Article

Defining the Future of Quality and Regulatory Operations in MedTech

Regulatory requirements constantly change because of the rapid integration of technologies, such as traditional and generative artificial intelligence

As seen in Medical Product Outsourcing.

The MedTech industry is in an era of evolving complexity. The ever-increasing number of regulatory requirements, plus the continuous evolution and divergence of global standards, alongside the rapid integration of technologies such as Artificial Intelligence (AI) and Generative AI (GenAI) have created a challenging path forward for the MedTech space.

The harmonization of MedTech quality and regulatory regulations and standards is not likely to occur anytime soon. Therefore, organizations must find successful ways to operate within the complexity of the global landscape. Successful navigation requires agility, flexibility and the ability to both understand and leverage technological tools to ensure patient safety, data security and product performance while ultimately ensuring the provision of safe and effective product solutions.

Evaluating the regulatory impact

The regulatory landscape is dynamic. The discovery of novel therapeutic areas as well as the advancement of product solutions that typically combine a range of risk classes, product types and steps across the pharmaceutical and medical device industries contribute to the shifting environment. Additionally, the need to meet a range of varying global data and privacy requirements adds complexity to the product development space.

The use of AI and other advanced technologies in MedTech has led to the development of regulations that target the use of automation. These must be considered when products are developed for both local and global markets. As a result, regulatory experts now fulfill a key role in terms of the design of product hardware and software and have a need to consider a variety of inputs when supporting the gathering of global product design and market access requirements. In order to effectively communicate the need for a widened, global vision, experts must be able to clearly articulate global regulatory boundaries and product requirements, relate them back to commercial goals and predictably define market access timelines and dependencies that need consideration. This enables companies to effectively commercialize their product solutions.

Today's environment of connected devices presents an opportunity to leverage AI (including GenAI) to significantly enhance and provide new capabilities to quality and regulatory operations through supporting an

augmented user. These technologies can support core documentation drafting, such as regulatory submissions, adverse event reports or audit responses, as well as support signal identification to proactively assess product safety, production and quality trends. With AI reinforcing the augmented user, product performance and production activities can be monitored in real time, improving process and production controls as well as Post-Market Surveillance (PMS) activities. This results in enhanced compliance and optimized operational performance throughout production and post market activities.

Preparing all content required for global regulatory submissions can be a major burden for teams. AI can alleviate this strain, allowing users to combine and synthesize data from a variety of sources into combined evidence packages for review. The implementation of GenAI can generate high-quality regulatory documents, further streamlining processes. This advanced automation can produce draft regulatory submissions, draft labeling content and draft reports. It can even highlight areas within a written document that may need enhanced examination through a review of a company's precedent information within a quality and regulatory ecosystem. The reduction of transactional activities can also free up time for augmented professionals to focus on more critical, customer-facing market access activities, leading to increased engagement from a company's quality and regulatory teams.

On the regulator side, global authorities could readily assess product functionality, real-world outcomes and performance data as part of their country-specific product evaluations, saving valuable resources and time. Thus, the accessibility of products to local markets improves while maintaining appropriate levels of surveillance.

Prioritizing patient safety and product quality

While the MedTech industry operates under the concept of acceptable risk, patient safety is and must remain the highest priority. It is impractical to destructively test each medical device prior to release to the public, as no product would be accepted for commercialization. However, through generating product risk documentation and supporting product failure mode identification and associated risk mitigation plans, GenAI could significantly support the augmented user in their professional activities that ultimately support the improvement of patient outcomes.

Furthermore, GenAI can analyze aggregated patient data and device performance to build predictive models that can forecast potential device failures or safety risks prior to occurrence. Innovative technology can identify and flag trends at a rate that surpasses the thresholds defined in product documentation. This is especially useful in connected manufacturing ecosystems that enable instantaneous trending and the creation of preventative actions through real-time device monitoring and post market performance data. Real-time detection of potential adverse events or product quality issues for medical devices is possible through generative models that continuously scan published medical literature, clinical research, social media sites and call center audio files. These models can expedite post-market safety interventions and potentially reduce the impact of any necessary regulatory field action.

Strategic deployment and cautious excitement

As MedTech products and their therapeutic solutions continue to become more intricate, the challenge of managing go-to-market activities in a cost-effective manner grows. MedTech organizations recognize that while automation and AI-enabled technology are poised to play a significant role in the industry, there are limitations for some quality and regulatory activities. This is due to constraints such as data availability, quality, structure and maintenance, applicability of certain AI tools to key processes, legal concerns around the privacy of proprietary information, the validation of AI-driven tools and the costs of using and maintaining such technologies.

The excitement surrounding the capabilities of GenAI is widespread, and the prioritization of feasible and practical applications is critical. A one-size-fits-all approach will not lead to success. Rather, a customer-centric approach will be the determining factor. This begins with identifying the quality and regulatory customer problem statement (or opportunity), locating the processes and decision points that are mandated by global regulations and standards, narrowing the scope of what data sets or structures apply to these processes and then crafting the solution, with the appropriate technologies as needed, in a way that best fits the organization.

The enhancement of human-technology interfaces and the responsible use of AI to augment quality and regulatory professional expertise will lead to effective company and patient outcomes. To unlock the full potential of AI in MedTech, strategic technology deployment and robust processes are key. Overall, AI will enhance human-to-human interactions and ultimately help ensure the better provision of safe and effective products to global markets.

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With over 20 years of experience leading global teams in quality assurance and regulatory affairs, Mike King, as Senior Director of Product and Strategy at IQVIA, ensures healthcare solutions meet complex global regulations and oversees platforms like SmartSolve® eQMS and RIM Smart to streamline quality and regulatory compliance processes.

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