Embracing AI-Driven Technology to Augment Quality and Regulatory Activities

The benefits of AI in healthcare have been identified by many global regulators

Medical companies work in an environment of ever-increasing challenge and complexity. Global regulations continue to evolve with advancements in technology and variations in requirements from country to country. This brings unavoidable technical complexity to daily tasks of quality and regulatory professionals.

Additionally, the financial challenges of running a commercial organization mean that companies are often either looking to drive shareholder value (profitability) or — for companies that aren't listed on stock exchanges — become an attractive target for acquisition.

Healthcare product offerings also have become more complex, with solutions that combine a range of product types and cover an increasing number of clinical applications. This further complicates the compliance processes and structures necessary to address healthcare complexities.

It's in this multiplex environment of evolving regulatory complexity, global financial challenges, and advancing healthcare solutions that quality and regulatory professionals find themselves. And a key role of these quality and regulatory teams is ensuring that global markets and patients continue to receive safe and effective medical products. The primary question, then, is what role does technology (including AI) play in supporting quality and regulatory teams to enhance their daily performance?

Complexity upon complexity — the opportunities for AI

At a broad level, the global governance and regulatory framework of various regulations and standards aligns around the key principle of patient and public safety, which includes product security and data integrity requirements:

Objective evidence needs to be gathered, reviewed, and prepared to justify safety, efficacy, and performance claims.

Premarket approvals give governments and authorized third parties an opportunity to verify that a level of conformity has been reached in product safety and efficacy before a product is placed in a market.

Global and local standards govern GxP and quality management system (QMS) requirements to ensure controls are in place during the design, manufacture, sale, distribution, and life cycle management of medical products.

Postmarket activities are mandated to ensure that adverse events are captured and reported in a timely manner, and any systemic issue or threat to public health is swiftly confined and remediated.

Political and economic factors can drive global variations in how countries enact regulations to navigate the above activities as well as the differences between,

1. the mechanism of action of pharmaceutical and medical device/in vitro diagnostic products;
2. the economies of scale of these industries; and
3. the breadth of technologies across life sciences, which adds incremental complexities to the arena within which quality and regulatory professionals operate.

Technological solutions are needed to help businesses navigate the complexities of delivering global healthcare solutions in a regulated industry that requires solutions to be within validated processes. For example, the shift from running a paper-based QMS to an electronic, enterprise QMS is one that yields many benefits in transparency of decision-making, repeatability of process, customer and regulator response, and resource optimization, particularly when an organization is growing at scale.

Optimizing end-to-end processes is a key deliverable of many QMS, because moving data and documents effectively within an organization's workflows supports quality and regulatory professionals (among others) in their daily activities. Yet, even with technology supporting the optimization of such workflows, the underlying divergence of global regulation, pressures of financial performance, and complexities of healthcare solutions (particularly with novel technologies) remain. Quality and regulatory professionals must apply the context of their companies' product types and solutions to the written text of global regulations and standards.

It's perhaps in this arena where AI can bring about the next step in automating decision support — helping quality and regulatory professionals handle complexities as they strive to apply global governance to their product pipelines.

The benefits of AI in healthcare, including the activities of quality and regulatory professionals, have been identified by many global regulators as well as the U.S. Food and Drug Administration (FDA). The FDA's article, "Focus Area: Artificial Intelligence," identifies the importance of this technology:

"Artificial intelligence (AI) solutions have the potential to improve automation and learning of medical devices, the efficiency of diagnostic/therapeutic development, and commercial manufacturing, regulatory assessment, and postmarket surveillance, among many other potential applications. These improvements increase the accuracy of predictive modeling, enable efficient automation of medical devices and manufacturing processes, leverage knowledge management resources to improve regulatory review, and focus and improve postmarket surveillance."

The industry group MedTech Europe also identifies AI's ability to increase the quality of patient outcomes, and to support timely access to safe, effective, and innovative medical technologies. A key component of this is how AI is used within the systems of quality and regulatory professionals. For example, imagine if:

AI-driven technologies in the postmarket/safety arena were able to continuously search globally available data sets in social media, industry journals, publicly available papers, and news articles. From this high volume of data, potential adverse events and localized signals or trends could be quickly identified and flagged for a qualified human professional to review. The data provided in this review could come in a prepopulated template — precoded, should this be needed for a global regulatory agency report. The review could include prompts and suggestions on what additional text may need to be included in the regulatory agency report based on previous experience or precedence with the agency and other reports of a similar nature. For the complaint-investigation activity, AI could provide support by suggesting potential failure modes with a probability of likelihood that's calculated based on the data available in a company's system.

AI-driven technologies in the premarket/registration arena were able to provide to R&D and clinical teams a succinct list of regulations and standards affecting the product design, based on global and local country requirements driven by product type, product composition, risk class, and the target country for the launch. From this high volume of regulation, testing parameters and sample sizes could be suggested. The system could also indicate additional countries whose requirements may have been fully or partially met by meeting the requirements of those in the initial launch. To support the submission activity, AI drafts predefined country templates and populates content once the R&D phase of a launch is complete. Then it offers prompts and suggestions on what additional text or information will have to be included based on previous experience with the agency that will receive the submission, or from other submissions of a similar nature.

The above examples are only a snapshot of where AI can bring processing capabilities and a "digital eye" to enhance the daily operations of quality and regulatory professionals. Ultimately, AI capabilities augmented by human professionals could provide safe and effective medical solutions to global markets.

Key considerations for AI applications

The healthcare industry is a heavily regulated environment with an underlying focus on user and patient safety. As previously mentioned, regulations and standards govern the activities of systems, processes, and individuals involved in the design, manufacture, sale, distribution, and life cycle management of safe and effective products. Key systems need proven validation, and these validation activities are often reviewed during cyclical inspections by global agencies. It's no different for next-generation AI technology.

In a study commissioned by the European Parliamentary Research Service (EPRS) on artificial intelligence in healthcare in 2022, seven key risks were identified:

1. Patient harm due to AI errors
2. The misuse of medical AI tools
3. Bias in AI and the perpetuation of existing inequities
4. Lack of transparency
5. Privacy and security issues
6. Gaps in accountability
7. Obstacles in implementation

The EPRS paper describes both the potential risks and proposed mitigations around these risks, and while the paper also identifies the potential benefits of AI in healthcare as a whole, it does conclude that more research is needed — particularly in the areas of clinical, ethical, and technical robustness in medical AI. Many of the areas identified by this paper can also apply to the potential applications of AI in systems used by quality and regulatory professionals in their daily activities.

Process and system validation matters, and such validation activities are heavily mandated by regulation. Should AI transform a core quality or regulatory workflow from decision support (i.e., providing information for a qualified human to make a decision) to decision-making (i.e., AI decides in lieu of a qualified human), then the burden of evidence needed to demonstrate conformance to regulation and standards would be significant.

While validating such systems is key — and noting that AI's capabilities appear to be advancing rapidly — there may be some limitations to how AI can be applied to quality and regulatory professional activity. In a review of ChatGPT, a team from Bath University in the U.K. found that some of the responses from their test data displayed a lack of critical thinking.

This may be where we see AI augmenting the capabilities of quality and regulatory professionals. It can navigate with speed and repeatability a complex and changing regulatory landscape to provide regulatory requirements and operational precedence data on the basis of core target questions. AI could also provide insights into patterns and trends based on its "digital eye," and even recommend next steps. The industry professional then decides how to use this information and proceed, ultimately augmenting the AI data with human activities driving strategic planning and operational activities. AI can optimize the transactional, administrative nature of industry professionals' roles and provide insights but, ultimately, decisions would be made by humans.

Summary

Artificial intelligence has the potential to transform the activities of quality and regulatory professionals. This is particularly important in an environment where technology is a key solution for supporting industry professionals as they navigate a technical arena of ever-divergent regulatory variation, work with companies concerned with financial performance, and deliver safe and effective products to global markets to support clinical solutions of increasing complexity. AI can help automate transactional, administrative activities, increase process predictability, and provide significant insights with its capacity to screen data at a rate beyond human capabilities.

However, the use of AI should not and will likely not go without any controls. Healthcare is a regulated industry: Demonstrating that adequate controls and validations are in place is key, ensuring that patient safety remains the primary focus and deliverable of any technological solution.

AI can also come with a data bias, and using AI has been identified as having risk. The future is an exciting one and is likely to be a journey with points of evolution as the healthcare industry adapts to new AI technologies.

Using AI technology could be critical to quality and regulatory professionals in optimizing their daily activities. However, technology is only the facilitator. It's patient health that truly matters, and for this reason the use of AI is likely to come with some form of regulated control.

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