cloud

Operational

- Proactive adoption of new regulatory standards
- Standardized, end-to-end, processes for planning, creation, publishing, and tracking of submission documents
- Collaboration with partners through integrated processes and systems

Highlights

Governance

- Timely responses to health authority queries
- Seamless submission to multiple regulatory bodies in different regions
- Reusable artifacts across the enterprise and extended organization
- Disclosure of litigation information within an acceptable time-frame
- Enhanced visibility

Continuous upgrades

- Platform is compliant across sectors
- Responds to continuous assessments and upgrades to regulatory changes
- Supported by an expanding platform roadmap

Unique selling proposition

The Infosys Regulatory Submission platform has proven its capabilities at a leading pharmaceutical company. Here are some factors that give it a competitive advantage:

Best-in-class

- Designed exclusively for regulatory submissions in the pharmaceutical industry
- Hosted end-to-end solution that leverages best-in-class commercial-off-the-shelf (COTS) products as standard interfaces with a unified user interface
- Service-oriented architecture (SOA) layer to seamlessly integrate with other enterprise systems
- Secure framework that addresses pharmaceutical security and privacy requirements

Unique delivery model

- Solution and service from the secure, ISO 27001-certified Infosys Cloud
- Pay-per-use model based on usage volume with minimal initial investment
- Reduction of total cost of ownership (TCO)
- Single point of ownership and accountability to
  - Keep solution, technology, and infrastructure up-to-date and regulatory-compliant
  - End-to-end support service with minimal ticket transfers
  - Single-point support

Capability and expertise

- Strategic partnership with leading product vendors to provide cutting-edge technology solutions
- Right mix of expertise in technology and business domain consulting to craft innovative and extremely powerful business solutions

Flexible and current

- Flexible framework that enables seamless integration with client's existing systems and tools
- Expandable cloud-based infrastructure that matches usage expansions and performance standard

For more information, contact askus@infosys.com