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It's Time For Regulatory And Safety To Speak The Same Language

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Regulatory and Safety teams share the same goal: ensuring patients have access to products as quickly and safely as possible. Yet the language, processes and systems these two groups use to achieve that goal have diverged over the years. This siloed approach has complicated data reconciliation, created delays in getting products to market and blocked opportunities for these teams to effectively leverage predictive analytics.

Fortunately, companies no longer have to accept these limitations. To generate the most value from their teams' solutions, Regulatory and Safety leaders have to adapt their workflow and collaborative strategies to bring these vital processes back together.

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TWO ROADS DIVERGED

Historically, Regulatory and Safety were a single team working jointly toward a shared focus and goals. However, as volumes grew and activities became more specialized, the industry split Safety and Regulatory tasks, especially when the focus was on individual cases rather than mining holistic data and maintaining complete products. This caused the industry to start treating Safety as a stand-alone team that dealt with routine maintenance of a product, whereas Regulatory handled the overall strategy of the product.

Their different priorities and skills justified the separation, but dividing the functions led to unintended consequences. It put them on different paths, resulting in unique taxonomies, acronyms, processes and ways of holding products within their systems. This created efficiency barriers and led to sometimes conflicting views and priorities for product maintenance and management.

For example, if the Safety team could easily view the entire Regulatory intelligence of a product, it could efficiently assess cases and signals, and conduct risk management. However, the diverging workflows mean Safety rarely has access to data in the Regulatory Information Management (RIM) system. This forces each department to manually request information that ideally it would investigate itself, and to interpret even basic information, like which product sits in which market. This not only wastes the team's time, it creates risks for the organization on current products and delays patients' access to new medicines.

These are problems that no longer need to exist. When companies integrate Safety systems with their RIM platform, the teams are reunited, able to share information, communicate and collaborate in ways that benefit both functional areas, bringing safer drugs to market faster.

For example, when these solutions are used in concert, Safety reports can be created in the RIM system using Safety system data via a single workflow. This eliminates the need to create aggregate reports and then share them by email or document management systems, eliminating time and risk from the process.

Linking the two platforms also gives the Regulatory team access to all the Safety system data, which can facilitate more robust predictive analytics to inform the Regulatory strategy structure.

REUNITING REGULATORY AND SAFETY

The goal for Regulatory and Safety to once again work together is a long way from the reality on the ground today, but most pharma companies recognize it is the path they need to follow.

System integration is the first step to bridging the chasm, and identifying the commonalities that have become obscured by the lack of a shared language. Once integrated, the RIM system can drive every team's understanding of products to ensure seamless information sharing and alignment. The convergence will allow a shared language to reemerge, creating a common platform for discussions between Regulatory and Safety. This will make it easier to identify joint interests and share information that will drive benefits for all stakeholders.

The good news for companies that want to realize these benefits, is there are currently no technical barriers to integrating systems used by Regulatory and Safety. It is possible to link current generations of Regulatory and Safety platforms today, enabling shared data and more streamlined communication.

Once these connections are made, companies can make the leap to a single Regulatory-Safety system that supports the development of more rational processes, further streamlining both functions. In

this environment, business and process barriers will be to easier to overcome, and everyone will work from a single data environment.

THE BENEFITS OF INTEGRATION

IQVIA has already partnered with a number of companies to bring the Regulatory and Safety teams together through shared technology and integrated processes. By eliminating the barriers created by outdated technology, their systems can finally talk to each other in real time.

In these environments, the processes aren't just aligned – they are integrated, allowing both groups to work on each other's systems as strategy requires. The taxonomies and time frames are jointly approved, ensuring teams can work seamlessly together while also meeting their own team goals.

This has led to two significant benefits:

1. **A single viewpoint across the product life cycle.** Integration provides Regulatory and Safety teams with a consistent, harmonized view of the product. Companies can currently achieve this level of harmonization but only through considerable manual activity. By bringing Regulatory and Safety information and knowledge together through a single, shared platform, manual activities are eliminated while collaborative capabilities are enhanced.
2. **Accelerated time to market.** The ability of teams to speak the same language and share data eliminates unnecessary delays and miscommunication. As a result, products come to market sooner with a better understood and described profile. Our clients have found that housing all product information in a single location creates clarity about a product's population and potential risks, making it easier to monitor safety and performance over time.

SEIZING THE OPPORTUNITY

The current split between Regulatory and Safety is so entrenched that the idea of structuring the two groups as a joint team feels impossible in some quarters. This rigid thinking is holding Regulatory and Safety back. Denied a common language, the functions are unable to capitalize on the commonalities and shared purpose that led them to be grouped together in the past.

But when companies acknowledge the downsides of the divergence within Regulatory and Safety processes, and are willing to transform their technology and workflows to address these issues, they are rewarded with a more efficient operation that brings products to market sooner.

Solutions such as the new IQVIA™ RIM Smart and IQVIA™ Vigilance Platform were specifically designed to tear down these siloes and drive efficiencies that benefit all industry stakeholders. They were created by life sciences experts who understand how to best integrate data and analytics in ways that transform compliance beyond just following the rules. Our modern approach delivers compliance more effectively and more efficiently, so our clients can focus their resources on efficiently delivering valuable products to market.

However, achieving this transformation requires more than technology investments. Challenging entrenched thinking and bold action are required to seize opportunities and tear down barriers that prevent Safety and Regulatory from working in concert. When companies embrace the technology and culture change necessary to bring these two teams back together, time and cost benefits will quickly follow, ensuring pharma, biotech and providers can deliver the right therapies to patients in need as soon as possible.

IQVIA RIM Smart and IQVIA Vigilance Platform integrate Regulatory and Safety, simplifying their processes while boosting speed, accuracy and efficiency. Visit iqvia.com/globalcompliance to learn more.

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