Transforming Regulatory Affairs with Actionable Insights - A Transition from Hindsight to Foresight

Abstract

A unified Regulatory Information Management (RIM) system has helped the pharma industry achieve operational efficiency in regulatory affairs and realize significant value by reducing cycle time cost, improved global visibility, and better quality and compliance[1]. Similar progress on the Regulatory Intelligence (RI) front is the next target for the companies given the challenges from the proliferation of markets, products, information, scattered tribal knowledge, and resource constraints.

According to the Steve Gens (2018) Report, **58%** pharma companies plan to enhance their RI capability and 51% of them are prioritizing RI for the next two years[2]. In another survey report, 20 of the 22 participating companies consider leveraging AI significantly in RI activities of data processing (mining, searching, monitoring, alerting)[3]. Hence, RI is poised to be the next frontier of importance, where value realization is expected in the analysis and application of intelligence.

In order to sustain in a fiercely competitive world, the pharma industry has to stay updated and prepared for evolving regulatory changes and legal requirements, obtain proactive actionable insights to build robust regulatory strategies for new product development, and rapidly acquire market insights on competitor products.

Importance of Regulatory Intelligence (RI)

The regulatory intelligence group in pharma companies keeps track of new regulations for actionable RI. Besides analyzing, they summarize, evaluate and communicate the associated impact of the changes on product development to various relevant stakeholders for necessary action.

The entire product development life cycle is dependent on a well-defined and robust regulatory strategy. The foundation of this strategy relies on effective intelligence spanning various strategic and operational aspects, under the following categories[4]:

- **Regulatory Environment:** To get inputs for defining regulatory strategy and target product profile
- **Perceptive Intelligence:** Perspectives of industry thought leaders and various stakeholders to help companies with insights on how, when, and where to position their products
- **Procedural Intelligence:** To interpret the regulatory provisions to be consumed easily e.g. biomarker qualification
- **Competitor Intelligence:** To find the market perception of competitor products and strategize and plan accordingly e.g. to get away from risks like Refusal to File Submission (RTF), drug withdrawals, non-compliance, etc.
- **Regulatory Precedents:** To find novel regulatory approaches or deviation from normal practice (success or failure rate)

Future Perspectives: Fast evolving pharma industry has already started prioritizing RI. However, there is need to bring agility in the process to receive real-time regulatory feeds, such as updates on new legislation changes and impact, insights on regulatory position of the competitor that can offer market advantage, success rate of drug approvals and launches, timely feedback from regulators on product development for timely incorporations in product submissions, etc. Following issues keep the pharma companies from extracting such intelligence:

- Extensive efforts required in the extraction of relevant insights from excessive levels of information
- Lack of confidence in the accuracy of the information, maintenance, and accessibility

- High investment in sourcing skilled resources trained to gather the right intelligence of value and understand the applicability of the information
- Time spent on the entire process of extraction, analysis, and dissemination of information

Improving Agility in Regulatory Intelligence

In order to meet the current challenges, Regulatory Intelligence needs to be agile. Our vision of an agile Unified Regulatory Insights is to transform the processes of data acquisition, summarization, analysis, application, and integration. A high-performance computing powered RI Platform leveraging cognitive technologies such as RPA, NLP, and AI/ML can be used to enable autonomous data acquisition and ingestion, and abstraction of data models and content storage. Following key transformation enablers can be leveraged to transform RI:

- **Smarter Data Acquisition:** Smarter Data Acquisition can be achieved by the adoption of standards and abstracted and referenced data models, controlled ontologies and vocabularies. This will enable smart crawling, extracting, storing and indexing of the data for faster data acquisition. For example, crawling regulatory websites and other resources for instant information extraction for product label changes, or for various regulatory changes can be enabled by using industry-aligned ontologies driven by open standards.
- **Machine-First Processing**: Intelligent data contextualization, by leveraging high and faster computing cognitive capabilities, can help quickly recognize the context of the queries and extract relevant useful information. Commoditization of machine learning and deep learning allows better synthesis and AI-powered real-time analysis of information. Advanced analytics can help derive insights and produce an autonomous report from machine-driven intelligent analysis of information.
- **Smart Communication Execution:** Business agility can be achieved by the application of automated and intelligent technologies linking derived insights from smarter data acquisition with smarter communication strategy, like daily notifications, embedding insights into processes, automatic updates, and leveraging rule libraries to auto-purpose the content. This will transform RI delivery by automatically delivering the right insight to the right audiences in the right communication format, hence transforming the user experience.

Transition to Unified Regulatory Insights requires some foundational elements like:

- Defining regulatory data space/creating semantic data models and universal vocabulary
- Creating ontologies/referential to enable classification
- Abstraction of information, smart data management, and visualization
- Advanced analytics to derive impact analysis of insight

With the vision of unified Regulatory Insights in place, let us understand how such a vision can be realized in the context of Agility in Regulatory Intelligence.

a. Considering a case of a newly released guidance on new trial design considerations for oncology drugs: The system can autonomously sense for any new or changed guidance from regulatory sites, abstract the relevant information by applying controlled vocabularies, and autonomously prepare and communicate a summarized report based on predefined strategy with a link to the actual guidance document. Additionally, with the help of the rule library, it can provide hints and pointers to show the impact and follow-up actions.

b. In an another example of new guidance issued by regulatory agencies on change in content and format of labels in pediatric drugs, an alert may be sent to the identified stakeholders for necessary impact, which may include actions like the creation of new SOP or making new changes in SOPs or need for training.

The vision of Unified Regulatory Insights, in addition to identifying, summarizing, and reporting the impact of regulatory changes is to further assist in actions to be taken after impact assessment. For example, in the case of a new SOP creation, it can aid the drafting of the SOP by providing an updated version of the SOP template with prepopulated sections. For timeline-specific mandatory regulatory requirements, the system may send triggers and notifications for deadlines at fixed intervals to relevant regulatory SMEs for avoiding the risk of non-compliance.

Benefits

Unified Regulatory Insights we believe will potentially transform the entire Regulatory Affairs through:

- **Unified RI hub:** It can facilitate the end-to-end process of information/data acquisition, processing and communication, and enable data ingestion, intelligent synthesis and analysis, content storage and strategic communication. It is expected to transform the process of data/information management from manual to highly automated.
- **Efficient Processes:** The RI hub can promote a standardized approach to manage regulatory intelligence by the adoption of ontologies and semantic-based models. It is expected to increase the speed of information processing from weeks to days and hours.
- **Better Communication:** It can intelligently analyze the communication strategies as per the need and provide more dynamic and richer content rather than static insights. It can also provide high or extended granular visibility.
- **Proactive to Predictive Risk Management:** It can enable the generation of technical, procedural, strategic, and scientific intelligence, and provide inputs for product development strategy and go/no-go strategy based on calculated scores. With a predictive analysis of operational parameters, it can predict risks for better decision making.

The Road Ahead

To realize the significant value through the Unified Regulatory Insights, a minimum viable product (MVP) approach can be considered, for which it is important to consider the following:

1. Understand the need and plan to achieve the RI objective based on current challenges, desired outcomes, etc.
2. Assess where to focus, data availability, data harmonization and/or competencies available.
3. Visualize the technology investment buy-in roadmap to realize value from the platform.
4. Prioritize the capabilities to generate a high RoI.
5. Pick high-impact use cases rather than trying a big-bang approach.

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Rita Shah is a Clinical Research professional with over 23 years of experience in Pharma R&D. Rita has a PhD in Organic Chemistry from Council of Scientific & Industrial Research (CSIR) and Post doctorate Fellow in Endocrinology & Bone Metabolism from IUPUI, Indianapolis, USA. She has more than a dozen research publications in peer reviewed journals. At TCS, Rita is actively involved in numerous R&D outsourcing transformation initiatives with the current focus on automation and helping to conceptualize and develop innovative solutions, as well as enabled process optimization.

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