INSIGHT BRIEF

Beyond Compliance

How to create a robust postmarket surveillance program that cuts costs while enhancing performance.

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Postmarket Surveillance is the keystone of a strong vigilance program. It ensures that even after a medical device is released into the market, developers continue to monitor its safety and effectiveness in the real world. Activities range from reactive reviews of complaints and adverse events, to proactive tracking of device performance via customer surveys, interviews and focus groups.

This process ensures medical devices perform as expected, and provide opportunities to improve future iterations. However, it's a costly and time-consuming aspect of the life sciences operation, and demands on postmarket surveillance teams continue to increase.

22,000 new regulations annually

Like many other compliance and regulatory practices, this area of safety monitoring faces a number of emerging challenges in response to an uptick in postmarket surveillance-related data flowing into the organization and the evolving rules that govern it.

Changes in industry regulations are regarded as one of the top disruptive business trends facing life sciences organizations, and many leaders view these regulatory changes as a threat to growth. The pressure weighs most heavily on organizational quality compliance. . Over the past few years, we've seen a 150 percent increase in regulatory mandates, resulting in 22,000 new regulations annually. These changes are occurring across the globe in response to local trends, which means each country has its own set of rules and practices.

THE REGULATORY BURDEN

150% **Increase in regulatory mandates**

Every 22 minutes
New or changed regulation somewhere in the world

53% **Global life science CEOs**
Consider industry regulations a top disruptive business trend

Nearly 500,000
Global regulations and reference documents devices IVDs | drugs | biologics

22,000 new regulations/year

70% **Non-English speaking**
Over 100 countries, regions and authorized organizations

When companies rely on ad hoc and siloed processes, the evolution of the space is making it difficult to track and manage postmarket surveillance activities with consistency and confidence. As regulators tighten their requirements, the time and resources required to operate a successful postmarket surveillance program will continue to increase, along with associated risks. If companies fail to adapt to the changing rules and increase in demands, patient health and safety could suffer, and they increase the chance of product recalls, license/registration withdrawals, financial penalties and legal ramifications.

But when life sciences companies adopt best practices for streamlining the workflow, they can cut the time and frustration related to these tasks, while ensuring global oversight of the device environment.

Best practices for postmarket surveillance

Despite the many challenges facing these teams, postmarket surveillance goals remain the same: to conduct robust postmarket surveillance programs that demonstrate their devices safely provide benefits to patients, while enhancing the company's reputation for quality, safety and compliance. To do that, the postmarket surveillance strategy should take into account the following:

1. **Postmarket surveillance is an ongoing process.** While there are always going to be events that require attention, the primary goal is to create a proactive, systematic and continuous process that is built around a rigorous set of rules. Regardless of location, the postmarket surveillance technology and team must constantly collect, assess, and decide what measures must be taken to provide the promised benefits to patients as a result of using the product.

2. **Postmarket surveillance data comes from many places.** Surveillance platforms must be able to gather and respond to data from clinical studies, patient follow-ups, scientific and medical literature, customer requests, focus groups, surveys and other data sources. Processing this data must rigorously adhere to all regulatory and quality guidelines, regardless of its structure, language, source and timing. Focusing only on complaints and adverse events is no longer going to be sufficient.

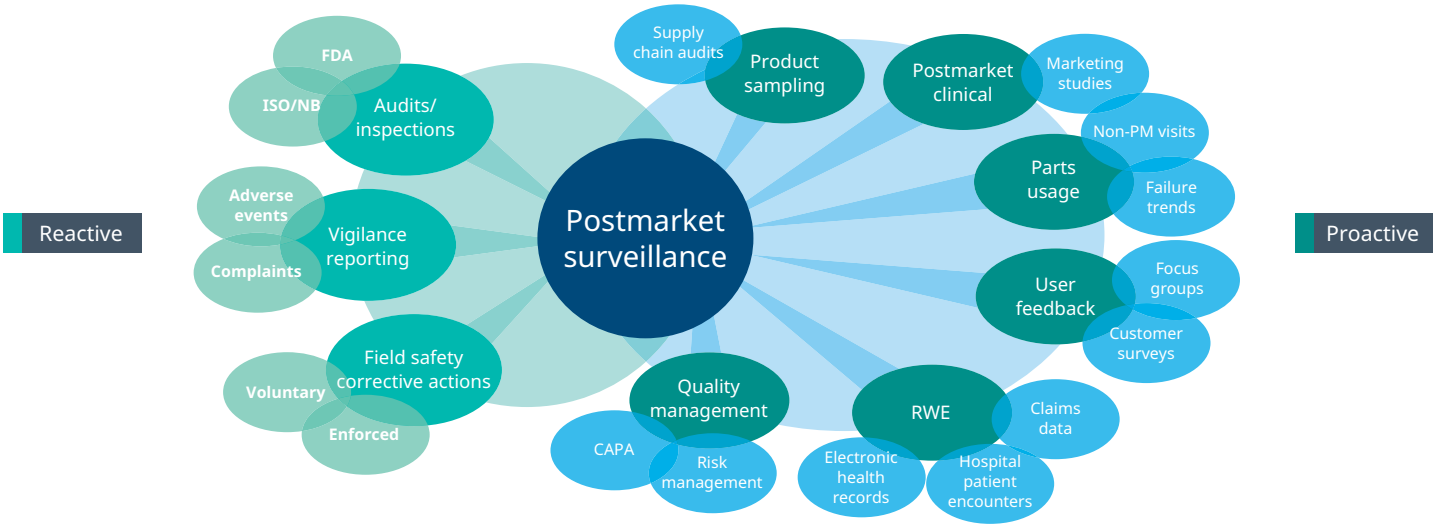
3. **Reporting demands are growing.** The postmarket surveillance environment is constantly changing, and teams must adapt. That includes accommodating new reporting requirements, including periodic safety report updates, postmarket requirements reports, postmarket surveillance plans, and postmarket clinical follow-up reports. This process requires that surveillance teams have updated surveillance data available, and processes in place to complete all related documentation within expected timelines in order to meet requirements. As the flow of data increases, these manual tasks will likely require companies to add additional human or technical support.

4. **Postmarket surveillance is much harder in siloed organizational structures.** Siloed systems can delay or conceal sources of data needed by the postmarket surveillance team. That makes it more difficult and time-consuming to complete surveillance tasks, and it raises the risk of mistakes and missed events. To streamline this process, the silos between departments have to be bridged, to create a single quality management system. Once this is accomplished, all tasks, including corrective and preventive actions (CAPAs), non-conformances, complaints, risk assessments, services reports, and other activities can be addressed and the focus on globally enabled operating models enhanced.

Postmarket surveillance from the cloud

Companies will also benefit from adopting a postmarket surveillance technology, like IQVIA's SmartSolve® Postmarket Surveillance solution, that is built to accelerate the workflow, while adapting to the constantly evolving regulatory environment. SmartSolve provides users with a cloud-based managed process for collecting and analyzing surveillance data, connecting surveillance activities with other quality processes, and consolidating process and data management across these activities.

WHAT MIGHT A MEDTECH PMS/SAFETY LANDSCAPE LOOK LIKE TO MEET THE NEW DEMANDS?

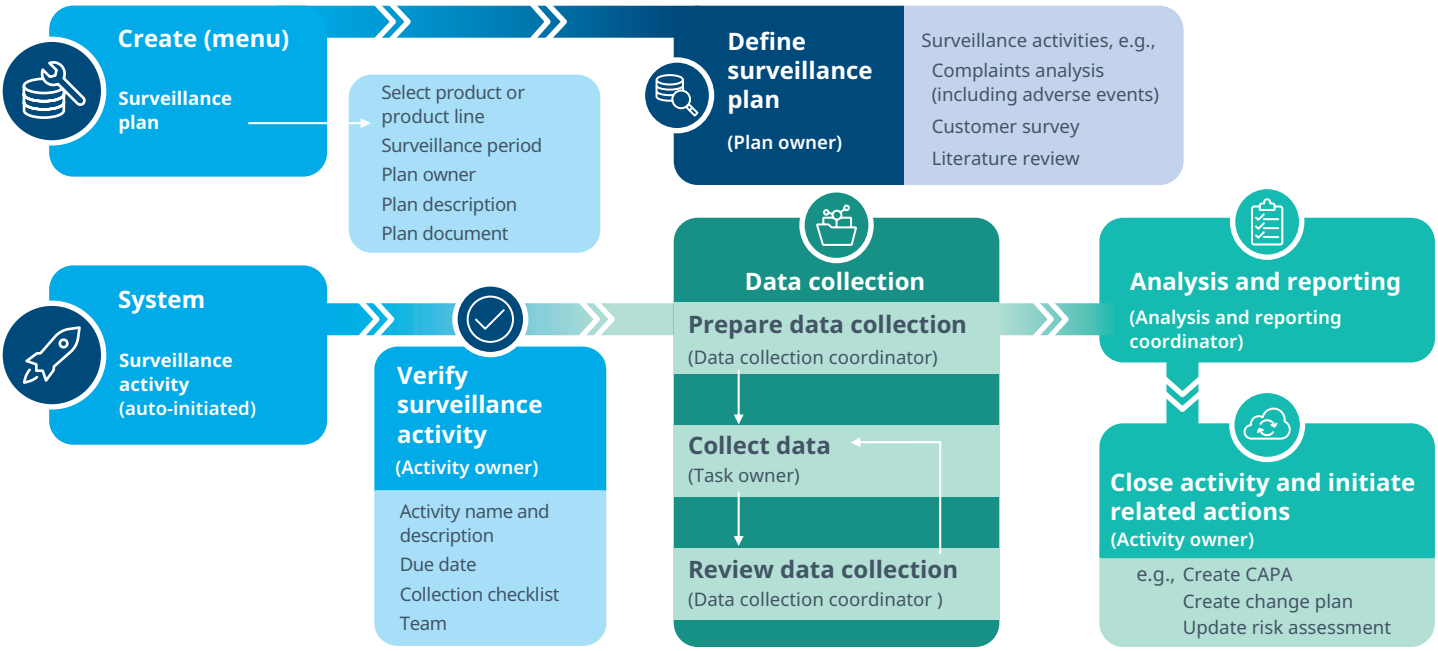


For each surveillance activity, the platform collects and records relevant data as controlled documents, attachments, or references to external data sources. This could include a review of customer complaints and adverse events, CAPAs, literature reviews, or customer surveys. Collected data is then analyzed and investigated if needed. Once the review is complete, reports and other documentation are created to summarize findings, including any relevant trending and analysis of reported events.

The system automatically initiates surveillance activities on scheduled start dates and assigns activity verification to the activity owner for review.

All activities, tasks, assignments, and reviews are easily accessible via the SmartSolve dashboard, which organizes surveillance activities by product, task and task owner, providing team members visibility across the entire surveillance process. Real-time status and access to evidence and reports ensures that all team members can access current and accurate information. Module

IQVIA SMARTSOLVE POSTMARKET SURVEILLANCE WORKFLOW



administration allows for easy setup and maintenance of surveillance products and product lines, surveillance plan documents and procedures, and all surveillance activities and the tasks to complete them.

Standards and guidance

IQVIA's SmartSolve platform has been written to take account of the new ISO Technical Report 20416, which provides device manufacturers with guidance on planning and executing postmarket surveillance activities.

This guidance extends the ISO 13485 standard, which provides guidance for planning, and monitoring medical devices; along with ISO 14971, which provides guidance for managing risk in medical device manufacturing. ISO 20416 provides additional guidance for monitoring device safety and performance and regulatory requirements through data collection and analysis as it relates to production and post-production activities.

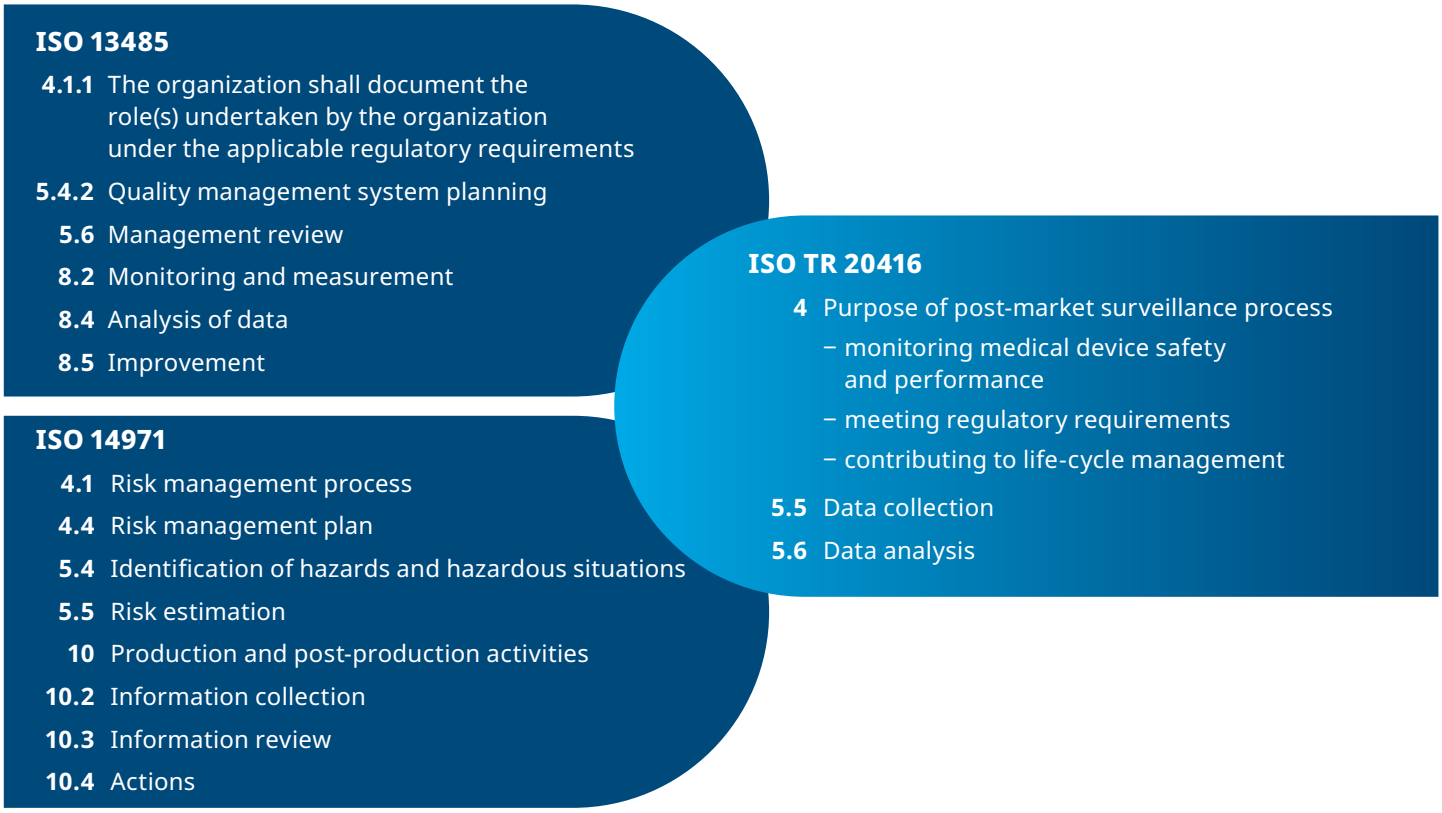
The future will be proactive

IQVIA has more than 30 years' experience helping customers develop best-in-class medical devices. We also have industry-leading quality and compliance expertise, enabling companies to create end-to-end pharmacovigilance for every product in their portfolio.

Our connected intelligence solutions help companies reduce costs, improve compliance and focus on creating a proactive environment that reduces adverse events and risks. This shift to proactive compliance, makes it easy to focus on continuous improvement and interdepartmental collaboration around regulatory and quality goals.

To learn more about postmarket surveillance best practices, and IQVIA's SmartSolve postmarket surveillance solution, check out our webinar on the topic, or contact Regulatory_Quality_Compliance@iqvia.com.

INTER-RELATIONSHIP OF ISO/TR 20416 WITH ISO 13485 AND ISO 14971 STANDARDS



About the authors

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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 University of Fond du Lac.

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Todd is Product Manager supporting IQVIA's Quality Compliance solutions, and is responsible for best-practice solutions for NC and CAPA Management, Design Control and Audit Management, as well as Postmarket Surveillance. Todd has extensive experience in leading the development of enterprise software solutions in life sciences and other industries.

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