Article

The Impact of AI on Quality Operations

Augmenting and empowering life-science professionals

In the ever-evolving life-sciences industry, market share is fiercely contested and companies must continuously optimize their operations to maintain their competitive edge, drive operational efficiency, and enhance the innovation pipeline.

Modern technologies and intelligence-driven solutions are revolutionizing how organizations work, empowering them to elevate their quality standards and ensuring safety, efficacy, and exceptional product quality. Artificial Intelligence (AI) capabilities have accelerated rapidly in recent times with the advent of Generative AI (GenAI) and the progression of Natural Language Processing (NLP), driving comprehensive improvements that position companies for success in end-to-end manufacturing, market access activities, and the provision of safe and effective solutions in a commercially viable manner.

Navigating an increasingly complex ecosystem

Navigating the dynamic and complex landscape of the life-sciences industry presents several challenges that include adhering to stringent global regulatory requirements and standards that vary across geographies while seamlessly integrating cutting-edge technologies. Additionally, the complexity of the situation is expected to increase, with the global market for life-sciences tools projected to reach $118.5 billion by the year 2028.

To capitalize on this surging opportunity, companies must embrace intelligence-driven solutions. AI is enabling businesses to (i) extract precise, actionable insights; (ii), automate transactional processes; and (iii) improve the decision-making capabilities of industry professionals. With AI-powered technologies, quality and regulatory professionals can envisage an immediate future where more of their time will be dedicated to decision-making and strategic market-access activities augmented by AI, as the use of AI and enhanced automation will reduce the time the same professionals need to invest in transactional activities such as manual paper chase and the human drive connection of information across multiple siloed IT systems. AI will also bring insights into process and product development opportunities that may not be seen by the human eye alone.

Smart solutions for life-sciences quality operations

Intelligent solutions can unlock the potential of the life-sciences industry's massive datasets. By mining, managing, and analyzing these datasets, companies can actively drive targeted, high-quality improvements in product design and process efficiency. For example, AI can automate in-process inspections in drug manufacturing, validating dimensions and flagging deviations for prompt human intervention, minimizing the impact of production deviations, and reducing the cost of non-quality such as scrappage/waste.

Quality management pervades the entire product life cycle, extending from design and manufacturing to sales and distribution, post market surveillance/safety, and life cycle management. Quality Management Systems (QMS) play a pivotal role in ensuring organizations develop and maintain safe and effective products that follow global and local regulatory requirements, standards, and best practices.

AI is transforming QMS, enhancing data analytics and data-mining capabilities, identifying areas for improvement, and providing insights for informed decision-making based on historical data and current signals and trends. AI also helps to navigate the labyrinth of industry regulations and quality standards, pinpointing specific requirements and linking company products to global and local mandates.

AI can also be used to monitor for regulatory changes and in a connected workflow this can drive the immediate notification of change so that a company can quickly evaluate the impact of global regulatory change and ensure their business operations remain compliant to global requirements, thereby ensuring continued market access of company products.

Additionally, AI can help organizations understand internal precedents for targeted processes and activities by mining their existing data to evaluate risks and empower quality and regulatory teams to make informed decisions on product and process improvements. Insights gained from such precedents can help in product submission and registration activities, audit and CAPA responses, and communications with government agencies on safety events such as product recalls and adverse event reports.

In an environment characterized by operational challenges and regulatory complexity, AI streamlines processes, enabling connected workflows that maintain accuracy and compliance. Reflecting the industry's strong embrace of AI integration, recent reports predict that AI in the global pharmaceutical market will reach $1.8 billion by 2030; the worldwide AI/machine learning medical device market, valued at a little over $4 billion in 2022, is expected to reach more than $35 billion by 2032.

AI in quality operations is a game changer

AI has a profound influence on quality operations across various dimensions. It is not just about elaborate technology. Moreover, it is about making real-world, commercially viable improvements that benefit patients, companies, and the global healthcare system. The impact extends beyond technological advancements and must, encompass economic considerations and, most notably, patient outcomes, in order to be widely accepted within the life-sciences industry.

Beyond fostering innovation and operational efficiencies, the integration of automated intelligence tools in an economically viable solution is a requirement for seamless adoption in the life-sciences industry. The overarching objective of the industry is to elevate patient safety and enhance outcomes, all while effectively controlling costs in a way that allows a company to maintain its economic viability to continue in the provision of healthcare solutions. This means ensuring that AI-driven innovations are both accessible and advantageous for companies, patients, and the broader healthcare system.

Below are a number of benefits that AI can contribute to quality operations:

1 Unlocking data insights

AI is a master of data analysis, sifting through mountains of information to uncover hidden patterns, trends, and signals. This means companies can identify areas for improvement in their quality workflows, for example, by spotting steps in the product manufacturing processes that are prone to errors. AI can also monitor social media, websites, and call-center audio recordings to flag potential quality issues and adverse events which, in turn, provides data that feed back into an understanding of product usage and product design.

2 Navigating the regulatory maze

The life-sciences industry is a labyrinth of regulations that AI can help navigate. It can keep stakeholders up to date with the latest global and local regulations and standards, ensuring continuous compliance by providing prompts when targeted regulations change. AI can also translate documents and draft submissions, and even suggest actions to address regulatory changes or provide information on submission precedents that may be relevant to a current submission.

3 Smarter decision making

AI puts a wealth of data and insights at the fingertips of experts, empowering them to make better decisions faster. This can lead to productivity gains of up to 25%, helping many achieve more in less time.

4 Automation is a force for efficiency

AI can automate many of the transactional, time-consuming tasks that bog employees down, such as identifying deviations and manufacturing errors. This frees up time and resources to focus on more strategic work and improves the quality of investigations and responses.

5 Catching errors before they catch us

AI helps spot potential problems before they become major issues, alerting teams to deviations from expected results and allowing them to take corrective action before things go awry. It can also predict potential manufacturing issues, equipment failures, or supply shortages, enabling proactive measures to minimize and hopefully prevent supply chain disruptions.

6 Adapting to change

AI supports companies to become more adaptable and flexible, allowing them to respond quickly to changes in regulations or market demands. It can help optimize manufacturing processes and submissions to keep up with an ever-evolving landscape.

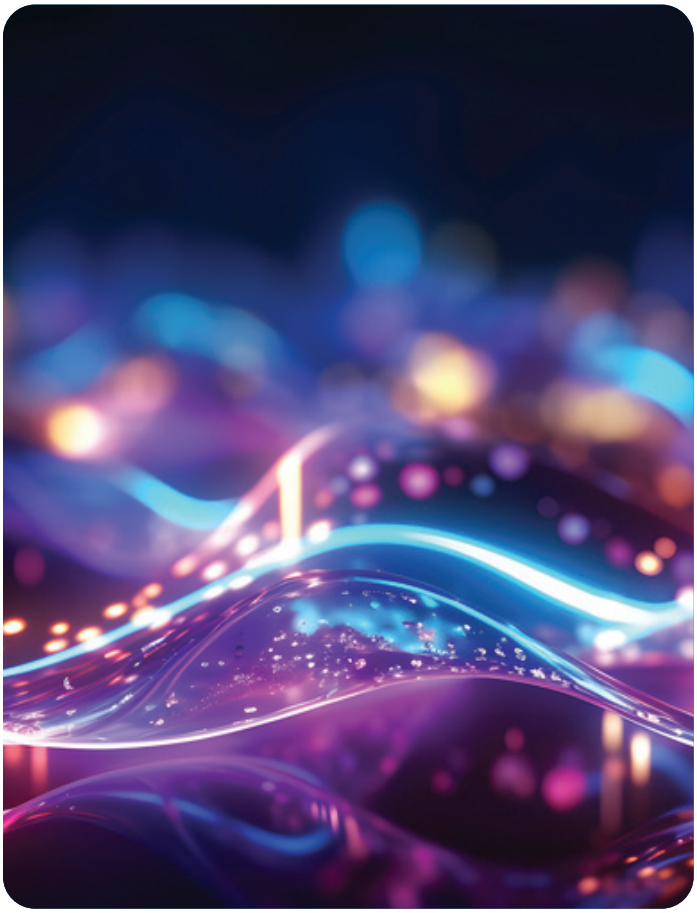
So, what is AI actually doing?

Digging deeper into one of the benefits highlighted above — navigating the regulatory maze — consider the following situation:

Globally, there are hundreds of countries with regulations and standards, and within each country there are hundreds of documented regulations and standards with data points that could be structured in a way for AI to mine information and drive enhanced automation. This dataset at its fullest could have billions of data points (100 countries x 100 documents x 100 points of codification, across 500,000 medical device classes = 5 x 10^11, or 500 billion data points) that could be extracted to drive enhanced automation and AI-driven insights across a range of end-to-end quality and regulatory processes.

Being able to identify the global regulatory requirements and standards that apply to a certain product type being targeted for a global launch, or the impact (cost, time, reregistration/notification activity) of a product change type on its existing global registration status at a granular, country level can greatly improve the efficiency of decision making and support increased predictability of product availability and change-control activities.

Additionally, Generative AI capabilities that are trained on global regulations and standards as well as company proprietary information can support drafting product documentation for global registration and product submission activities, responding to a regulator request for additional information on an adverse event report and/or recalls, and other draft initial content for a quality and regulatory professional to review to optimize their daily activities.



Theoretically, by leveraging data models with AI-driven technologies, a professional working in a company that wants to launch a new product — for example:

- A closed loop, diabetic insulin pump system (a combination of hardware, software, disposable accessories that is used to deliver the pharmaceutical product insulin) — can click a button and generate sets of requirements and testing parameters that apply for launching the system in several different countries.
- Another company working in the dental sector might ask, "What are the global registration and technical testing requirements for a 3D dental X-ray machine that could be wall-mounted, ceiling-mounted, or mobile?" The output of such a query would support in the preparation of information that is required to register the product in global countries as a precursor to a global product launch.

In such examples, the value of using AI to codify, maintain, and extract information from a multidimensional dataset has significant value for an organization and, more importantly, supports the optimization of healthcare solutions in global markets.

The future of AI in quality operations

There is no doubt that AI will continue to reshape quality operations in the life-sciences industry, fostering innovation, increasing efficiency, and leading to enhanced patient outcomes.

As this technology evolves, even greater patient benefits can be anticipated where this technology can be leveraged by companies in a cost-effective way. In this dynamic landscape, automated intelligence is pivotal in managing global complexity, driving profitability, and retaining a skilled workforce. It empowers individuals by augmenting, rather than replacing, their human capabilities, and facilitates transparent, precise decision making in the face of complexity. AI adeptly handles diverse data, offering targeted insights to augmented workers at all stages of manufacturing and distribution operations.

Leveraging AI's capabilities promises sustained growth, improved healthcare solutions, and heightened operational quality and efficiency. Ultimately, This technology can be key in empowering companies to deliver safe and effective healthcare solutions to global markets.

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As senior director of product and strategy within the technology solutions business of IQVIA, Michael King is responsible for ensuring that life sciences solutions support increasingly complex and diverse global regulations. He is particularly focused on optimizing business workflows through intelligence-driven simplification and automation within and across quality, regulatory and safety functions.

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