WHITE PAPER

TATA CONSULTANCY SERVICES

Envisioning Smart Regulatory Intelligence in Pharma

Abstract

For a long time now, pharmaceutical organizations across the globe have been plagued with several challenges concerning the deluge of data they have to handle. These can be summarized as the twin challenges of manually researching the changing regulatory guidelines to ensure better compliance, and reducing re-work as a result of departmental silos within the organization and the non-availability of past records for reference on demand. These two issues lead to reduced operational efficiency, increased time, effort, and cost.

This paper addresses how these challenges can be holistically resolved by embracing a technology-centric approach to design a smart solution for regulatory adherence. This solution will be able to provide actionable insights and facilitate precise, readily-available, and contextual information that enables reference to literature on-demand, provides regulatory intelligence and accelerates response to health authority queries.

Empowering regulatory processes with machine intelligence

Regulatory departments of pharmaceutical companies are always expected to stay abreast with the ever-changing and evolving regulatory guidelines and ensure 100% compliance. They are compelled to browse through various regulatory updates manually to understand the latest changes, global advancements, approval trends, clinical evaluation findings, regulatory filings, etc. However, such manual approach to tracking is almost always error-prone, time-consuming, and effort-intensive. In addition, within pharma organizations, regulatory data is usually stored in silos across various departments and/or locations. Multiple departments store Health Authority Queries (HAQs) in spreadsheets, making it difficult for other departments to access them for reference.

With ever increasing market demand, new regulations and evolving regulatory compliance requirements, the industry is facing diverse challenges to manage regulatory lifecycle and change management. At the site level, regulators are unable to quickly respond to changes proposed by pharma due to non-availability of required submission documents under assessment leading to increased cycle time, effort and cost.

With the help of a smart regulatory intelligence solution, life sciences organizations can reduce manual work and stay updated on the latest trends in the domain. Such a solution would also help in limiting the number of submission queries received from Health Authorities (HA), reducing response time for HAQs, and centralizing all regulatory information for the entire organization. As it facilitates faster discovery of information, it can quickly indicate key factors during an unforeseen situation like the COVID-19 pandemic. Based on these findings, pharma organizations can decide between suspending or continuing an ongoing study or initiating a new study altogether.

What is Regulatory Intelligence (RI)?

Regulatory Intelligence leverages the power of automation, Artificial Intelligence (AI), Natural Language Processing (NLP), and real-time analytics to provide meaningful insights into regulatory processes. The RI solution has two facets to it – market intelligence and operational intelligence.

- **Market Intelligence:** This pertains to building a system for data that is available in the public domain, including HA websites, regulatory or medical news portals/articles, drug manufacturing companies' portals, patents, journals, Orange Books, etc. An AI-powered RI solution with web-crawling capabilities and the ability to process text and image components is leveraged to access documents in PDF, DOC, and XML formats or even image files. The extraction is done based on predefined rules, dictionaries, and ontologies covering medical entities like Therapeutic Areas, Indications, Study Types, etc. The extracted data, which can be structured, semi-structured or unstructured, is then processed, indexed and fed into a huge and scalable repository with a link to the original source for traceability. A smart search functionality to provide meaningful and relevant results by extracting the metadata present in the user's query is built. Smart search enables the auto-handling across various parameters such as synonymization, antonymization, spellcheck, Booleans, aliases, 'containing,' 'not containing,' 'within,' and negative sentiments in the query and also extracts the context of the query with the help of NLP.

- **Operational Intelligence:** This is similar to Market Intelligence, but it deals with data such as correspondence with the HAs that is proprietary to each individual organization. This includes Response to Queries (RTQs) by an organization, as well as Minutes of Meetings (MoM) between the two. Operational excellence can be achieved by employing an AI-powered cloud-based solution with the capacity to read or scan letters and meeting minutes from PDF files or e-mails received from HA with attachments. Relevant data can be extracted from the scanned document through various techniques, and a single repository is built to store all regulatory queries and their responses with complete reference to the original document. Based on the requirement, the techniques – either separately or in combination – that can be used for extraction are:

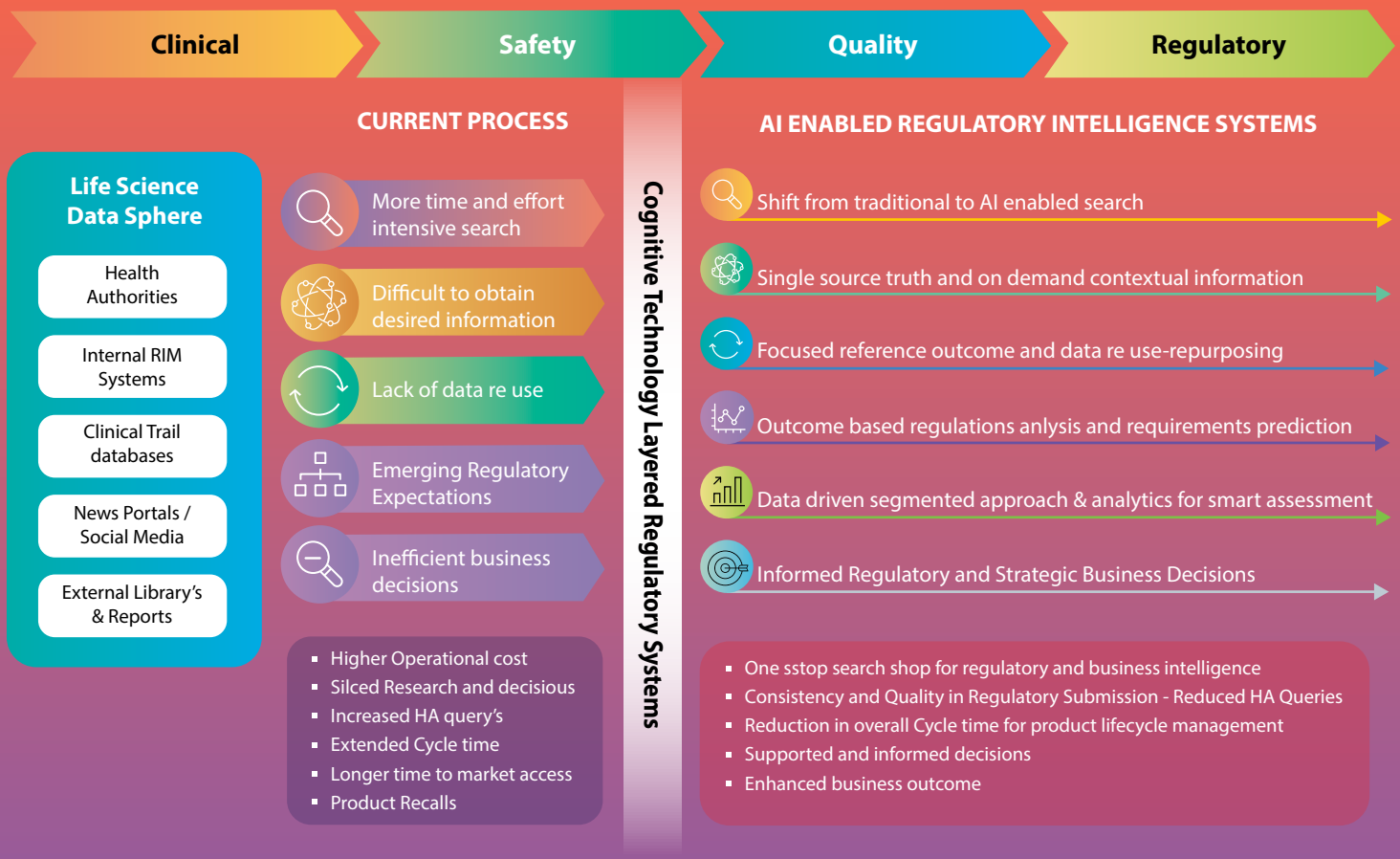
  - Generic entity extraction
  - Ontology-based extraction
  - HRM (Human Reading Mimicking)-based extraction
  - Gazette-based extraction

Just as with Market Intelligence, the extracted information can be stored in a centralized repository with traceability for the original documents. Text-based content can then be indexed in the search engine to enable keyword-based search. Further, NLP can be leveraged to train the model continuously on extracted questions and enable context-based search rather than keyword-based ones to find similar HAQ responses from the past.

In addition, an AI-powered RI solution capable of processing text and image components can be leveraged to monitor regulatory guidelines updates and access documents in PDF, DOC, and XML formats thereby providing intelligent assessment of regulatory updates. A digital repository with advanced analytical capabilities over regulation updates can provide near real-time requirement prediction for new changes, to make sure that the requirements are completely met at the first submission. This effectively reduces assessment time, accelerates lifecycle management quality and regulator assessment, and enables timely market access.

An advanced RI solution should also provide personalization for users, including the option to perform contextual search, configure fields to be displayed on the screen, save searched queries for later use, provide 'yes/no' inputs on answer accuracy, etc. A real-time analytical capability in the tool will help identify various regulatory trends and provide insights through a cutting-edge rich visualization framework. Actionable insights provided by the tool will enhance decision-making capabilities, increase efficiency, and improve compliance. In addition, a user-friendly and intuitive mobile app can be created to provide the above information in a concise, crisp, and self-explanatory manner.

A robust regulatory intelligence platform drives efficiency in regulatory processing, improves stakeholder collaborations, promotes transparency, provides ease of requirement prediction and enables quality with data driven submissions.



Pictorial Representation of Traditional vs AI-enabled Regulatory Intelligence System

Conclusion

By restructuring legacy processes and reimagining regulatory information with the help of digital technologies such as artificial intelligence, pharmaceutical organizations can operate more efficiently and respond with speed to any emerging critical situation. The integrated Regulatory Intelligence solution facilitates the reuse of internal information and enables a more streamlined flow of global regulatory requirements. The need of the hour, thus, is to envisage a connected future with the aid of digital technologies and RI. Through its myriad capabilities and possibilities, it can help pharma organizations overcome critical challenges and assist them in their pursuit of building a smart enterprise.

About The Author

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Nilam Kumar is working with the ADD Regulatory and Regulatory affairs services team as a Domain Consultant with Chemistry, Manufacturing and Controls (CMC) as core expertise. He is an Analytical Chemist with a masters' degree in Analytical Science. Nilam possesses over 14 years of work experience in global regulatory affairs with 8 years in strategy, chemistry, manufacturing and controls (CMC) and regulatory operations, and 6 years of work experience in Analytical Research & Drug Development. He has been part of the TCS ADD platform for past 3 years and works in regulatory process enhancements through creation of lean processes; regulatory bench marking; use of automation, Artificial intelligence and best practice for Regulatory Processes.

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Digital Advangage for Life Sciences

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