Optimizing Business Processes to Drive Efficient Global Submission Management

red paper

Introduction

Regulatory activities tend to be cross-functional and global in nature. Many organizations struggle with achieving excellence, reducing costs, and increasing compliance due to lack of organizational and process efficiencies.

Several factors contribute to the complexity of submission management in the pharmaceutical and biotechnology industry.

- While submission management is traditionally "owned" by Regulatory Affairs, the content, data, and infrastructure that support a submission are the responsibilities of several other functions.
- Continually changing global regulations require constant upkeep and modification of business practices to ensure compliance.
- Complex information landscape necessitates the optimal use of resources and technologies to set in motion simultaneous global submissions.

To streamline the complex nature of global submission management, the industry must establish a robust organizational foundation based on sound business processes. Through these processes, roles and responsibilities are clearly defined, timelines for time-sensitive activities are established, hand-offs from one activity to the other are articulated, bottlenecks and risks are identified and mitigated, and metrics and key performance indicators are put into motion to track and report outcomes.

Establishing the processes may seem daunting and costly at first, but once the optimal processes are in place, the long-term value, including increased compliance and overall cost reduction, will be felt and appreciated over years to come. Furthermore, companies who have an established set of processes are in a great proactive position to quickly adapt to changing regulations compared to those who will be forced to react each time a regulation changes.

Staying Ahead of the Regulations and Your Competition

Regulations are continually changing, and that constant churn will not stop. It is simply the nature of the global pharmaceutical landscape. Putting in place optimal processes today ensures your organization is ready for the next set of regulation changes that are on their way. Companies who stall on change will find themselves in an unfavorable reactive situation, in which they establish business practices that are a band-aid approach. These companies tend to be loaded with inefficiencies (intensive time constraints and cost and resource overloads).

Transformation Opportunities

There are plenty of opportunities to gain efficiencies in your global submission management processes – in both the investigational and commercial side of the business. Below are examples of types of submissions and regulatory information that can offer new opportunities to optimize electronic processes. These frequent scenarios are based on the Red Nucleus R&D experience but will probably sound familiar to members of global teams.

1572 Submissions

A large global pharmaceutical company was anticipating an audit by the FDA for several of its time-sensitive submissions. The company did not have visibility in the end-to-end process, was unable to track or report on the status of these submissions, and was at risk of receiving a warning letter for non-compliance.

The company required an assessment and optimization of the processes and supporting procedural documentation to ensure compliance with regulated submission timelines and a mechanism for tracking and reporting against those timelines.

Some of the identified processes were cross-functional in nature and spanned multiple systems; alignment of functions and streamlining the fragmented systems were key measures for a successful delivery.

Within 6 months of implementing the optimized processes, the company's compliance rate was significantly improved. Business leaders were able to confidently report metrics and saw a MEASURED IMPROVEMENT FROM A BASELINE OF 30% TO A 96% COMPLIANCE RATE for their 1572 submissions.

2253 Submissions

On June 24, 2019, the FDA issued a final guidance for industry titled, "Providing Regulatory Submissions in Electronic and Non-Electronic Format–Promotional Labeling and Advertising Materials for Human Prescription Drugs." Twenty-four months after the issuance of this guidance, firms will be required to submit electronically all promotional submissions that fall within the scope of this guidance. Companies who have an established proactive approach to optimizing their business processes have successfully transitioned from paper submissions to electronic submissions as early as possible. Today these companies are well positioned to address the emerging requirements of submitting 2253s via electronic common technical document (eCTD).

Companies who are still submitting their 2253s on paper will need to make a leap in preparation for the eCTD requirements. The degree of change management required to transition will be far more significant for teams who are still working with paper-/-CD based processes.

Identification of Medicinal Products

The US FDA describes Identification of Medicinal Products (IDMP) as,

> ***"...a suite of five standards developed within the International Organization for Standardization (ISO). These standards provide an internationally-accepted framework to uniquely identify and describe medicinal products with consistent documentation, coding and exchange of product information between global regulators, manufacturers, suppliers and distributors."***[1]

The IDMP standards were developed to improve pharmacovigilance efforts and to promote global detection of safety signals. The standards help to communicate medicinal product data globally while also enabling health authorities to identify pharmaceutically equivalent products to help mitigate drug shortages and lower risks to patient health.

Companies who have a proactive process and culture have started to implement critical changes to their data and information structures in readiness for the IDMP standards.

[1] US FDA: https://www.fda.gov/industry/fda-resources-data-standards/identification-medicinal-products-idmp, Updated August 23, 2019.

Where Should You Start?

It is important that your business leads define and/or optimize the detailed business requirements, workflows, and process maps for submission management. This effort requires a combination of skill sets and experience from across the organization. Domain expertise, an understanding of relevant guidances and best practices, and an awareness of technology requirements are important for success. Most organizations don't have the complete set of skills available for such a large initiative. Therefore, external experts are often called upon to fill the skill gaps, help to develop processes that are optimized for efficiency and compliance, and facilitate difficult territorial discussions of current and ideal processes.

This cross-functional approach often requires a liaison to work with the chosen technology vendor to ensure that the submission management solution meets the needs of the business. By communicating these needs to the vendor, the team is able to align expectations and coordinate key deliverables.

This scenario can also be the foundation for a deeper technology partnership. As process stakeholders begin to gain efficiencies and utilize new technologies, they naturally develop best practices and "short cuts" within the submission management system. As clients share these experiences with the technology partner, they can have a big influence on the product strategy and direction. New requirements or new understandings of old requirements help to improve the technology as clients and vendors position themselves to meet the needs of future requirements.

The cross-functional aspect of global submission management adds complexity to the challenge. Departmental or functional boundaries are often the main obstacles that keep teams from optimizing their processes. It is important to get continued buy-in from functional leads as processes span different geographies, departments, systems, and organizations.

Most life sciences teams outsource some of their clinical and regulatory processes to contract research organizations (CROs). The practice of outsourcing is commonly accepted but it does require consideration when optimizing global processes. The level of integration between CRO and sponsor processes will dictate the degree of optimization that is possible. If these processes are not tightly integrated, the optimization effort and any efficiency gains will be limited to accessible processes. If the processes are tightly integrated, or are being transformed for greater integration, the possibilities for new efficiencies are far greater. Most CRO/sponsor partnerships are moving toward greater integration in order to optimize R&D.

Global submission management is a mission-critical process that demands optimization. As sponsor teams look inward to improve operations, they often look outward for assistance facilitating and managing such a daunting task.

Why Red Nucleus R&D

Red Nucleus R&D is comprised of a dynamic team of management consultants and R&D subject matter experts specializing in cross-functional R&D delivery.

Delivering over 100+ engagements in over 40 companies, Red Nucleus R&D offers robust professional services in strategic and operational business and technology solutions for the pharmaceutical, biotech, and medical device industries.

Our operational, strategic consulting, and technology services span across R&D with a focus on all regulatory specialties within and across the entire product life cycle, for both major and emerging markets.

Red Nucleus R&D delivers unrivaled R&D capabilities for life sciences teams. Our cross-functional expertise, process-driven approach, and proven methodology reduce costs, remove silos and increase compliance and efficiency.

red nucleus
rednucleus.com

Authors:

Dalia El-Sherif, PhD, Partner

Red Nucleus R&D Consulting
Practice Lead

delsherif@rednucleus.com

610-909-8831

Michael Swalina, Partner

Red Nucleus R&D
Submission Management
Practice Lead

mswalina@rednucleus.com

610-427-9570