How the Role of Regulatory Operations Professionals Will Evolve in the new Decade

By Rachel Belani

This article introduces forward-looking trends that may affect how the role of regulatory operations professionals will progress over the next 10 years. Regulatory operations professionals from three biopharmaceutical companies also share their perspectives on the changing regulatory landscape and emerging challenges.

Introduction

Regulatory operations professionals face a much different world from the one they did 10 years ago, as novel therapy development increases, regulatory standards are evolving and technology is starting to play a more prominent role in the management of regulatory information.

The industry is shifting its focus from developing blockbuster therapies that treat various diseases, to developing precision medicine, specialty drugs and targeted gene therapies that focus on treating, or even curing, specific diseases and disorders. In some areas of medicine, these products are being paired with medical devices to improve the quality of delivery, monitoring or adherence; adding another layer of complexity when it comes to defining the overarching regulatory strategy and pathway to market.

This volume and pace of innovation is adding to the complexity that regulatory professionals have grown accustomed to managing on a daily basis. They must now figure out how to collect, aggregate, manage, analyze and intelligently act upon an ever increasing volume of data coming from health authorities and other competent authorities around the world. Many recognize that the existing processes and technology, e.g., spreadsheets, file sharing applications and business systems, are no longer sufficient.

Modern regulatory professionals are prioritizing solutions and strategies that will help them keep pace with three industry trends expected to impact their role in getting medicines to market over the next decade. These include:

- more drugs and therapies entering new markets
- the deployment of cloud capabilities
- the maturation of new industry standards and requirements

More Drugs and Therapies in new Markets

FDA's New Drug Therapy Approvals 2019 Annual Report highlighted the steady increase of novel drug approvals over the last 10 years, reporting that an average of 37 drugs were approved per year from 2009-2019.[1] In the last three years, this average has increased to 51 approvals per year; an almost 40% increase. Of the 48 novel drugs approved in 2019, 33 (almost 70%) were approved in the US before receiving approval in another country. Growth in approvals also was observed for new and expanded use of already FDA-approved drugs, biosimilars and other emerging therapy classes. Lastly, the rate of expedited development and review pathway designations also has been increasing, allowing regulatory reviews/approvals to happen more frequently and with greater speed. Many expect this trend to continue, and the overall impact on the regulatory operations role could vary, depending on the sponsor's focus and geographic reach.

With the rise of specialty medicines and precision treatments, the volume of ongoing clinical trials requiring regulatory oversight has increased significantly. In December 2019, for example, there were 325,352 registered studies in 209 countries—nearly four times the volume of 2010, when there were 82,867 active studies.[2]

This increase in activity means sponsors and Contract Research Organizations (CROs) must now handle an enormous amount of project-critical data coming from multiple sources. It is not uncommon, for instance, to receive information from genomic sequencing, medical imaging and mobile health systems—and for that to be generated and delivered by thousands of different devices.

More often these days, regulatory professionals are expected to be experts on the changing regulatory climate globally. Today, they need to know almost as much about the inner workings of the National Medical Products Administration

(NMPA) in China as they do about the US Food and Drug Administration (FDA). Similarly, they must be well-versed in the requirements and implications of all new and emerging privacy regulations in every country in which they operate, whether it is the *General Data Protection Regulation* (*GDPR*) in Europe or the *Health Information Portability and Accountability Act* (*HIPAA*) in the US.

Between the data related to their daily jobs and information coming from various regions or countries in which they operate, regulatory operations professionals have their hands full.

"The biggest challenge for us is absolutely the amount of information coming our way that must be processed, understood and considered each day," said Mark De Rosch PhD, FRAPS, chief regulatory officer for Epizyme, Inc., a late-stage biopharmaceutical company developing epigenetic therapies. "Nearly all of that information is originating from regulatory agencies around the world, which was not the case five or 10 years ago. Trying to manage and process the sheer volume of information from so many locations is incredibly difficult."

Most organizations recognize the need to get their arms around data. However, many still depend upon a mesh of manually intensive and business software tools for Regulatory Information Management (RIM). In fact, depending on company size, regulatory processes can involve anywhere from a dozen to more than 100 different systems and spreadsheets to securely manage correspondence, commitments, submission documents and archived dossiers.[3]

This reliance on fragmented technology and manual processes can cause delays, hamper visibility and access to key data, and lead to unnecessary inefficiencies. This is why 86% of pharmaceutical organizations surveyed by Gens and Associates are embarking on digital transformational journeys in one or more regulatory areas. The goals of such efforts are clear. Most organizations want to improve visibility and oversight of the constantly growing volume of information about their products, programs and in the end, insights about the market response and the patients. They seek a single source of truth for relevant information that can be stored in a secure, unified, and globally accessible hub.[4]

Deploying RIM Capabilities

A major benefit of adopting a modern RIM system is that it does more than just store documents related to a drug application. Modern RIM systems connect regulatory content and data to give companies of all sizes an authoritative source for submission documents, published dossiers, product registration information and health authority interactions in one platform. This platform approach aides global regulatory teams, giving them better visibility and control into upcoming priorities and other critical regulatory obligations or initiatives. Technology is an enabler for regulatory; however, the timing and development stage of the company is important as these factors impact the regulatory team's ability to gain efficiencies by implementing a modern RIM system.

Startups tend to start out with uncontrolled systems or outsource regulatory functions because they do not have the activity and submission volume to justify the need for managing their own RIM system. In some cases, it's not part of their strategy in the first place—especially if funded by or sharing resources with a larger pharmaceutical company. Startups and small pharmaceutical companies are incredibly busy, accounting for 63% of all new prescription drug approvals the past five years, but few have large regulatory teams. More commonly, they will have individuals doing the work of several people, which is why many augment or outsource regulatory capabilities to partners or consultants and defer on bringing capabilities in-house.[5]

Many smaller companies think this approach is their only choice. However, others find that implementing modern, cloud-based RIM system is easier than implementing the RIM systems of the past—and is something they can accomplish in a reasonable amount of time. A single platform also makes it easier to trust the integrity of the information since it resides in a validated, controlled system.

"Bringing our first regulatory publishing system in-house was very costly and took a long time to accomplish, but replacing it with a modern, cloud-based solution only took about six weeks and cost significantly less from an implementation and licensing perspective," acknowledged Mike Epstein, senior director of regulatory operations for ACADIA Pharmaceuticals, a biopharmaceutical firm focused on central nervous system (CNS) disorders. "In the cloud, we are now able to centralize many of our regulatory activities, including preparing submissions and tracking health authority interactions, in a single, unified system. This allows us to easily and quickly generate reports, analyses, and other data that can be shared more broadly across research and development."

One other advantage of modern RIM systems is that some—not all—have been specifically optimized for use by regulatory teams. They are built to support end-to-end regulatory processes for drug development; as opposed to some solutions that started outside of life sciences and then were customized to meet the needs of global pharmaceutical companies.

RIM systems are also adding capabilities that allow for the capture and aggregation of business intelligence—in this case regulatory intelligence—into the technology used by global regulatory teams.
The Organization for Professionals in Regulatory Affairs (TOPRA) defines regulatory intelligence as the act of processing targeted information and data from multiple sources, analyzing the data in its relevant context and generating a meaningful output. The industry's focus is shifting to improving their regulatory intelligence capabilities.

This involves reducing the number of repositories, connecting internal and external intelligence in meaningful ways, and ultimately making intelligence more accessible and actionable to better support decision-making. The aim is to apply regulatory intelligence throughout the entire lifecycle of a product—from

pre-clinical development through commercialization. Some regulatory teams are even extending their regulatory intelligence efforts by investing in Real World Evidence (RWE) and predictive analytics to mine existing information for valuable insights, augment planning efforts and mitigate risk.

"We are always looking to measure how and what we are doing more accurately to advise business decisions," said Scott Cleve, vice president of regulatory operations and compliance at bluebird bio, which is developing gene therapies for severe genetic diseases and cancers. "From a regulatory perspective, we are researching how predictive analytics might suggest new ways of approaching regulatory authorities to increase the probability of approval."

Some firms are also considering the value Artificial Intelligence (AI) and Machine Learning (ML) for automating manually intensive and time-consuming processes, said Analyst Steve Gens, founder of Gens and Associates, who believes most will be in "experimentation" phases in 2020 and 2021, but that AI could become common in three to four years.

Bluebird bio is among a growing number of companies exploring how AI can facilitate regulatory processes.

"We are starting to look at AI and build use cases to see what it could do for us," Cleve said. "There is a lot of work that must happen first, though, to cleanse our data and ensure that it is correctly labeled and identified so we can feed it into the (AI) algorithm and retrieve something useful from it."

Contending With Data

For decades regulatory submissions have taken the form of document dossiers. Over the last several years, regulators have taken an interest in data feeds to complement the dossier. In 2012, the European Medicines Agency (EMA) mandated the submission product details via the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD). EMA will soon mandate the submission of far greater volumes of product information through the Identification of Medicinal Products (IDMP) initiative.[6]

While organizations could get away with manually curating and entering XEVMPD data, IDMP's scope is far greater and reaches well outside the regulatory organization. One key IDMP objective is to standardize data commonly referred to as Substance, Product, Organization and Referential (SPOR) data. To comply efficiently, companies must master their SPOR data, and many are embracing IDMP as the impetus to make the necessary changes.

SPOR data is generated from within safety, regulatory, manufacturing and other departments. The variation in data definitions and terminology across these systems and across regions makes it challenging to aggregate it all. While a challenge, IDMP also presents an opportunity. The process of establishing a consistent nomenclature, adopting coded values and controlled vocabularies,

and identifying the authoritative source for each data point will naturally produce significant process improvements.

The expected arrival of IDMP is compelling organizations to harmonize their data, with most teams preparing to modernize their regulatory information management capabilities, said Gens.

"Many companies completed their IDMP gap analysis and were alarmed by the size and complexity of the necessary IDMP compliance project," he said. "They are subsequently focused on how to keep all this mission-critical data clean and updated over the long term."

The Industry Prepares for Change

This article discussed some of the trends that will change or expand the role of regulatory operations professionals in the coming years. Emerging therapies and markets will play a big part in changing the face of the regulatory landscape, while technology will serve as an important enabler and less of a commodity, in getting drugs to market. Looking ahead, regulatory operations professionals' role will continue to broaden and evolve significantly. They will need to adjust to the constant change around them by transforming their processes and technology—ultimately helping to improve the speed and chances of regulatory approval worldwide.

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About the Author

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