TATA CONSULTANCY SERVICES

Building on belief

Reimagining pharma regulatory affairs in the age of AI

Abstract

In the current state of highly competitive markets and accelerated drug approvals, most of the pharmaceutical giants are looking for a productive change, majorly with a focus on improving efficiencies, maintaining compliance with new standards, and gaining greater internal alignment along with past learnings. The pharma industry has identified new priorities and key areas to be addressed, striking a balance between novelty, performance, trust, and streamlining regulatory operations, to better manage challenges facing the industry by improving regulatory operations.

Regulatory affairs has emerged as a key function that curates R&D data, submits information as a coherent whole to health authorities, and maintains licenses on the market. From drug discovery to clinical trials, and from marketing and to product management, the use of natural language processing, cognitive computing, machine learning, and analytics supports increased automation within regulatory affairs and offers promise and possibility. Intricate, time-consuming tasks that once took weeks, months or even years to accomplish are now being reimagined, through AI and other digital technologies.[1]

The competitive advantage of an adaptive mindset

The modern regulatory affairs has become a drive for strategic advantage. As the industry is being held to increasingly high standards designed to improve patient safety and efficacy, it is being asked to take a greater enabling role.[2]

An adaptive mindset is one of the key requirements for regulatory professionals. On a day-to-day basis, we deal with hyper-complex situations with ever-changing regulations, which cannot be responded to with the 'usual' way of thinking. For any pre- and post-approval changes, one needs to remember the dynamics of local health authority regulations and product development complexities and in turn, we cannot apply the same approach for other products considering their dynamics. Further, we have no control over how the regulations are evolving; however, we do have control over dynamic planners, integrators, and solvers. In a practical scenario, sometimes we need to adopt the agency recommendations, and in some scenarios, we need to provide a rationale for the proposal we made against agency recommendations. Hence balancing the regulatory change with an adaptive mindset is vital to providing strategic innovative proposals for getting drug product approvals.

Imperative changes needed in this transition

The potential of modern technologies, such as digitalization, machine learning, and artificial intelligence are already standard in other industries such as banking, and insurance sectors where regulations are applied, although it has not been leveraged extensively within pharma regulatory affairs. To capitalize on

[1] Journal for Clinical Studies, Reimagining the Pharmaceutical Life Cycle with Artificial Intelligence, accessed 19 Nov 2021, https://www.google.co.in/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwilra3CmaT0AhXhmuYKHfmCDlwQFnoECAEQAQ&url=https%3A%2F%2Fwww.jforcs.com%2Fwp-content%2Fuploads%2F2019%2F04%2FReimagining-the-pharmaceutical-life-cycle.pdf&usg=AOvVaw1jKFkG7yeSnqcOl3quznC-

[2] Pharmexec, The evolution of regulatory operations, accessed 24 Nov 2021, https://www.pharmexec.com/view/evolution-regulatory-operations

advanced technologies, pharmaceutical majors should develop and implement a solution roadmap, identify new opportunities within the existing tools, or enhance the existing tools through further development, to be deployed for the collection and digital management of the global and country-level regulatory requirements, strategic needs, and associated intelligence. The content is ultimately needed to automatically develop a regulatory strategy and filing plan, which can digitally integrate with other regulatory submission tools to automate downstream tasks such as, but not limited to, the auto construction of a dossier submission build, intended for health authorities throughout the world.

Considering the boundaries of regulatory requirements, intelligence, and past submissions and strategies as indicators of future progress- the desired transfer state and delivery of this initiative requires getting investigational and commercialization approvals for products in global markets and maintaining them in the most efficient, and strategically effective manner possible. This initiative is seeking to look beyond solving the dilemma of understanding what regulatory requirements are from the perspective of a transactional database of requirements. Pharma majors should look at regulatory areas to address the ultimate need to apply regulatory data, by expanding technologies to employ natural language processing, cognitive computing, machine learning and analytics to support increased automation within regulatory affairs.

Reimagining regulatory requirements and intelligence

To obtain drug product approvals globally and maintain them through their lifecycles in the most appropriate and strategically effective manner possible, one should understand the given boundaries of the regulatory data sets like the source of regulatory intelligence, global and country-specific requirements, data repositories and document management systems where primary source data is located. Once this is attained, one could look for an innovative approach to driving regulatory outputs from significant data repositories and intelligence.

Irrespective of the fact that technology can benefit pharmaceutical companies, regulatory chemistry manufacturing, and controls, and operations teams need to assess the real need for automation and the ways it can improve process efficiencies. To begin with, specific process automation requirements can be defined by:

- Mapping the entire end-to-end processes.
- Identifying process steps that can be automated.
- Leveraging appropriate criteria to understand the logic for automation, maturity of process and business value, and availability of data.

The target model for automation can be defined with the help of these steps following the evaluation process. For effective management of regulatory automation, organizations must pay attention to the following aspects:

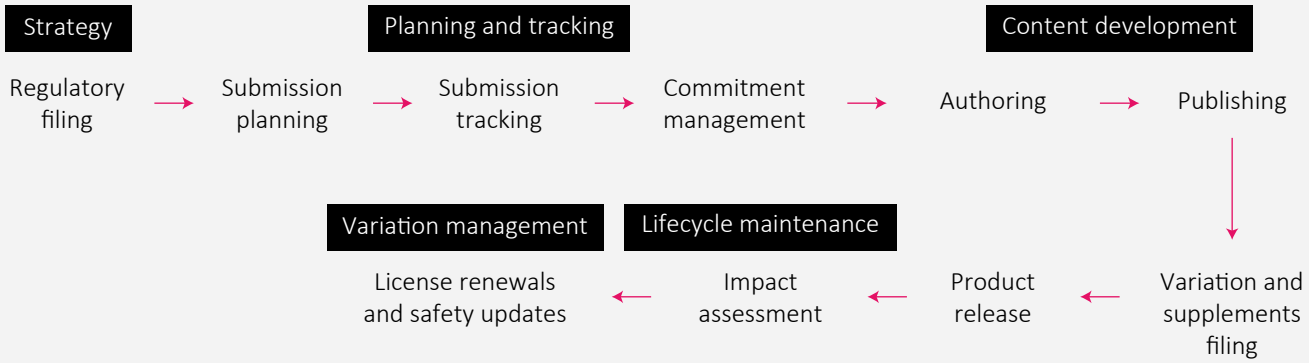
Intelligent operations: Pushes data-driven models through smart alerts and workflows.
Technology simplification: Enables programs focused on process automation and rationalization, and makes the technology landscape smarter, scalable, and future ready.
Data repositories: Implement databases and invest in development capabilities in advanced analytics. Improve data quality and accuracy by adopting standard approaches and allied technologies.
AI and cognitive: Leveraging AI technologies to convert information from structured and unstructured sources into knowledge and actionable insights.

The problem—as it relates to regulatory data—has majorly two dimensions, mainly at data collection and data utilization including:

- Highly decentralized, manual, cumbersome, and inefficient processes followed.
- Regulatory data is decentralized, manual, indirect, and imprecise.
- Inability to effectively access across and assess operational data for the reuse of existing artifacts.
- Inability to identify regulatory requirements common across countries to effectively align submission content resulting in duplication of efforts for same or similar submission packages.

- Feeding of regulatory data by individuals or by the system is needed at varying levels thereby hindering the ability to increase efficiencies majorly at regulatory strategy, submission or filing plan, global or national dossier structure, authoring content, and submissions.

All these challenges could be handled through proper usage of data and integrating apt technology with the systems and repositories while data collection and data utilization focusing from strategy till variation management is shown below:



A schematic representation of the input, process, and output is provided in Figure 1.

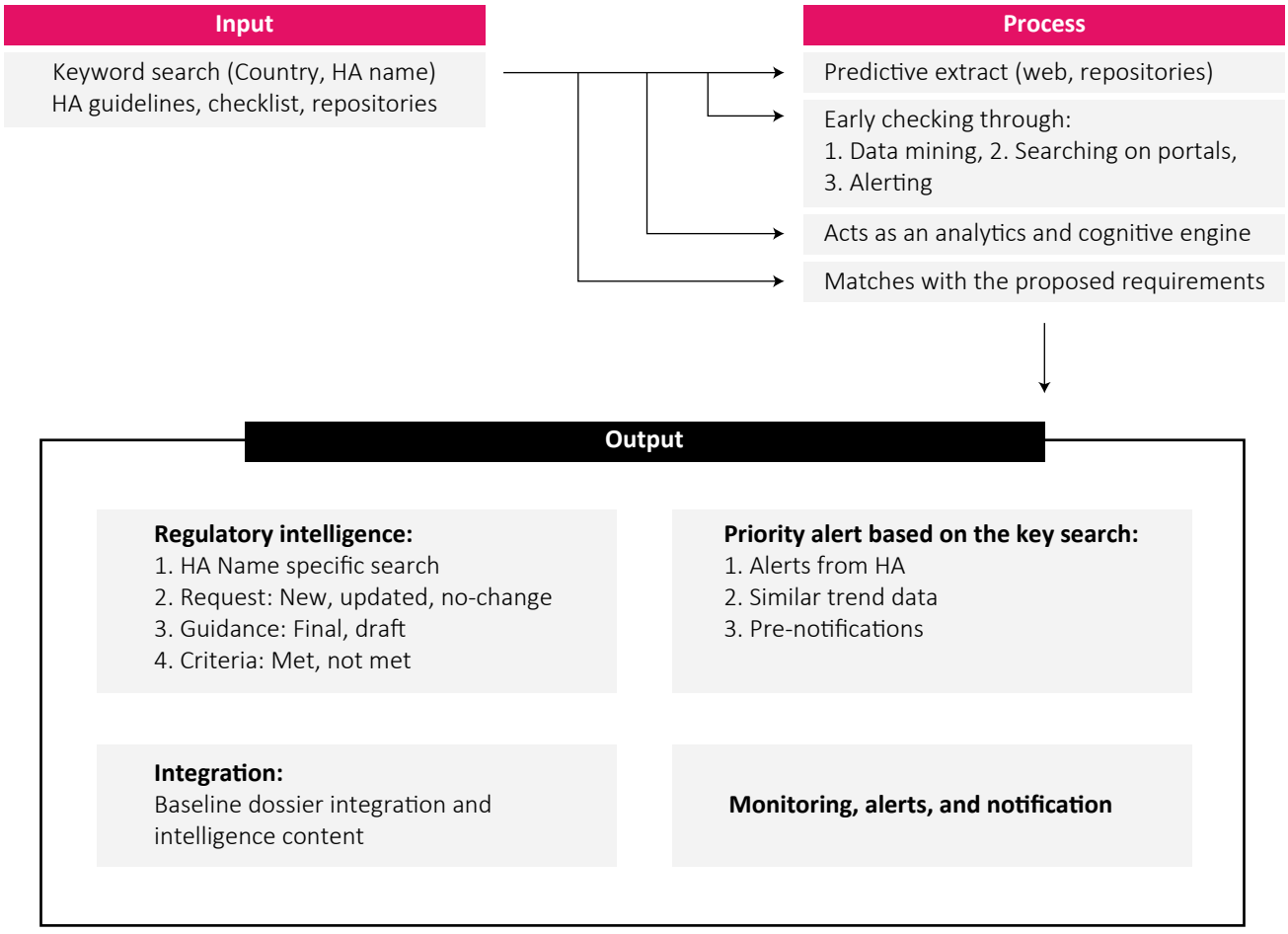


Figure 1: Reimagine pharma regulatory with advanced technology

Reimagined intelligence anticipates meeting the following key needs: Automatically capturing regulatory requirements and guidance and describing the information appropriately, effectively collecting the data, enabling a centralized search, and displaying relevant requirements, intelligence, and priority inputs.

As a result, it should be able to integrate with both upstream and downstream systems to allow automated consumption and execution of requirements and/or strategies, as well as to improve process efficiency through improved monitoring, alerts, and notifications, and by reducing submission management efforts. Better control over the process through real-time monitoring.

How we embrace technology to reimagine regulatory will in turn shape the future pharma regulatory, performance, and its reputation. Although there is no set playbook for how regulatory functions should operate in an uncertain future, now may be the ideal time to identify the right technology, people and apply the right approach for your organization's most important pharma regulatory work. The end goal is to achieve optimal timely regulatory compliance, tailor the regulatory strategy to consider the unique profile of the product and its license, in turn to get most optimal approval by successfully exploring all regulatory pathways and best practice options.

About the author

Vijaya is an assistant general manager and senior domain consultant working with the Regulatory Services group within TCS' Life Sciences 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). He is currently leading the regulatory affairs SMEs in TCS, and his current portfolio includes CMC, submission management strategies, compliance services, and RA automation transformation initiatives. 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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