

PHARMACEUTICAL REGULATORY SERVICES

Intelligent | Agile | Compliant

Trending

Dynamic and evolving regulations and guidelines of submission requirements across health authorities (HA) require pharma companies to adapt and implement changes across the regulatory value chain before regulatory submission. Pharmaceutical companies strive to balance complex regulatory documentation and cost-effectiveness, which compels them to outsource the regulatory documentation practice to consulting and regulatory experts. According to a recent research study, the pharmaceutical regulatory affairs outsourcing market stood at USD 2.7 billion in 2020 and is bound to double by 2027.

Pharmaceutical companies are operating a large number of affiliates, local offices, and local consultants. There is a need for the consolidation of local/ regional operational activities for cost optimization. Companies are aiming to centralize their regulatory operations to drive cost efficiency and create opportunities for business transformation.

Moreover, as pharma functions work in silos, a cross-functional work-flow solution must harmonize the business operations in Regulatory Content Authoring. Hence, to streamline and harmonize regulatory processes across regions, businesses are moving towards content reusability & cross-functional knowledge sharing between teams.

Opportunities & Challenges

The dynamic nature of regulatory guidelines has led to a greater need for knowledge-centric and intelligence-driven processes within the regulatory value chain. Pharmaceutical companies are looking for consultative partners with more comprehensive regulatory domain understanding and technology backbone to digitize processes and seamlessly address regulatory changes.

The industry is moving fast towards structured electronic documentation and submission management processes as more agencies are adopting eCTD formats. From region to region, variation in regulatory guidelines has presented a challenge in harmonizing the process and content reusability. One of the industry's essential imperatives is to use AI-based contextual automation to reduce documentation cycle time, simplify regulatory operations, and build structured assets for content reusability.

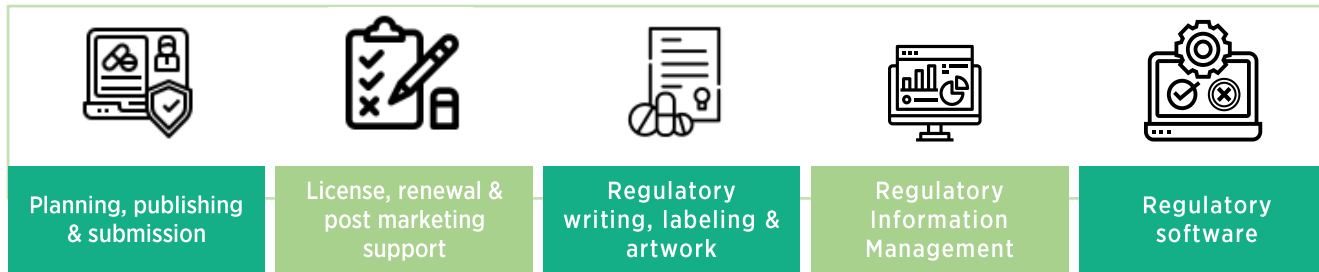
Furthermore, a key challenge for regulatory operations is to build skillsets with knowledge and experience of multiple markets. As a hub for pharma regulatory services, India provides a great solution to global pharma in terms of the availability of multi-regional skillsets. It offers overall cost efficiency in business operations. Centralization of regulatory function will also enable companies to drive process efficiency, build standard processes across the region, identify use-cases for re-usable regulatory content.



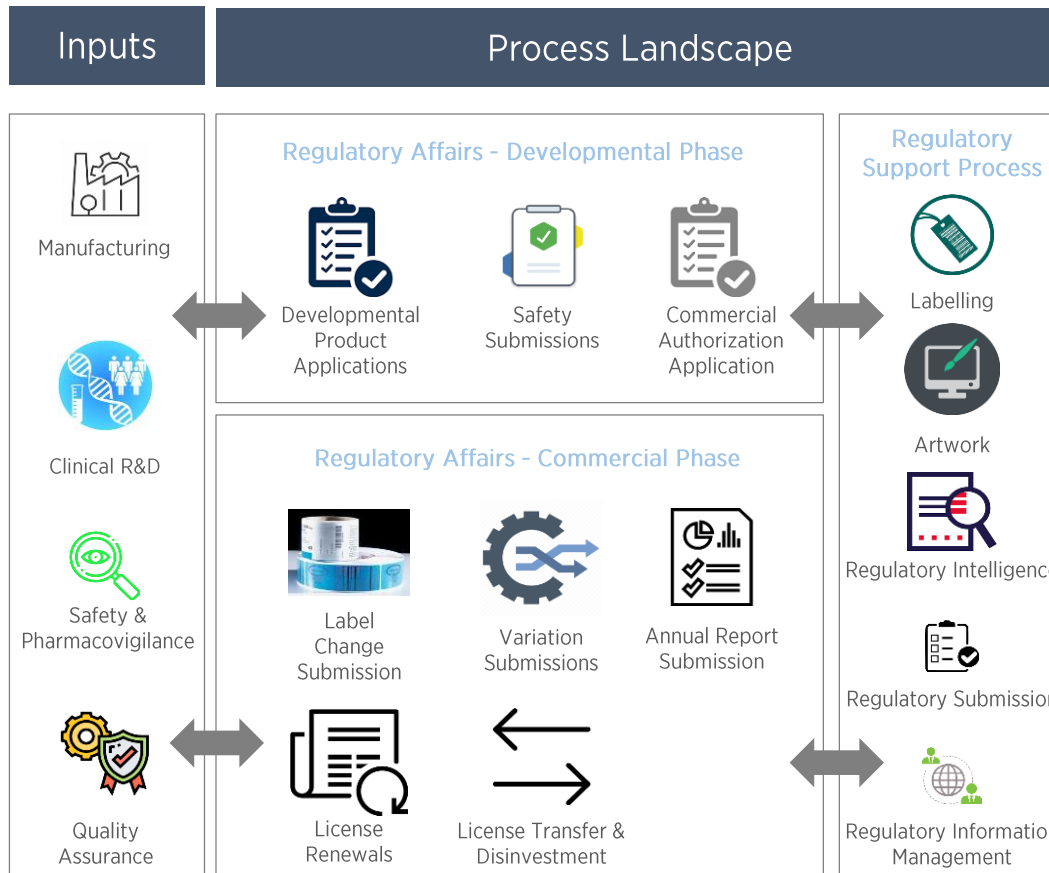
Benefits for the manufacturers

- Increased speed to market by reducing submission preparation timelines using AI-based technologies
- Integrated solution approach for greater cross-functional synchronization
- Methods to minimize the cost of compliance and its impact on R&D investments
- Centralized program management to foster collaboration between all the functions (Quality, Regulatory, R&D, etc.)

Pharmaceutical Regulatory Services



Service Architecture



Service Assets



Inter-disciplinary Team of Regulatory SMEs & CMC Experts



Automated Label Proofreading Tool



Ecosystem: Partnerships & Alliances

Differentiators

- Embedded Regulatory Intelligence framework for proactive decision making and cross-functional knowledge sharing
- Accelerated submissions through robotic process automation (RPA) interventions and home-grown regulatory intelligence solutions
- End-to-end regulatory service portfolio ensuring meticulous quality control and timely submissions
- Standard SOPs & customizable templates along with multi-layered quality checks to increase the first-time-right quality

Cases

Published 800+ submissions and 70+ minor and major variation submission for a leading global pharma company

- End-to-end lifecycle submission management for 10 product portfolios within therapeutic areas of cardiovascular, pain management, and diabetes
- Transitioned end-to-end team for renewals and annual reports within 12 weeks

An agile, sustainable, and scalable lifecycle management operations for the regulatory function of a US-based pharma

- Streamlined maintenance process led to 35% reduction in operational cost
- Boosted efficiency by 70% and improved process management across global operations