Pink Sheet
Pharma Intelligence

WEBINAR SUMMARY

September 8, 2022

Futureproofing Your Quality Operations Through Digital Transformation

Mike King, Senior Director, Product & Strategy, IQVIA
Matt O'Donnell, Global Lead, Life Sciences ISV Partners, Microsoft
Don Soong, Senior Director & GM, Quality Solutions, IQVIA (Moderator)

KEY TAKEAWAYS

- In developing new products, the pharma and MedTech industries align on patient safety principles but differ in operational details.
- A connected intelligence ecosystem can unite pharma and MedTech operationally.
- AI can propel connected intelligence systems to higher levels of insights.

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OVERVIEW

The activities of Product Quality teams in the life sciences industry are attracting rising levels of attention. Whereas in the past their role in the product lifecycle was primarily seen as a records-keeping function, today their activities are being increasingly scrutinized from efficiency and compliance standpoints. In response, heads of quality are searching for areas of optimiziation and improvement, including digital innovations, to transform quality management.

Against these pressures, organizations can benefit greatly from implementing a comprehensive AI-powered quality management system (QMS) that yields intelligence-driven insights to speed time to actions and outcomes, increase productivity through automation, and predict and identify risks.

CONTEXT

Mike King and Matt O'Donnell discussed the need for the pharmaceutical and MedTech industries to converge strategically and operationally, and how the use of an AI-enabled connected intelligence system across QMS functions can accelerate and optimize that convergence.

KEY TAKEAWAYS

In developing new products, the pharma and MedTech industries align on patient safety principles but differ in operational details.

Compliance with ever-evolving global and local regulations is a perennial concern for the pharmaceutical and MedTech industries. Nevertheless, despite growing requirements and between-country nuances in interpretation, the primary focus of those regulations remains patient safety and designing, manufacturing, shipping, and monitoring products in a way that ensures their efficacy and safety.

When filing new product submissions for regulatory approval, the pharma and MedTech industries align on the four key principles that underpin their supporting data and documentation. Those principles, which reflect regulations and standards focused on patient safety, are:

1. **Safety and performance** as demonstrated by clinical and technical data.
2. **Good practices** in product design, development, manufacture, sale, and distribution.
3. **Pre-market approval** subject to independent third-party review.
4. **Post-market activities,** including vigilance and surveillance, to monitor for potential adverse events as well as product misuse.

Yet, because of intrinsic differences in their economies of scale and in their products' mechanisms of action, the pharma and MedTech industries diverge on many of the details. Among the key differences between the industries:

Area of Difference	Pharma	MedTech
Global market size	$1,000 billion	$455 billion
Number of product types	20,000	500,000
Length of development lifecycle	Pharma tends to have longer development lifecycles	
Effectiveness factors	MedTech is more dependent on clinician skills and experience	

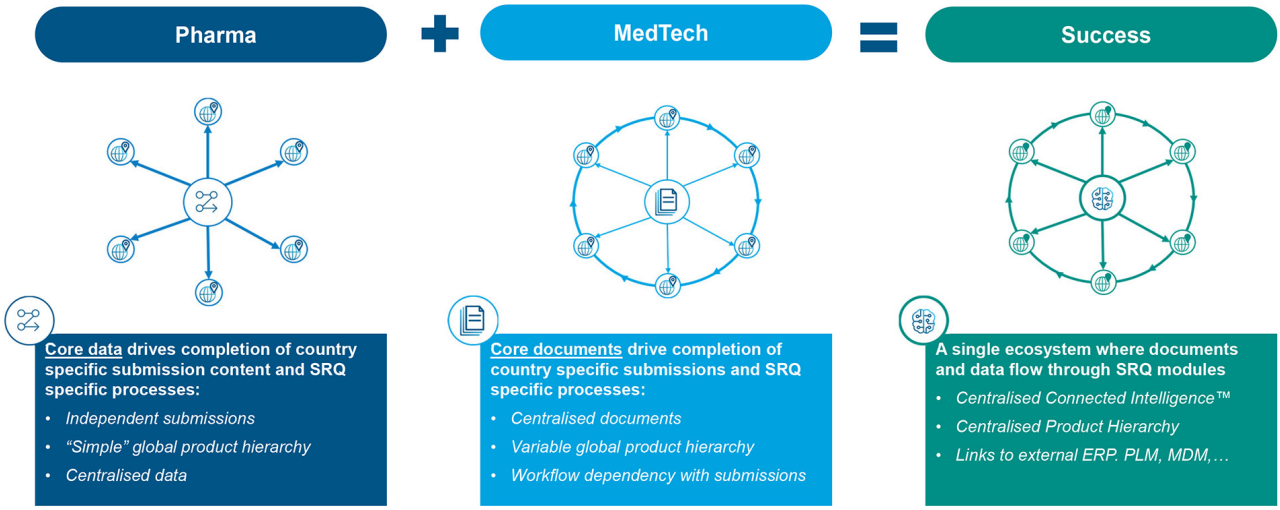
These fundamental differences drive operational differentiation, which presents challenges when managing drug-device combination products that blend pharmaceutical and MedTech technologies. For example, in the dental industry, some countries regulate professional prophy pastes with a high percentage of fluoride as medical devices, while other countries consider them as having a pharmacological action and regulate them as pharmaceuticals.

> The [differential] economy of scale really pulls into the manufacturing and distribution processes, which results in a slightly different approach that is needed in systems. This is the challenge that technological companies face in supporting industry with good quality management systems.
>
> *Mike King, IQVIA*

A connected intelligence ecosystem can unite pharma and MedTech operationally.

To resolve these differences and align pharma and MedTech timelines, processes, operations, and go-to-market strategies, it is necessary to build a system that can handle both data and documents, perform structured data build, and integrate workflows, as well as transfer data, documents, outputs, actions, and activities in between and across QMS, supply, and other support systems.

Figure 1. An aspirational view of a connected pharma-and-MedTech ecosystem



The concept for such an ecosystem originates in *connected intelligence* systems—where *regulatory intelligence often drives requirements and functionality of such connected systems*—which are designed to: 1) **capture in near-real time the requirements** that govern how the industry operates in the safety, regulatory, and quality spheres.

The systems then: 2) **assess** how those regulations impact companies' product portfolios across the different countries in which they are marketed and 3) **produce relevant insights** as to how the rules can be applied while adjusting for local variance.

"That filtering of regulations down to actionable tasks within the quality management system is absolutely key because it allows you to take very complex regulation and begin operationalizing the theory into practice," said King.

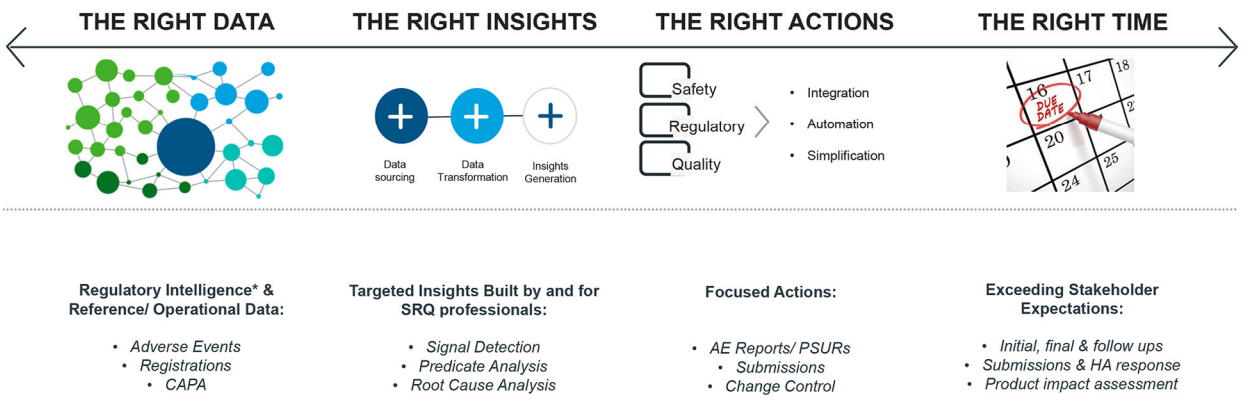
The other core feature of connected intelligence systems is 4) their ability to **recognize precedence** within organizations' operational history or audit trail, understand what decisions were taken historically, and deduce what potential pathways lead to certain outcomes. "That's where AI can really provide some insights across the quality management systems that we operate in," King noted.

AI can propel connected intelligence systems to higher levels of insights.

With advances in technology, AI can now be embedded into connected intelligence QMS platforms, where its value-add lies in distilling insights that conventional systems and the human eye cannot detect. This enhanced capability, which can be leveraged across safety, regulatory, and quality aspects and functions, enables companies to pull up the right data at the right time to derive the right insights that drive the right actions.

> In most of the regulatory process, making a connection between the [information contained in] thousands of documents and making sense of it is so critical. AI is being used to identify connections that might not have been known before and make it easy for an individual to gain knowledge from semi-structured, structured, and unstructured data.
>
> *Matt O'Donnell, Microsoft*

Figure 2. Transforming connected intelligence with AI



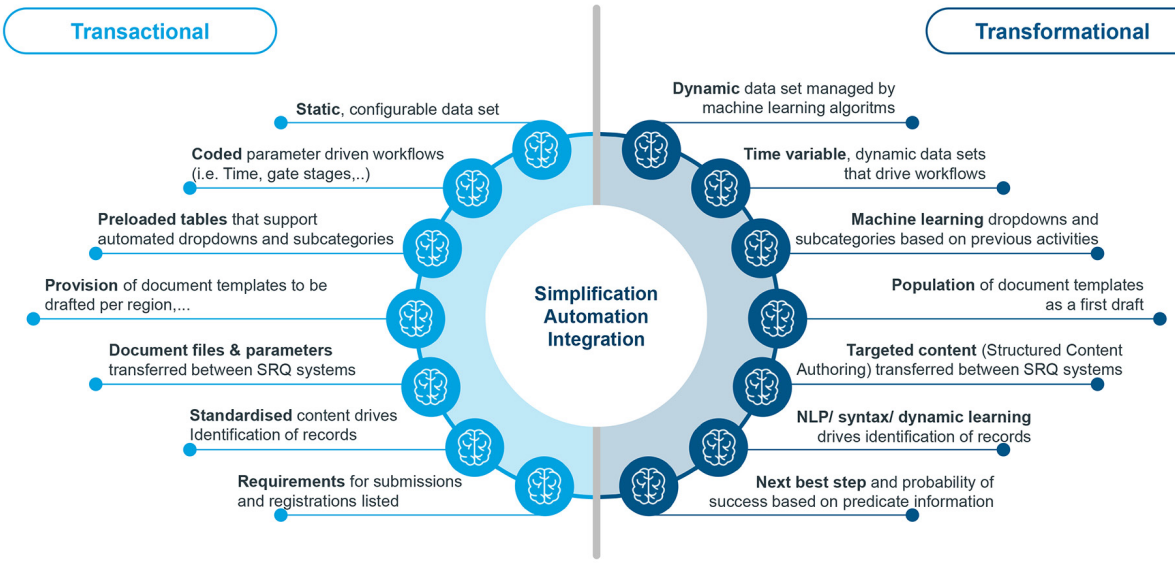
Industry examples of how an AI-powered connected intelligence system, such as the one developed by IQVIA, can supercharge pharma and MedTech organizations' intelligence capabilities illustrate its potential. Three use cases are:

- **Safety:** Identification of patterns, trends, or signals that—if unnoticed and un-acted upon—could lead to adverse event reporting. Methods of identification include leveraging natural language processing (NLP) algorithms to mine social media sites and scan the contents of customer service inboxes.
- **Regulatory:** Pre-population of submission templates, identification of additional content needed to match a country's local requirements, and indication of the probability of approval. These templates and supporting documentation could be automatically translated for review by those teams compiling the submission.

- **Quality:** Identification in real time of the cost, timeline, and "hot spots" of proposed design changes to allow earlier identification of the feasibility of the proposed change and/or the impact of a mandatory change from a safety related issue.

Beyond those applications, AI can advance connected intelligence by evolving it from transactional to transformational. The figure below depicts what elements those transformations touch on.

Figure 3. Moving connected intelligence from transactional to transformational



> Ultimately, AI-driven connected intelligence isn´t just about moving quickly, it´s about moving with control and with a focus on patient safety.
>
> *Mike King, IQVIA*

CONCLUSION

With AI innovation advancing by leaps and bounds—in the last few years AI algorithms have reached human parity in terms of conversational speech recognition, reading comprehension, and translation of news articles—its utility and applications in the life sciences are expanding as well. IQVIA's AI-augmented connected intelligence system is a testament to that evolution.

"The next wave that is happening, and it's happening rapidly, is introducing AI at scale. [That means] taking the learnings that had been done for decades and applying them in a new way to massive training sets and learning from them in a recursive way," O'Donnell said. "We believe the application of AI to healthcare in general is the most urgent application."

BIOGRAPHIES

Mike King

Senior Director, Product & Strategy, IQVIA

As Senior Director of Product and 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 optimising 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 localised and global teams in Regulatory Affairs and Quality Assurance and has worked within the Medical and Surgical, Orthopaedic, 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 organisation 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

Global Lead, Life Sciences Partners, Microsoft

Matt O'Donnell is currently an industry advisor at Microsoft. During his nine years at Microsoft, Matt has focused on strategic pharmaceuticals and life sciences customers as a client technology lead, client executive, and most recently, life sciences industry advisor. Before Microsoft, Matt's 25 years of experience involved applying innovative technology to solve complex business challenges within biopharmaceutical companies. 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 and product management director at Avaya and IPC. As a part of the health & life sciences global ISV team, Matt currently leads a portfolio of market-leading global ISV partners focusing on the pharmaceutical and life sciences industry. With the Microsoft partner ecosystem, Matt is applying data analytics and AI to improve processes across the pharmaceutical value chain.

Don Soong (Moderator)

Senior Director & GM, Quality Solutions, IQVIA

Don Soong has devoted his career to the delivery of technology solutions to the life sciences industry. Don's experience over 25+ years has covered CRM, MDM, and compliance solutions by combining technology, product strategy, and regulatory knowledge. Don has led all aspects of the product evolution process including product management, engineering, delivery, and client engagement. His ability to combine technology and business knowledge has established his expertise within IQVIA and the industry. Don currently leads the product team for IQVIA's QMS pillar.