WEBINAR SUMMARY

October 12, 2022

Pink Sheet
Pharma Intelligence

Transforming Your Organization with a Fully Integrated eQMS

Phil Johnson, Senior Principal, Quality and Compliance Solutions, IQVIA
Michael King, Senior Director, Product & Strategy, IQVIA

KEY TAKEAWAYS

- Successful QMS deployment hinges on multiple factors and has important benefits.
- As organizations consider deploying an eQMS system, they must focus on three key dimensions.
- A confluence of forces is driving Pharma and MedTech companies' move toward an integrated eQMS.

in partnership with

IQVIA TECHNOLOGIES

OVERVIEW

The MedTech and pharmaceutical industries have experienced many changes over the past few years that have impacted how they handle data and manage workflows across their safety, regulatory, and quality functions.

With elevated regulatory and market requirements for managing complex processes compliantly and efficiently, the importance of a fully integrated electronic quality management system (eQMS) that can reduce transactional administration and onerous paper-based documentation has never been greater. However, there are important considerations that companies assessing the prospect of adopting an eQMS system should keep in mind to be successful.

CONTEXT

Phil Johnson and Michael King discussed common challenges faced by heads of quality and regulatory functions and how an integrated eQMS platform can automate and optimize inefficient processes, increase predictability of global product launch cycles, and raise confidence when undergoing inspections from government regulators, notified bodies and other third-party auditors.

KEY TAKEAWAYS

Successful QMS deployment hinges on multiple factors and has important benefits.

Factors that drive the successful deployment of any paper-based or electronic QMS include control of scope creep, availability of dedicated resources, process harmonization prior to deployment (to avoid process changes mid-flight), and recognition of broader system integrations and dependencies. It is important to also understand the culture of the organization to make sure that all resources are suitably prepared and understand the implications of QMS deployment.

Two in-webinar polls revealed that process harmonization prior to deployment was seen as the biggest challenge for 60% of webinar attendees, while improvement in compliance was seen as the most significant benefit of a successfully implemented eQMS platform, with 43% of attendees choosing that option. Other benefits include optimized resource utilization, improved customer satisfaction, and enhanced information management.

As organizations consider deploying an eQMS system, they must focus on three key dimensions.

To surmount the challenges and realize the benefits associated with deploying an eQMS platform, organizations need to focus on three main elements.

1. Organizational considerations

These considerations are essential for selecting an eQMS based on commercial and compliance drivers related to company scale, therapeutic area, and route to market. Core elements of those drivers include:

- **Company scale:** company size, geographic footprint, type of activities, and type of enterprise or legal entity.
- **Therapeutic area:** impact on product design control, risk profile, and manufacturing processes.
- **Route to market:** use of third-party dealers, direct shipment to patients, and outsourced services. "A key component of a QMS is how product is taken from manufacturing to market and thereafter [monitored] in terms of post-market activities," said King.

As companies go through this evaluation process, they should ask themselves what is the most significant opportunity or risk they are facing, and identify what element(s) of an eQMS are best placed to support delivering on this opportunity and/ or reducing the identified risk. For example, a MedTech organization that ships urinary catheters directly to patients may benefit from having access to an eQMS-enabled customer feedback database to learn in real time how the product is received in the market and address potential performance issues in a timely manner.

> When you consider where your company is and ask [what its most significant opportunity or risk is], you'll begin to get a feel of where you should focus first and what should come second or third within the deployment of a quality management system.
>
> *Michael King, IQVIA*

Other key issues companies should explore as they embrace eQMS adoption is how it relates to market expansion, supplier control, design, and development, and audit/CAPA/nonconformance. Johnson noted that an eQMS platform can help companies exercise better scrutiny over suppliers and thus raise their standing in the eyes of regulators: "If you show good supply controls, you will keep the regulators away from some of your suppliers."

2. Deployment considerations

This set of considerations is critical for focusing on customer deliverables and can be used to assess the benefits of a full migration to an eQMS system versus interfacing between an eQMS and existing enterprise resource planning (ERP), warehouse management system (WMS), item master, or paper-based QMS tools.

As companies approach this stage of considerations, a central question to ask themselves is, "Is this a change for compliance or a change for comfort," the answer to which should steer them away from "copy-pasting" suboptimal features from an existing QMS system over to the new QMS system. Five additional aspects of deployment to be considered are illustrated in Figure 1.

Figure 1. Key questions to consider when assessing QMS scope of deployment

> Communication is one of the key aspects where companies fall down. The worst thing [a company] can do is bring in external help to help implementation while the workforce does not know what these people are there to do because it hasn't been adequately communicated.
>
> *Phil Johnson, IQVIA*

3. Change control considerations

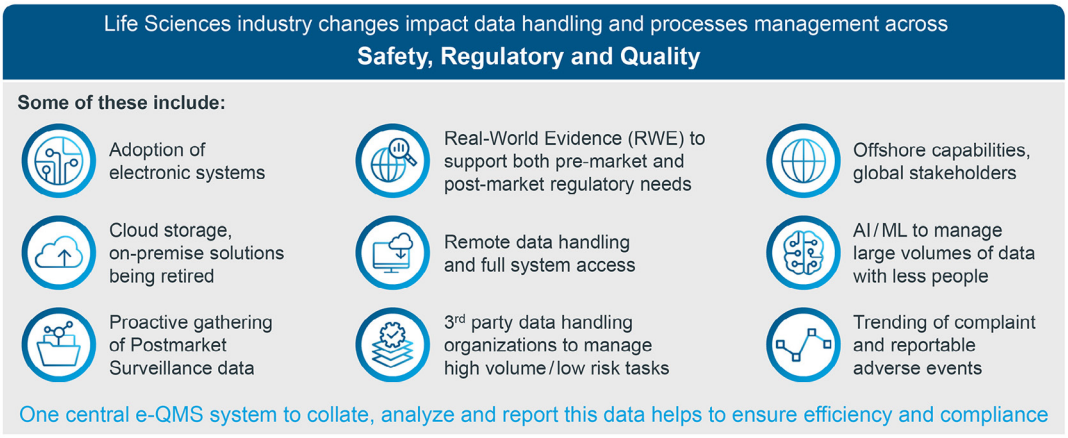
Once a decision about eQMS deployment has been made, change control considerations can help evaluate its global impact, including the following aspects:

- **What is the overall eQMS deployment plan,** how will it be phased and sequenced, and what gate reviews will there be between the steps of deployment?
- **What level of harmonization should take place prior to deployment** in terms of processes, systems, datasets, documents, notified bodies, and outsourced services?
- **How should the eQMS be certified** (e.g., one global certificate, localized certifications)?

A confluence of forces is driving Pharma and MedTech companies' move toward an integrated eQMS.

Growing volumes of available data relevant to product development and commercialization, an explosion of electronic data collection and processing devices and capabilities, and escalating regulatory requirements to capture data from multiple sources are some of the reasons why manufacturers are gravitating toward central eQMS platforms.

Figure 2. Reasons for rationalization across manufacturers of multiple QMS systems



Specifically, a unified eQMS system can help MedTech and pharma organizations simplify, automate, or optimize processes that form part of meeting several critical business needs:

- **Safety needs,** via streamlining complaint management and global adverse event reporting. "When you see regulators are requesting trended complaint data back over three years, you may not have all that data in one place, so putting it into a single eQMS can obviously make trending much more efficient," said Johnson.

- **Quality needs,** via consolidating multiple sites under a limited number of ISO and EC certificates. This is highly relevant for companies that have gone through mergers and acquisitions and are operating different QMS systems.
- **Regulatory needs,** via post-market surveillance processes that require proactive gathering of data, which can be problematic when the datasets are contained across multiple QMS systems.
- **Annual product reviews,** via centralizing compliance-related data that is traditionally often captured in spreadsheets or shared files accessible to only a few individuals.
- **Supplier management,** via identifying, approving, and monitoring suppliers, auditing them, and keeping their ratings updated, without having to rely on ERP systems for the relevant data.

CONCLUSION

Regardless of the context or scenario a company finds itself in as it initiates eQMS deployment—whether implementing an eQMS system for the first time, replacing an existing eQMS system with a new or updated one, or consolidating different QMS and eQMS systems across sites and/or vendors—there are common processes that need to be in place to ensure success.

Invariably, those processes include a well-developed change control mechanism sustained by continuous communication throughout the implementation journey, ownership of the eQMS plan throughout the organization (with management buy-in), an adequate number of skilled internal resources dedicated to the implementation and not diverted to other tasks, and excellent project management so that the business keeps running while it is "changing the wheels." In a nutshell: rigorous pre-planning.

BIOGRAPHIES

Phil Johnson

Senior Principal, Quality and Compliance Solutions, IQVIA

Phil Johnson is an experienced regulatory and quality-based professional who has worked in the medical device, in-vitro diagnostic, and pharmaceutical industries for over 25 years. His core expertise is in the quality and manufacturing requirements for medical devices, diagnostics, and pharmaceuticals. This has included the writing, implementation, and maintenance of quality management systems, auditing of external suppliers and manufacturing/distribution sites, and due diligence auditing.

His current role in IQVIA is senior principal, leading the quality compliance consulting team that covers GMP & GCP consulting for both pharma and MedTech.

Prior to joining quintiles in 2002, he was an independent regulatory and quality consultant after holding different management positions within various organizations. For 10 years he was the founder and director of a UK central laboratory providing world-wide IVD services to the pharmaceutical industry. He has also held senior manufacturing positions in medical device, diagnostics, and pharmaceutical companies.

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.