

INFOSYS COMPLIANCE EDGE SOLUTION SUITE FOR REGULATORY INFORMATION MANAGEMENT

The tedious process of regulatory submissions often prevents organizations from realizing the benefits of investments in research and new markets, making it a critical function to be managed for Life Sciences organizations. Several hundreds of weeks of lost sales revenue can be owed to poor document management for regulatory processes and submissions. The need of the hour is thus to optimize regulatory submissions to accelerate time-to-market, reduced cycle times with regulators, save patients' lives, and maximize research investments and value. There is an increasing need to streamline related operations and smartly manage global submissions' life cycles.

The Infosys Regulatory Submission platform accelerates and streamlines all aspects of regulatory submissions — from planning, document creation, review and approval, and tracking to submission.



Business Challenges Addressed

- Exponentially increasing global regulatory complexity and scrutiny
- Scattered technology landscape
- Unsynchronized data across different divisions in different formats
- Multiple applications, vendors and accountabilities
- Product registration inaccuracies
- Regulatory notices, fines and possible product recalls
- Failure to respond to regulatory queries on time
- Market introduction of multiple regional tools for submission validation and publishing

Solution Features

Compliance Edge platform is a suite of applications designed to support the business in the preparation, authoring, submission, publishing and tracking of regulatory information.

Compliance Edge solution suite has three functional components



1. Document Management

Set of processes and technologies for creating, editing, reviewing, approving and storing documents. It also provides controlled access to information, and secures and protects the data

2. Publishing

Process of preparing, compiling, validating and submitting regulatory information to Health Authorities (HA) across the globe

3. Tracking

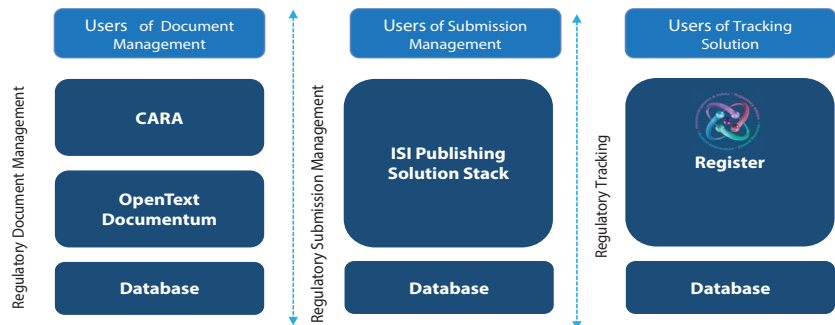
Process of managing the overall progress of products, submission status, Health Authority Interactions and responses to queries

Infosys Compliance Edge Solution is a next generation regulatory platform where its users will be able to collaborate and work effectively with a consistent user experience for all types of users and functional modules, across the value chain. The solution is built on top of class leading technology components and integrates them for addressing business needs.

Solution Highlights

- Designed exclusively for Life Sciences Industry for their R&D, Manufacturing and Quality operations
- Ability to support the new business model of externalisation to alliance partners
- Modern, cost-effective technical solution ensuring timely regulatory submissions
- Offers extreme security and maintains data integrity
- End-to-end integrated and hosted solution leveraging best in class COTS products as standard interfaces with single sign-on, unified user interface, optimized search, easy and intuitive reports/dashboards
- Platform roadmap aligned to core product releases and regulatory compliance requirements
- Unified and controlled product registration process
- Highly scalable in supporting the demanding performance needs
- Systematic monitoring, tracking of regulatory queries and publishing interfaces
- Provides seamless workflows with real time alerts and notifications
- Fully hosted and managed by Infosys.

Architecture Overview



Case Study for a leading Life Sciences Organization client

Shaping the Business - Making the Business transformation possible

- Alliance management: Flexible externalisation and virtualisation
- Emerging markets: Increased activity in the far East

Adhering to regulatory standards - Elimination of Compliance issues and risk

- Multifold reduction in risk of product recalls
- Good Regulatory Practice: Including EVMPD mandated capability
- 100% Compliance with legal/litigation requirements

Delivering the Business - Faster and Cheaper

- Two- fold increase in likelihood of product submission schedule adherence
- Reduced documentation cycle time
- Ability to find and reuse information for speed, quality and compliance

Along with the direct business benefits of the solution, we also helped the client to migrate from their legacy solution with our content migration framework.

For more information on Infosys Compliance Edge Solution, please write to us at ContentServices@infosys.com

For more information, contact askus@infosys.com

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