INSIGHT BRIEF

IQVIA TECHNOLOGIES

Embracing AI in Quality Operations

Harnessing the power of AI speeds time to insights while reducing pressure on busy quality teams.

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Introduction

Artificial intelligence (AI) applications can deliver huge efficiencies to quality operations for pharma and MedTech. Yet, many quality teams are hesitant to embrace AI fully.

Transformation in quality operations can be daunting. If a quality team already has a system that they know will comply with all regulatory audits, introducing change feels risky – especially when it involves AI.

However, their concerns can be overcome. When quality teams work with AI technology vendors with deep life sciences experience and begin with low-risk pilot projects to prove their reliability, they can build a business case for deploying AI across the department with confidence that they can trust these tools. Additionally, suitable validation strategies can ensure that the implementation of AI will meet the global requirements of medical device and pharmaceutical product manufacturers.

In a recent webinar entitled Futureproofing Your Quality Operations Through Digital Transformation[1], Matt O'Donnell, Global Lead, Life Sciences ISV Partners at Microsoft, and Michael King, Senior Director, Product & Strategy at IQVIA, explored the benefits AI brings to quality operations, and how quality teams can overcome their hesitation to this digital evolution in a safe and compliant way.

Why AI?

Quality operations exist to ensure patient safety is paramount throughout the lifecycle of a medical device/ pharmaceutical product. Before any quality team can confidently integrate AI into this setting, they must be confident that the technology is reliable and fully transparent so that staff can verify that it is meeting strict regulatory requirements.

That confidence is possible but can be hard to come by.

Many quality teams fear AI will require them to replace human oversight with digital decision-making that could result in errors. That can lead to stalled shipments, failed audits, and patient safety risks that result in recalls/market withdrawals — all of which are unacceptable in the quality environment and can harm company perception and brand equity. Others worry that transforming a manual quality workflow using AI will be cost-prohibitive and put their best people out of work.

Suitable validation strategies can ensure that the implementation of AI will meet the global requirements of medical device and pharmaceutical product manufacturers

Both concerns are slowing adoption of AI in quality. In a flash poll conducted during the recent webinar, 72 percent of respondents said they aren't yet using AI in their quality operations and more than half (54 percent) believe AI would improve their process time and consistency of performance. The good news is that these fears are largely unfounded. The current generation of AI tools for quality has been proven to meet the exacting expectations of regulators and corporate stakeholders and do not put experienced quality teams out of their jobs.

FLASH POLL CONDUCTED DURING THE RECENT WEBINAR

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Source: flash poll conducted in the recent webinar entitled Futureproofing Your Quality Operations Through Digital Transformation

MYTH #1: AI IN QUALITY OPERATIONS WILL REPLACE HUMAN OVERSIGHT

AI for quality tasks takes over all the repetitive, lower-value work that must be completed in these operations. That frees quality teams to focus on more critical, high-value decision-making steps. For example, an algorithm could be trained to translate adverse event documents to other languages; monitor data sets to support Post Market Vigilance (PMV) or Post Market Surveillance (PMS) activities; and read emails, social media, and academic articles to find signals (i.e., trends on local and/or global levels) that indicate a potential safety issue needing further human investigation. In these examples and most instances, customized AI takes as much (or as little) work as the team wants, with built-in review steps where a human verifies results before making final decisions. It accelerates the time to insights and reduces the burden of work without handing over decision-making authority to an AI application.

Myth #1

AI in quality operations will replace human oversight.

Myth #2

Implementing AI in quality operations is too expensive.

MYTH #2: IMPLEMENTING AI IN QUALITY OPERATIONS IS TOO EXPENSIVE

While any new technology requires investment, the financial benefits that AI can bring to quality operations can far outweigh the upfront costs. The most obvious benefit is in optimizing the time of existing professional resources. Quality teams face constant pressure from regulators and government agencies to demonstrate product safety and efficacy more concisely. The changing regulations, surge in data that must be reviewed, and demand for faster results are making traditional quality workflows unsustainable. On an operational level, pharmaceutical and medical device companies can't infinitely add more highly trained headcount to teams so alternative methods of supporting capacity are needed — this is where AI can support company activities.

AI can pick up that slack. By automating transactional activities with controlled and predictable tasks, existing human teams are free to focus on work that requires their expertise and training. The combination of AI and humans can increase the speed and quality of output, allowing quality teams to meet deadlines without adding new headcount.

How it works

AI adoption for quality is all about automating transactional tasks and optimizing industry activities using the right clinical and technical data, actions, and timing.

In these applications, AI algorithms leverage machine learning (ML), optical character recognition (OCR), and natural language processing (NLP) to rapidly read and interpret all types of structured and unstructured data. The algorithms are trained using existing data and historic decision-making to identify relevant information in the masses of data produced in the pharma environment. These can include information found in PDFs, doctors' notes, lab scans, social media, and other relevant sources.

When this training is combined with advanced interpretation and search capabilities, AI algorithms can quickly read huge data sets, identify issues, and make predictions with far greater speed and accuracy than a human team can achieve. The support of a "digital eye" greatly enhances human activity and has a direct, positive impact on patient safety.

The algorithms can also be trained to simulate desired decision-making based on the results of past searches and to perform actions in response. These activities include: identifying safety issues and adverse events; adapting documents and submission templates for regulatory review and suggesting additional content; and identifying costs, timelines and risks related to design changes in real time to support timely impact assessments and keep critical path activities on schedule.

LESS WORK, BETTER RESULTS

Using smart AI technology within an intelligently connected technological ecosystem leads to a working environment where people's activities are enhanced and optimized by technology to make better, faster, and more predictable decisions. The AI "digital eye" can rapidly identify patterns and trends in vast volumes of data, freeing quality staff to spend more time validating outputs, making decisions, and engaging with relevant stakeholders.

The speed that AI brings to the quality workflow can be a huge benefit, especially for the surveillance of a drug

INDUSTRY APPLICATION EXAMPLES

Safety

- Identification of product complaints, potential adverse events, signal detections and systematic issues
- Pre-population of reporting templates and content based on current trends

Regulatory

- Identification of global design requirements applicable to specific product types
- Pre-population of submission templates with content drafted from predicate experience and an indication of the probability of approval

Quality

- Real-time identification of the cost, timeline and "hot spots" of proposed design changes
- Pre-population of change plans and associated project timelines, interdependencies and critical path

or medical device that is new to the market. Monitoring for early indications of adverse events requires reviewing thousands of documents to find relevant connections. AI can find those connections often sooner than humans, making it easy for quality teams to harvest knowledge from semi-structured and unstructured data sets.

For example, many companies must review records of submission pathways for audits of nonconformances, or Corrective and Preventive Actions (CAPA) closures, which results in a huge volume of tasks. The AI can rapidly mine precedents in the existing data to determine what decisions were taken historically, what potential pathways led to specific outcomes, and where additional pathways or alternatives could bring faster safer results.

This speeds up the decision-making of the work and can result in more robust, more accurate, and more repeatable decisions across the quality workflow.

With the right technology, AI in quality applications can save lives. These algorithms have been found to detect signals and adverse event trends in data faster and with greater accuracy than humans can achieve. Such rapid insights can be life-changing for patients using products or devices that could potentially put their lives at risk.

We know through history that many industries have successfully embraced AI, and the opportunity is real for the MedTech and pharma industries. Quality is no different. We can adopt these technologies and work with regulators to drive the joint goal of improved patient safety.

The ideal transformation plan features incremental adoption of AI for low-level tasks that deliver measurable results. Quality teams can then build on that success, introducing more AI over time to reduce the burden and scale their operations. It gives teams the time to adjust to the change and trust that this technology can control the controllable, automate the transactional, and optimize and enhance all their industry activities.

To learn more about IQVIA's approach to AI in Quality, visit https://www.iqvia.com/solutions/integrated-global-compliance/quality-compliance/smartsolve-eqms

WHAT IS CONNECTED INTELLIGENCE™?

Requirements

(Curated data)

- Machine readable
- By regulatory and/or quality activity
- Product-type specific

Insights

(Client's own interpretation)

- User edits/tribal knowledge
- QC'd by data steward
- Ready for analytics and reuse

Precedence

(Client's own experience)

- Operational history
- Audit trail
- Ready for analytics and reuse

About the authors

MICHAEL KING
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As Senior Director of Product & Strategy within the Technology Solutions business of IQVIA, Michael King is responsible for ensuring that the Medical Device solutions have the necessary functionality to support the increasingly complex and diverse global regulations. He is particularly focused on optimizing business workflows through intelligence-driven simplification and automation within and across the Safety, Regulatory and Quality functions. Michael has over 15 years of knowledge and experience leading localized and global teams in Regulatory Affairs and Quality Assurance and has worked within the Medical and Surgical, Orthopedic, In Vitro Diagnostic, Diagnostic Imaging, Dental and Urology sectors. Before joining IQVIA, Michael was the Vice President of International Regulatory Affairs for a dental technology organization and had oversight of the International Product Registration, Adverse Event Reporting and country-based Quality Management Systems. Michael holds a degree in Physics from Oxford University and briefly worked for a consulting firm in the telecommunications industry prior to beginning his career in the medical industry.

MATT O'DONNELL
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Matt O'Donnell is currently the Global Lead for Life Sciences ISV Partnerships at Microsoft. During his nine years at Microsoft, Matt has focused on strategic pharmaceutical and life sciences customers as a Client Technology Lead, Client Executive, and Life Sciences Industry Advisor. Before Microsoft, Matt's 25 years of experience involved applying innovative technology to solve complex business challenges within biopharmaceutical companies and other industries. Matt began his career as a consultant for Accenture in the Life Sciences practice, was co-founder of two successful startup companies, and was a Strategy & Product Management Director at Avaya and IPC Systems. As a part of the Global Partner Solutions team, Matt currently leads a portfolio of market-leading Global ISV partners focusing on the pharmaceutical and life sciences industry. Together, Microsoft and its partner ecosystem are applying data analytics and AI to improve processes across the entire pharmaceutical value chain. Matt holds a degree in Mechanical Engineering and Business from Villanova University.

References

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