



## A New Prescription for Regulatory Compliance: Syntel's Intelligent Regulatory Services Platform

Global life sciences companies are facing exceptional business pressure. In today's evolving regulatory environment, new directives and regulations increasingly pose not just a long term need, but a real-time operational challenge as well.

As a consequence, many life sciences companies find it difficult to manage the products they market across the globe, while focusing on new investigational compound development. The most common challenges they face are:

- **Achieve optimal planning:** Reduce time spent on submission planning in order to bring products to market faster
- **Enable effective global coordination:** Ensure complete data, and coordinate and manage stakeholders around the world
- **Manage regulatory documents:** Difficulty managing documents across numerous systems and data sources
- **Standardize processes:** Overcome the challenges of inconsistent templates in use by regulatory groups across the organization
- **Handle geographic and regional differences:** Deal with frequently changing global and regional regulatory requirements
- **Effectively manage submissions:** Implement an end-to-end solution for submission to health authorities

### Syntel's Solution

Based on our years of experience working with top global life sciences companies, Syntel has developed an end-to-end suite of regulatory services to help life sciences organizations address these and other global challenges.

Our **Intelligent Regulatory Services Platform** employs a higher degree of automation and a unique, factory-based methodology to enable:

- **Improved collaboration** across multiple stakeholders such as Clinical Teams, Statisticians, Medical Writers, etc.
- **Strong business alignment** with clients and a hand-in-hand approach for faster drug launches
- **Increased agility** for frequently changing global and regional regulatory requirements
- A focus on **operational excellence** for flawless global delivery, minimal risk, and maximum value

### WHY SYNTEL?

#### ▪ One Global Team

Centralized teams from our global pool of regulatory professionals are strategically located to meet your organization's business needs. These teams bring together a wide range of experience in global/regional regulatory knowledge and health authority interaction.

#### ▪ Digital Technology and Market Acceleration

Take advantage of Syntel's cutting-edge technology solutions, powered by the SyntBots automation platform and the latest digital and data analytics technologies to improve transparency and insight into the quality and performance of your regulatory submissions.

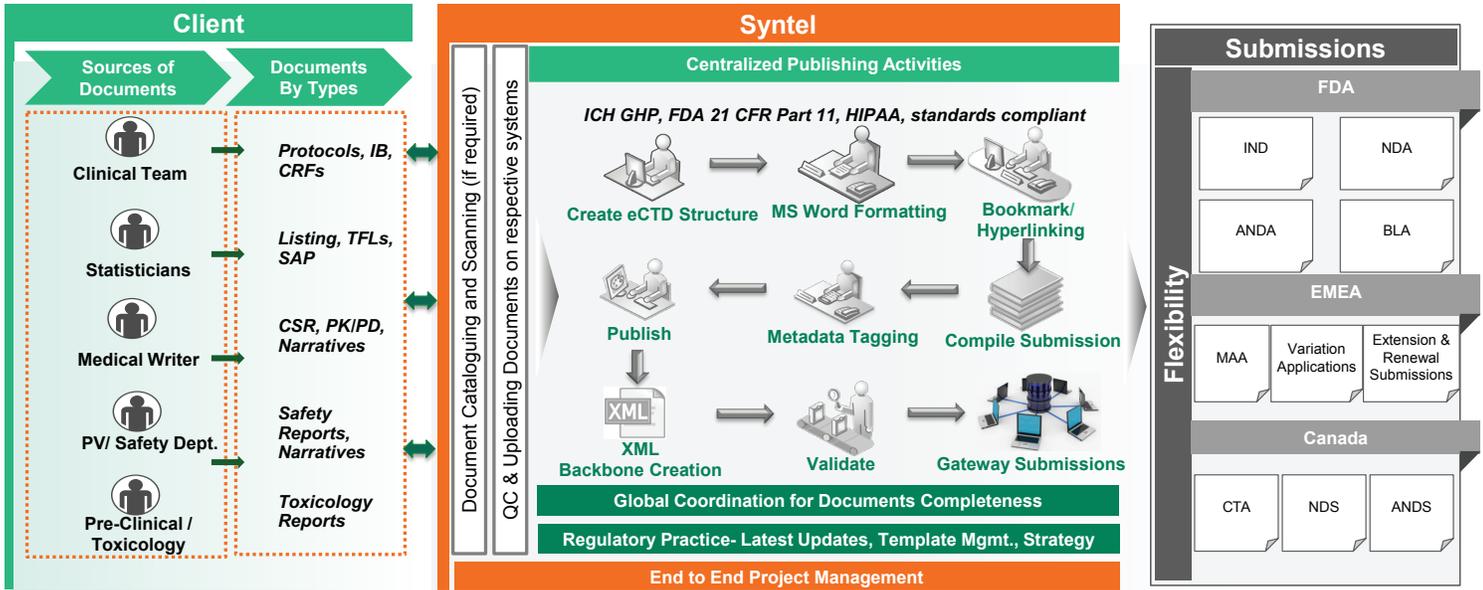
#### ▪ Scalability and Flexibility

Syntel's model gives your organization an immediate global footprint, with a scalable pool of talent spread across geographies to meet changing business demands, and a well-established governance model that ensures the highest standards of quality, transparency, and accountability.

#### ▪ Strategic Fit

Syntel is not simply a vendor, but a committed strategic partner that continuously focuses on developing new regulatory solutions for the life sciences industry, supported by investments in skills, IP, and infrastructure.

## Intelligent Regulatory Services Platform Architecture



### Syntel In Action

#### Reducing Pharma Regulatory Submission Turnaround Time by 20%

##### Challenge

A top-10 pharmaceutical company needed to register their products in new markets under stringent timelines. They chose Syntel based on our experience, our flexible operating model, as well as our ability to accelerate the execution of the project.

##### Solution

Syntel set-up a dedicated Center of Excellence (CoE) and employed its **Intelligent Regulatory Services Platform** to manage the client's submission requirements. Syntel's centralized team and streamlined, automation-driven processes enabled the client register their products quickly and accurately, without the need to make major investments in staffing, training, or infrastructure.

#### BUSINESS BENEFITS

- Submissions were prepared 25% faster than required
- 35% cost reduction by employing Syntel's Intelligent Regulatory Services Platform
- 100% accuracy for the submission documents

#### About Syntel

Syntel (Nasdaq:SYNT) is a leading global provider of integrated information technology and knowledge process services. Syntel helps global enterprises evolve the core by leveraging automation, scaled agile and cloud platforms to build efficient application development and management, testing and infrastructure solutions. Syntel's digital services enable companies to engage customers, discover new insights through analytics, and create a more connected enterprise through the internet of things. Syntel's "Customer for Life" philosophy builds collaborative partnerships and creates long-term client value by investing in IP, solutions and industry-focused delivery teams with deep domain knowledge.

To learn more, visit us at: [www.syntelinc.com](http://www.syntelinc.com)



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