The life sciences industry is witnessing stringent compliance requirements when it comes to legal and regulatory aspects of drug development. The need to manage and track the process and progress through the system has evolved. Hence, digitizing all the submissions and deriving data directly from the source systems will help enhance regulatory reporting compliance.

Tata Consultancy Services’ (TCS) ADD Regulatory Insights platform has been developed in close collaboration with a leading pharmaceutical company to reassess the existing regulatory process. It helps the enterprises reimagine their existing processes and automates key processes to reduce turnaround time, thereby leading to a transformed governance and compliance operating model.

Overview

Pharmaceutical companies are currently facing issues in managing process requests. Every work request that is created, is required to be tracked to closure, and currently the process is manual. There is a dependency for customer to request this information from project team leads who collect and provide this information in excel format. There are challenges such as executing real-time Quality control (QC), avoiding Retro QC, and choosing right method in performing QC on various items and managing the QC information/reports. Additionally, regulatory affairs team finds it difficult to track the status of submissions real time, which is imperative for them to take any kind of required action. Another challenge faced is providing senior management with report for products in pipeline on a monthly basis, which is a time-consuming and error-prone person-dependent manual task as it is not on any central system.

ADD Regulatory Insights platform ensures compliance in various legal and regulatory aspects of drug development. It also plays a vital role in ensuring regulatory compliance in non-regulated parts of the world for people safety. Flexibility in implementation and adoption of trends such as digitization and AI in regulatory space will be key differentiators.

Our Solution

ADD Regulatory Insights platform consists of following modules, which can be used separately or in combination.

- **Regulatory pipeline dashboard**: Detailed program for a product to track its status in different regions. Readily available published program with different presentation styles and exportable feature.
- **QC checklist setup and usage**: Robust Quality Control system can be setup for multiple processes with branch control to Key performance indicators (KPI) and milestone fixation.
- **Submission Tracker mobile app**: Anytime submission status on fingers with live detailed tracking and involved stakeholder information.
- **Publishing process**: Covering all Health Authority requirements for development and Life Cycle Management (LCM) of product in structured and time-frame manner.
- **Annual reports**: Complete annual status of all geographical regions with respect to product maintenance in all aspects.
Benefits

ADD Regulatory Insights platform enables the enterprises to realize the following benefits.

- **AI powered platform**: Leverage AI technologies to convert the information from structured, semi-structured, and unstructured sources into knowledge and actionable insight.
- **Quick access**: Make Regulatory Pipeline reports available to senior management, as and when required.
- **Better visibility**: Track global pipeline projects real-time with easy navigation and gain a better insight into regulatory processes.
- **Reduced compliance issues**: Decrease turn-around time for various regulatory processes thereby increasing productivity.
- **Submission tracker mobile app**: Track all submission information and view detailed reports of initiated tasks on-the-go.
- **Easy Quality Control (QC) checklists**: Enable different users to perform uniform quality control checks.
- **Scalable solution**: Open, cross-industry BPaaS/SaaS platform where different stakeholders involved in Pharma Regulatory process can collaborate and view reports.

The TCS Advantage

With ADD Regulatory Insights platform, pharmaceutical companies will be able to leverage the following differentiators.

- **Domain expertise**: TCS has a vast pool of consultants, including physicians, pharmacologists, and information technology professionals, with domain experience gained through diverse engagements with leading global drug manufacturers. CRI’s subject matter experts have an average experience of 15 years in managing global clinical projects, site selection, and clinical monitoring.
- **Digital Recognition**: TCS has been named a Leader in Everest Group’s Services PEAK Matrix™ 2018 for Life Sciences Digital Services in North America. TCS partners with leading life sciences companies in leveraging next generation platforms and emerging technologies to drive innovation, gain speed-to-market, and drive internal efficiencies. The company offers a full set of digital transformation services and solutions including consulting, predictive and prescriptive analytics, genomics research, advanced platform solutions, and cognitive business operations.
- **Process maturity**: TCS’ well-defined and widely acclaimed quality management systems and standard operating procedures (SOPs) facilitate cost-effective optimization of business processes associated with the regulatory process in pharma industry.
- **Analyst recognition**: TCS has been recognized as a Leader in the IDC MarketScape for Worldwide Life Science R&D BPO Services 2018. The report credits TCS’ leadership to strong discovery research, clinical data management, and pharmacovigilance BPO services. Among other strengths, the report cites TCS’ innovation offering, the Advanced Drug Development platform, which provides BPaaS solutions based on cognitive computing, artificial intelligence (AI), and robotics automation.
Awards & Recognition

To know more
Visit the Life Sciences & Healthcare page on tcs.com
Email: ADD.platforms@tcs.com

About Tata Consultancy Services Ltd (TCS)
Tata Consultancy Services is an IT services, consulting and business solutions organization that delivers real results to global business, ensuring a level of certainty no other firm can match. TCS offers a consulting-led, integrated portfolio of IT and IT-enabled infrastructure, engineering and assurance services. This is delivered through its unique Global Network Delivery Model™, recognized as the benchmark of excellence in software development. A part of the Tata Group, India’s largest industrial conglomerate, TCS has a global footprint and is listed on the National Stock Exchange and Bombay Stock Exchange in India.

For more information, visit us at www.tcs.com

IT Services
Business Solutions
Consulting