TATA CONSULTANCY SERVICES

Building on belief

Regulatory intelligence: Ace it with analytics and automation

Abstract

Intelligent automation is now an inseparable part of several business functions. From reducing costs to simplifying data gathering between different systems, automation presents numerous opportunities to enhance quality and efficiency. Advanced technologies such as artificial intelligence (AI), machine learning and natural language processing take over manual, repetitive, and time-consuming tasks to achieve self-evolving, automated systems with rapid outcomes. In a survey to identify potential development paths for these technologies, twenty of the twenty-two participating pharmaceutical companies stated that AI offers significant opportunities for regulatory intelligence (RI) activities in data processing (mining, searching, monitoring, alerting)[1]. Technology presents an opportunity to enhance the quality, speed, and efficiency of RI activities.

RI drives strategic decision making

RI is playing an important part in acquiring knowledge through data collection, aggregation, analysis, and interpretation of information sources which enable timely decision-making. As a result, RI has become a crucial skill for regulatory professionals working in the pharmaceutical, medical device and biotechnology sectors. RI can be described through three prongs: policy, strategy, and operations. For small companies, RI is an essential component of a person's job and not a distinct function, and it will not remain current since it is not a priority. For a small company, it is very unclear and not differentiated. As a company grows, RI needs to be differentiated as a distinct function to support strategy and policy needs. This transition time can be the hardest for companies (from small to medium to large). Depending upon the size of the company, RI plays a key factor as a business function[2].

In pharma regulation, a small but problematic detail can lead to a significant error. This could be a trigger for compliance and data integrity issues. After identifying errors and taking corrective actions, it is necessary to identify the source of the error to avoid similar issues in the future. This is the area where automation could play a major role, especially in handling data silos.

Handling data silos: Regulatory teams across the world face issues such as inconsistent and incomplete data. This is due to the prevailing non-interoperable legacy enterprise systems. It is cumbersome to determine if the organization is using the latest documentation process. This is especially true when users across the globe are using disparate systems, leading to inconsistent filings and submission errors. The system should act as a 'single source of truth' that can provide consistent and complete data through a central repository. Further, automated processing and AI improves customer service, increases productivity, helps groups meet compliance requirements and reduces costs.

[1] Springer, Potential Use of Artificial Intelligence for Regulatory Intelligence: Biopharmaceutical Industry's Views, accessed August 24, 2021, https://link.springer.com/article/10.1177/2168479018812778

[2] RAPS, Regulatory Intelligence and Policy, Regulatory Focus. 20 December 2019, accessed August 24, 2021, https://www.raps.org/news-and-articles/news-articles/2019/12/regulatory-intelligence-and-policy

Enhancing regulatory intelligence capabilities:

As regulatory personnel, one needs to deal with external and internal data sources to keep their most recent submission strategies up to date. Failing to meet this requirement will jeopardize the application approvals. Gathering inputs from external and internal data sources covering all phases of pre-production, production and distribution, and data like corrective and preventive actions, deviations, risk management, development and maintenance, supply chain are complex, which involve humongous efforts. All the core steps in this process for extraction of data, validation, cleaning of desired data, organizing it as per submission requirements and ensuring to place it in desired drug product folders for apt usage are challenging. The contextualization of the data for intended usage covering filter, compare, refine, review, sort, context, interpret, precedent, trends of the data may not be complete and not necessarily compliant always. Hence every organization faces inconsistent outcomes.

The regulatory environment is complex and continuously changing. The perfect drug product regulatory submission plan is dependent on a well-defined and robust regulatory strategy. Any disparities in strategy which indicate drug product quality, safety and efficacy followed by compliance issues will lead to strict enforcement actions by the regulatory agencies or health authorities. In a larger context, non-compliance leads to loss of reputation and negatively impacts companies' brand value.

As depicted in Figure-1, the basis for this approach relies on effective RI covering various strategic and operational aspects, including data processing, contextualization, and RI report generation. In the current scenario, almost all these features are handled manually with the help of available RI tools where these tools address change management to the larger extent.

The practical challenges that impact the drug product approval cycles, that need to be addressed:

- **Access to data:** Difficulty in obtaining, assessing and/or compiling the data
- **Staying on top of regulatory changes:** Keeping abreast of the regulatory changes is challenging as there is no fixed schedule for the health authority to introduce these changes
- **Analyzing data:** Contextualizing data manually to make strategic decisions
- **Result interpretation:** The inability to interpret regulatory guidance based on key search and communicate effectively

At the data processing stage, it is possible to automate predictive extraction and early checking, validating the entire data set, pulling guidance/data, ensuring compliance, and setting up rules and loading, ensuring traceability as per the appropriate requirements of each module and product.

At the contextualization stage, potential areas such as filter, compare, refine, interpret, precedents, trends could be automated.

RI stages such as an easy and understandable data presentation, a regulatory strategy report that is region-specific or therapy-specific, and multiple options to choose for the best strategy based on business and operational goals may qualify as automation.

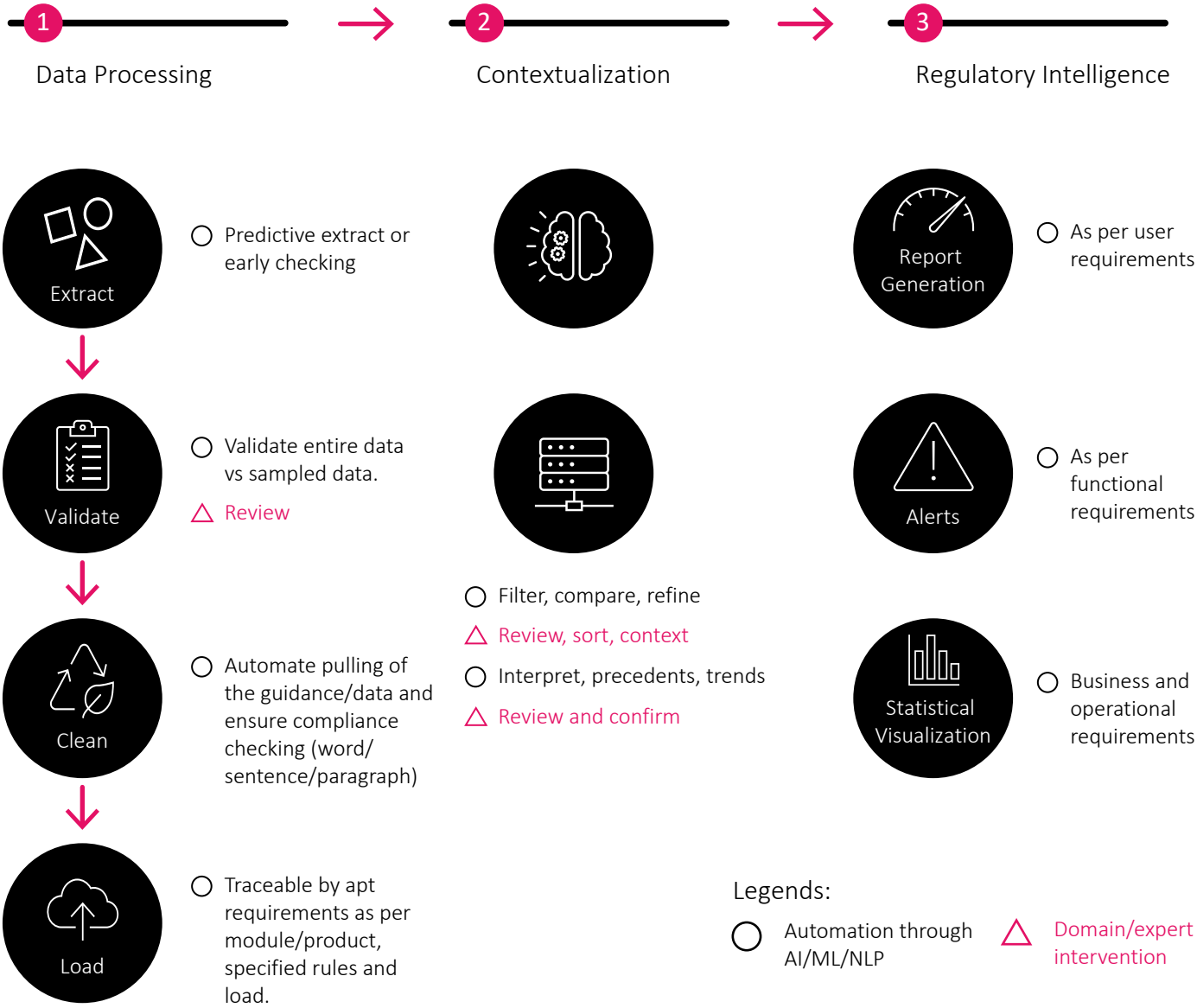

Figure-1: RI – Amalgamation of automation and domain intervention

The Double-A factor

In the current scenario, RI is an essential instrument that enables the utilization of existing or available information to take certain preemptive measures that help avoid the cost of non-compliance. Pharma regulatory professionals deal with the collection of data from source documents and convert them into manageable information as per regulatory submission requirements. Through RI analytics and automation, the major realization is focused on the need for proactive rather than reactive measures.

Analytics and automation offer an integrated solution where regulatory professionals can access all intended data on a single platform at any time; it enhances consistency in strategic and compliance outcomes, maintains enduring audit trail to enable the auditor to monitor them as and when required. As it provides perceptive reports and analysis on a single dashboard, it facilitates tactical and proactive decision-making, reducing time and cost spent.

RI and the future of pharma

We are in an era of ever-changing regulations and increased enforcement activities; hence, targeted RI allows the users to accurately identify the information which is most relevant to them. Organizations would be on the top ranking only when they keep their strategies ahead of the competitors in R&D and operations.

Justifying the imperative for RI investments is challenging. The following areas can showcase the organization the value of RI:

1. **Changing regulations and increased liability:** Small changes in the regulatory or business environment can have enormous repercussions in the modern world. Thus, it becomes even more crucial to keep up with new technology and regulations.
2. **Data-driven decisions can mean higher productivity and profits:** Analysis and interpretation of data are critical to the success of data-driven decisions.
3. **Hard benefits of RI:** Reduction in costs can be achieved by eliminating manual processes and preventing non-compliance, as a consequence of eliminating manual processes.
4. **The 'soft' benefits of RI:** Keep in mind cost avoidance strategies (action taken to reduce future costs). An integrated RI system that automates a manual submission process can formalize and improve the accuracy of each submission. This could allow the company to increase the number of new products in the market and standardize processes at the same time.

The approach aimed at driving the business momentum consists of refactoring and reinventing the existing processes, without affecting the desired outcomes. Assessing the potential benefits of RI can be done effectively by leveraging the existing repository and modifying the processes through analytics and automation.

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Vijaya is a senior domain consultant with TCS' Life Sciences business unit. A registered pharmacist with a Master of Pharmacy degree, he has over 17 years of experience in regulatory research and development. With core expertise in chemistry, manufacturing and controls (CMC), Vijaya has designed regulatory strategies for major regulated markets. He works with TCS' pharma clients to manage regulatory risks and strategize regulatory filings. Vijaya has published several research papers in both international and national journals, mostly on regulatory, clinical, and community pharmacy.

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