

Reducing Pharma Regulatory Submission Turnaround Time by 20%

BUSINESS GOALS

The client is a top-10 global pharmaceutical company. They wanted to quickly register their existing products in new markets such as Europe, Canada, and the U.S. They needed a scalable and flexible operating model along with a team with expertise in global regulatory requirements. They chose Atos Syntel as their partner, based on our expertise and ability to meet their stringent deadlines.



BUSINESS BENEFITS

- 20% reduction in turnaround time for regulatory writing and submission publishing
- 35% cost reduction generated by Atos Syntel's Intelligent Regulatory Services platform
- Faster, easier preparation of regulatory submissions with document lifecycle management
- 100% submission document accuracy through quality checks and consistent clinical document templates

CHALLENGES

- Multiple teams at locations across the globe
- Difficulty adapting to evolving regulatory submission requirements
- Inconsistent MS Word templates
- Changes to business processes and tools
- Difficulty adapting components to eCTD standards

SOLUTION

- The required timelines were very tight, so Atos Syntel set-up a dedicated Center of Excellence (CoE) to serve as a global hub for managing the submissions. This CoE model enabled us to quickly build a centralized team with the right skills and blend of global and regional knowledge. Some important features of the CoE are:
- Integrated submission publishing and regulatory writing teams, reducing hand-offs and turnaround time
 - A team of regulatory experts that monitors changing regulatory requirements that could affect submissions
 - Established MS Word templates for all clinical documents, ensuring correct formatting
 - Provided training on eCTD publishing tool
 - All documents received a quality check before submission publishing

Atos Syntel also employed its **Intelligent Regulatory Services Platform** to apply automation and standardization to streamline the process of registering the client's products in new markets.

Atos Syntel's CoE Model

