WEBINAR SUMMARY

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Pink Sheet
Informa Pharma Intelligence

Breaking Down Silos with Connected Compliance: Driving Transformation in Quality, Regulatory, and Compliance Environments

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KEY TAKEAWAYS

- The current regulatory environment is creating growing pressures for companies in terms of time and resource needs to ensure compliance.
- To overcome these challenges organizations must break down silos.
- Cross-functional data and information management systems can transform compliance from a burden to a competitive advantage.
- To deliver a successful connected intelligence program, investing in technology and people is key.
- Best practices for regulatory intelligence can illuminate the way to success.

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OVERVIEW

Evolving global regulatory requirements are becoming more complex and placing an ever-greater burden on drug and medical device manufacturers. To meet those requirements and demonstrate that products are safe and effective, the quality, regulatory and compliance functions are essential—yet all too often they reside in organizational silos. By breaking down those silos and enabling better communication and collaboration, life sciences organizations can pave the way for a connected compliance ecosystem that leads to shorter development cycles, lower operational costs, while minimizing compliance-related risks.

IQVIA has a vision, strategy, and solution for supporting companies in building out their connected compliance ecosystem through connected intelligence. The firm has developed an integrated technology and solutions platform that utilizes up-to-date data from global regulatory authorities, interpreting its impact and transforming it into actionable insights. These insights can then be channeled to the relevant internal functions for automated end to end compliance.

CONTEXT

Kari Miller and Sue Plant discussed the concept, and IQVIA's implementation, of an enterprise-wide connected intelligence platform that can help companies accelerate alignment between the quality, regulatory and safety functions.

KEY TAKEAWAYS

The current regulatory environment is creating growing pressures for companies in terms of time and resource needs to ensure compliance.

While regulators work to harmonize requirements across countries, national regulations are still in place which means that companies have to navigate global and local rules simultaneously. The magnitude of the regulatory burden is such that there has been a 300% increase in regulatory mandates, about 25,000 new regulations being issued per year, and a new or changed regulation occurring every 21 minutes somewhere around the globe. To manage this complexity and keep up to date, companies are spending about 80% of resources on collecting, cleaning, and checking regulatory data and only about 20% on utilizing it. The excessive time it takes to locate and process all this information distracts regulatory staff from higher-value strategic work and creates bottlenecks in product development and approval cycles.

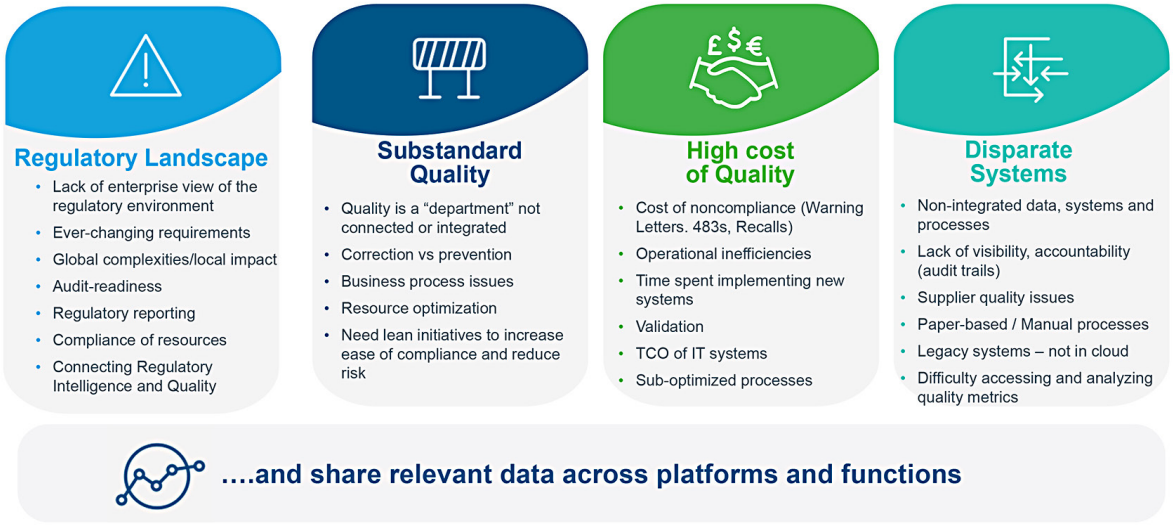
However, compliance is not only a concern for regulatory departments. Quality assurance staff also have an important responsibility in making sure companies are inspection-ready at all times and their Quality Management System, along with the content within it, is compliant. Quality teams have to be prepared to take corrective action if needed; instill a quality culture that reduces data integrity risks; develop appropriate metrics for monitoring performance; provide insights for improvement and extend vigilance beyond the four walls of the organization to their supply chain. Asking a single department to assume all these activities without sharing knowledge, insights and feedback with other functions is imbalanced and inefficient.

To overcome these challenges organizations must break down silos.

Companies can promote a shared understanding of what regulations have changed, what those changes are, and how they are expected to impact the business going forward by creating an enterprise-wide view of the regulatory environment.

The lack of such a unified view currently leads to operational inefficiencies, suboptimal use of resources, reactive rather than proactive approaches to corrective actions, disjointed audit trails and supplier quality issues, to name a few. In turn, those inefficiencies increase risk and therefore impact patient safety, result in denied approvals, license or registration withdrawals, financial penalties and legal ramifications.

Figure 1: The high cost of managing compliance-related data in silos



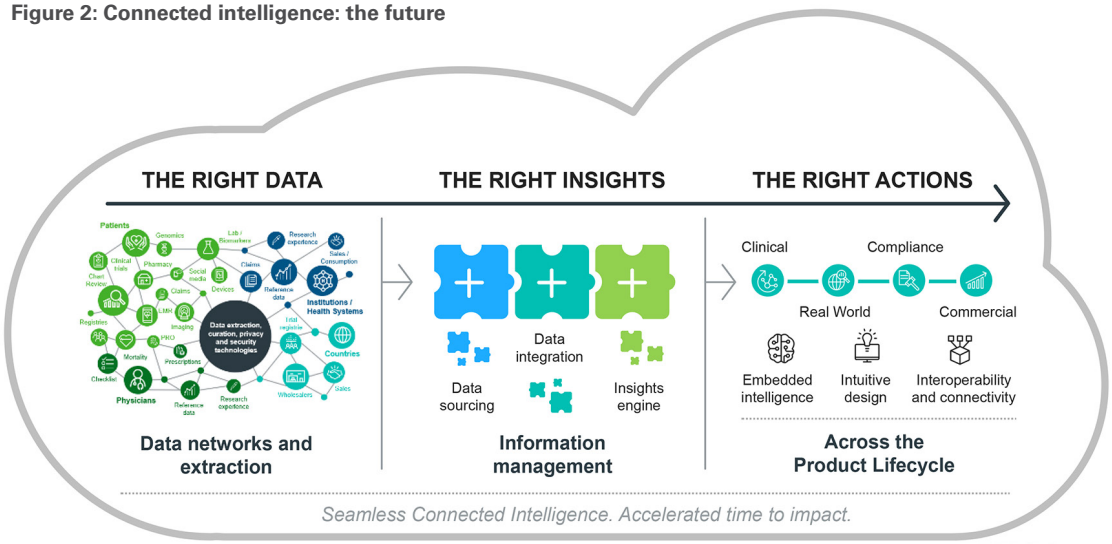
By sharing and connecting data across departments, platforms and functions, organizations can scale data assets in the key areas of clinical, quality, regulatory and safety, while distributing the regulatory burden and the high costs of compliance.

> Critical to this redesign is ensuring that organizations have an up-to-date single source of truth for all their regulatory intelligence, considering both external sources, such as requirements and guidelines, and internal sources of precedent and intelligence, such as interactions with health authorities.
>
> *Sue Plant, Director, Regulatory Intelligence, IQVIA*

Cross-functional data and information management systems can transform compliance from a burden to a competitive advantage.

As automated technologies mature and are capable of processing data intelligently even in highly interpretive fields, such as regulations solutions that embed connected intelligence have important implications for life sciences companies. As a concept, connected intelligence involves three steps: having the right data, generating the right insights from it so that teams can make the right decisions, and taking action. Organizations that deploy such systems to enhance knowledge-sharing across functions can ultimately create a connected compliance ecosystem that increases speed, efficiency and accuracy in managing regulatory changes across the value chain.

Figure 2: Connected intelligence: the future

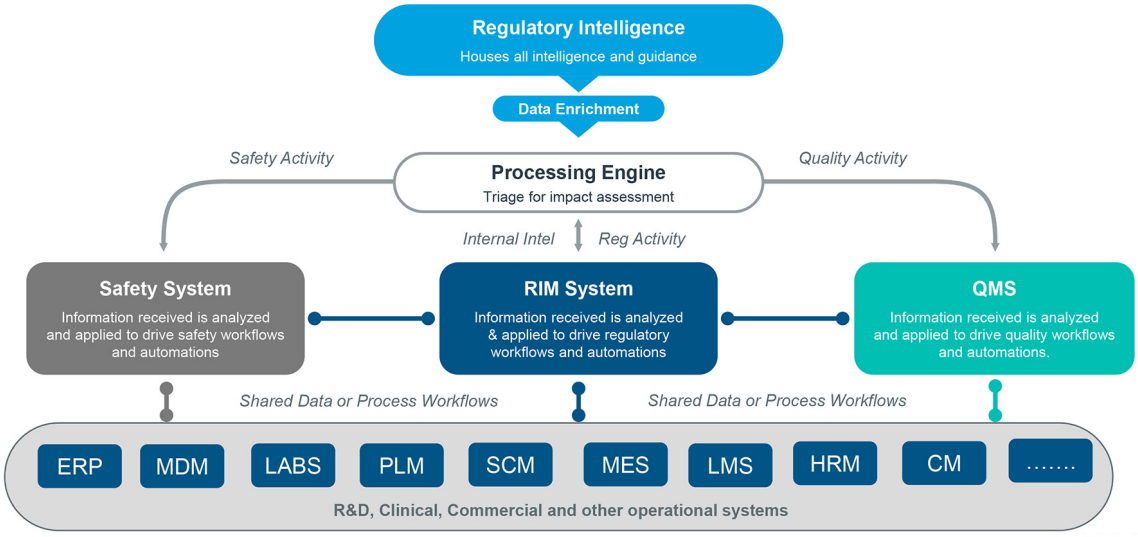


IQVIA's vision of connected compliance builds on that notion. It aims to go beyond optimizing disparate systems in the regulatory, safety and quality functions, and seeks to embed compliance throughout internal processes automatically, without placing additional data management burdens on staff.

To bring that vision to life, IQVIA has developed a connected intelligence strategy based on three levels of automation:

- **Foundational automation** that allows the right technology and data to be used at the right time. Today, as much as 85% of operations are already using some kind of foundational automation.
- **Intelligent automation** that processes the data received and projects the impact of regulatory updates downstream into the organization's regulatory, safety, or quality systems.
- **Deep automation with AI** that learns from previous inputs and iterations and delivers highly accurate projections of the impact of regulatory changes, as well as decision support across the impacted processes and functions.

Figure 3: IQVIA's connected Regulatory Intelligence technology solution



An example of how IQVIA operationalizes its connected intelligence strategy is the company's cross-functional technology solution for automating regulatory intelligence. It has four key components: access to content; a regulatory intelligence layer that contains up-to-date information on regulations for clinical, safety, regulatory and quality issues harvested from more than 110 regulatory authorities worldwide; a data enrichment layer; and an intelligent automation data-processing engine that analyzes inputs from the preceding layers and derives insights from them. The processing engine then triages those insights and feeds them downstream to the regulatory, quality, or safety systems—or a combination of the three—to drive automated compliance.

To deliver a successful connected intelligence program, investing in technology and people is key.

Investing in technology, however advanced that technology may be, is relatively straightforward: it involves identifying and acquiring the right enterprise software solutions and integration tools.

However, investing in people is more nuanced, as it implies not only developing the skill sets of current employees but also initiating a wholesale cultural shift within the organization. Teams in previously siloed departments will have to start working in more collaborative ways and jointly make appropriate situational decisions, and management will have to facilitate this by blurring departmental lines and harmonizing internal processes.

> It's very important to include people in this process from the outset and train them as your organization embarks on this journey, because the probability of having connected intelligence experts within the organization is small.
>
> *Kari Miller, Director, QMS Regulatory and Product Management, IQVIA*

Best practices for regulatory intelligence can illuminate the way to success.

To enhance their chances of a successful connected compliance transformation, life sciences companies can consider the following best practices:

- **Encourage interaction across departments.** The purpose is to identify all internal stakeholders that would be impacted by regulatory changes or decisions and collaborate from the outset to meet their needs.
- **Define unequivocally the project scope.** Given the rapidly evolving regulatory landscape, it is essential to have a clear view of the extent of raw data that needs to be transformed into regulatory output. Doing so helps anticipate quick wins and challenges, and sustains momentum.
- **Create a "single source of truth" to align teams.** Developing and maintaining a database of updated regulatory requirements increases the visibility of information across the organization and aids in unifying processes.
- **Facilitate change management by internal workshops and training.** Giving internal stakeholders the knowledge and tools to support the shift toward connected intelligence and compliance helps embed those new ways of working throughout the organization.

Conclusion

Embarking on the connected compliance journey advances the maturity of life sciences organizations and sets them up for becoming industry leaders. The incorporation of new technologies and collaborative processes that this paradigm shift entails also reduces the overall cost of compliance while improving accuracy and accelerating timelines. This in turn enables organizations to make well-informed decisions more quickly, maintain compliance in highly regulated markets with constantly evolving requirements, and bring products to new and established markets with greater speed.

BIOGRAPHIES

Kari Miller
QMS Regulatory and Product Management, IQVIA

As the QMS Regulatory and Product Management Leader for IQVIA, Kari Miller is responsible for driving the strategic product roadmap and delivery of industry best practices and regulatory compliance solutions for quality management. Kari has more than 25 years of experience delivering software solutions for life sciences. She brings that knowledge to her current team as they focus specifically on translating market and industry requirements into industry-leading enterprise quality management solutions that meet the needs of the heavily regulated life sciences QMS market. Kari earned a Bachelor of Science in Business Administration and a Bachelor of Science in Psychology from Marian College of Fond-du-lac, Wisconsin.

Sue Plant
Regulatory Intelligence, IQVIA

Sue Plant leads the offering team for IQVIA Regulatory Intelligence (Tarius), responsible for understanding customer needs and ensuring that the offering meets those needs, now and in the future. Sue has more than 20 years of experience in the life sciences industry, including roles in sales, marketing, client services, consulting, and offering development, with experience in medical devices, pharmaceuticals, technology, and compliance/regulatory.