WEBINAR SUMMARY

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Pharma Intelligence

MedTech Market Access Trends in 2022: Embracing Change and Dealing with It

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Michael King, Senior Director, Product & Strategy, IQVIA
Jason Berning, Associate Business Development Director, Regulatory Technology Solutions, IQVIA (Moderator)

KEY TAKEAWAYS

- Change is a constant in the world of Medical Devices and the frequency of changes increases with Innovation
- A rugged change process should contain feedback from global regulatory teams to fully understand impact assessments
- Intelligently designed systems can support the change management process across the safety, regulatory, and quality ecosystems
- Change flow between different systems needs to be bidirectional, technology/platform agnostic and consistent. Designing such a system would be key to robust change management across safety, regulatory, and quality.

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OVERVIEW

Implementing product improvements and managing those changes from a regulatory, quality, and safety perspective is crucial for MedTech companies. As health technology advances, the compliance curve is constantly playing catch-up with the innovation curve. The advancement in technology introduces newer avenues for risk, threats and vulnerabilities that could affect quality, safety, and security requirements around not just the products but also the processes involved.

With technological advancement, frequency of regulation releases and updates around quality control, safety, security, privacy, and the very recent - consistency is going to significantly increase. This necessitates MedTech industries to consistently track, adapt and maintain changes to ensure continuous market access across the globe.

Yet, change management along safety, regulatory, and quality systems are complex and have challenging design considerations due to the need to integrate multiple dynamically moving levers for the same change triggers. Those triggers effect changes across product lines, authorities, countries, and internal processes—and aligning the underlying workflows is key to managing change events.

To thrive in this dynamic environment, organizations must ensure that their safety, regulatory, and quality systems are capable of reconciling data, workflows, and feedback linked to different internal and external functions that are central to medical device change management.

CONTEXT

Anusha Gangadhara and Michael King discussed the increasingly complex regulatory environment MedTech companies face when it comes to implementing product improvements, and how a comprehensive change management system can support them in navigating regulatory hurdles with confidence while keeping the focus on patient safety.

KEY TAKEAWAYS

The MedTech industry is facing unprecedented regulatory complexity.

With advances in healthcare technology, the frequency of regulations is increasing. This trend is felt acutely in the MedTech industry due to the nature of medical devices, which often require product improvements during their lifecycle, and the need to ensure that those changes are compliant with evolving regulatory measures. With **up to 25,000 new regulations published per year** and a new or changed regulation happening every 21 minutes somewhere in the world, it is no surprise that **53% of global CEOs consider industry regulations a top disruptive business trend**.

"Even though there have been great efforts around harmonization across the globe in terms of device classification and identification requirements, we still see emergence of local regulations and standard releases," said Ms. Gangadhara.

Mr. King gave the example of Brexit and how the removal of the UK's ability to act as a European authorized representative affected the way that localized changes to labeling and packaging reverberated beyond the UK. He added that at a regional level, the US, Canada, and Europe tend to always be included in companies' change management plans, while China, Russia, and Brazil—which often give rise to additional technical, toxicological, or clinical regulatory requirements—are sometimes overlooked, but should not be.

> While the regulations and the change may start in a single specific country, the global implications are huge and that's the impact that also needs to be considered.
>
> *Michael King, IQVIA*

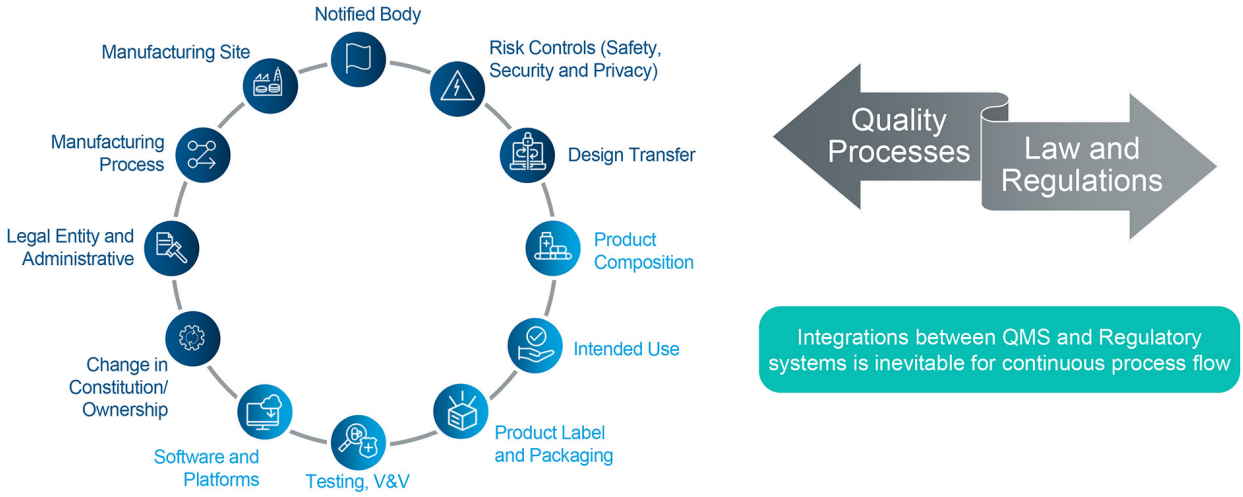
A closed feedback loop between quality and regulatory verticals is key for sound decision making.

When a company plans to make a change to an existing product, it:

- **Conducts an impact assessment** that begins by identifying whether the change is significant enough to affect market approvals and regulatory compliance requirements.
- **Traces the planned change down to the product line, processes, and key areas** such as manufacturing, verification, distribution, labeling, and packaging.
- **Considers whether a resubmission is needed** across the globe or only in some countries, and what are the timelines associated with each jurisdiction where a resubmission may be required.
- **Automates some of the steps and processes** deemed necessary for implementing the change.

Throughout this flow, quality-driven and regulatory-driven processes continuously interact with each other, so it is important that they are sufficiently integrated and communication between them happens back and forth. "The quality management system relies on documentation that is often compiled and supplied by regulatory affairs. Regulatory affairs, in turn, for local or global submissions is pulling documentation out of the quality management system," Mr. King said. "A **closed feedback system** helps capture the impact and helps conscious decision making."

Figure 1. Integration between quality management and regulatory systems



> The feedback loop is typically around what you learn, what you process, and the analytics that could be fed in to ensure that the change control process is much more automated and efficient.
>
> *Anusha Gangadhara, IQVIA*

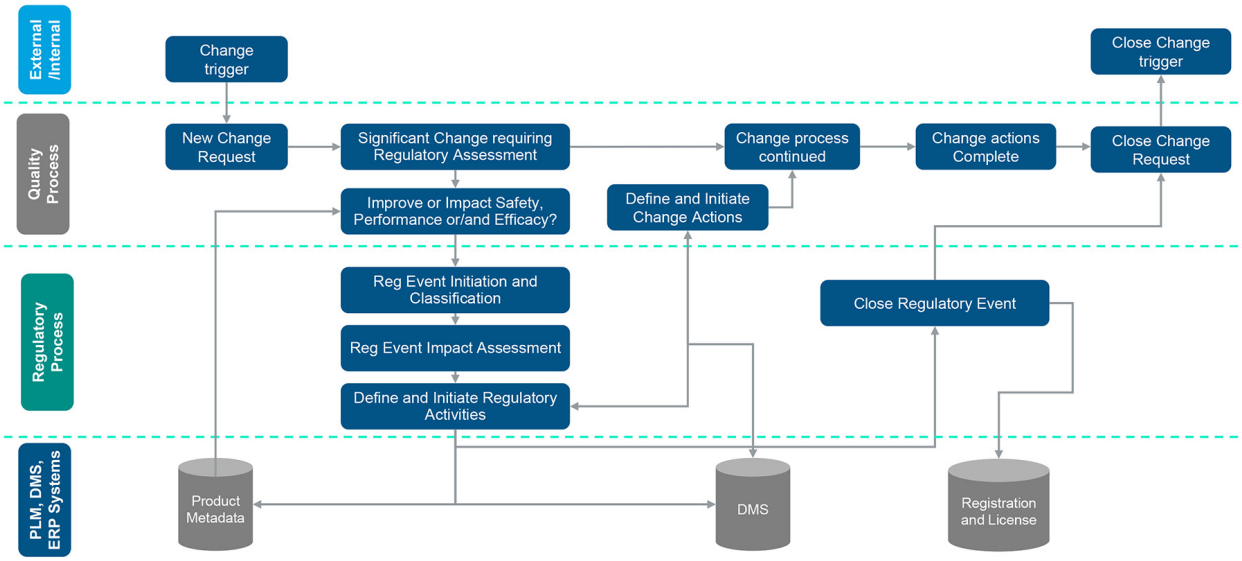
Designing an intelligent change management system entails four key considerations.

The continual emergence of country-specific regulations along with global laws creates complexities, not only from a compliance perspective, but also in terms of designing an ideal change management system, including its tracking, adaptation, and implementation layers.

There are four key considerations when designing such a system:

- **Product definition** relates to how companies bundle their products in a global market versus how they bundle them in country-specific markets (e.g., some countries accept product bundling via a single registration while others require multiple single-product registrations).
- **Submission structure** differs by country and implies variations in technical documentation requirements.
- **Risk classification and pathways** are also subject to variation across countries, despite advances in international medical device regulatory harmonization and convergence (e.g., there can be variations between what is considered a pharmaceutical product, a medical device, or a combination product).
- **Data consistency** between quality management systems, product lifecycle management (PLM) systems, regulatory systems, and commercial units is crucial to obtaining actionable feedback and managing the change event.

Figure 2. Bird's-eye view of an intelligent change management system

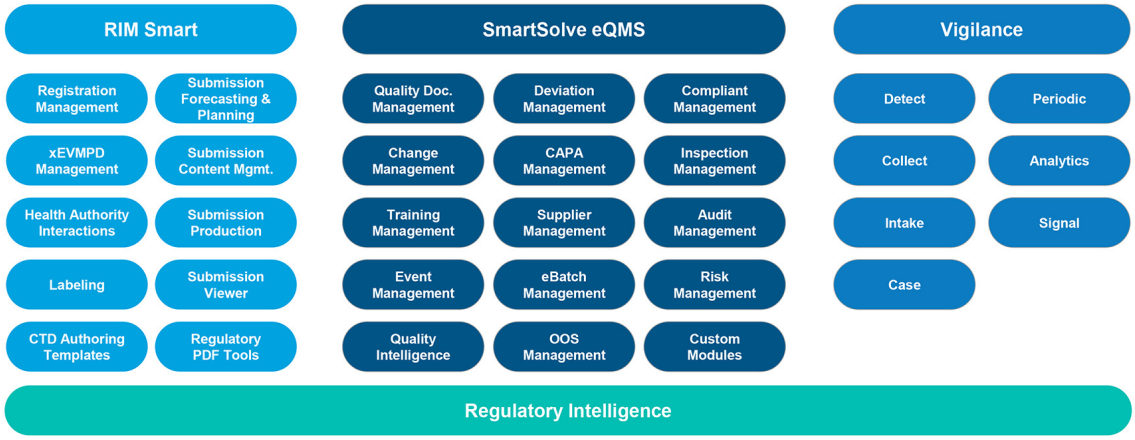


> The data flows across external databases and internal processes need to be consistent, technology- and platform-agnostic, and rugged. Designing such a system would be key to building a robust change management across safety, regulatory, and quality.
>
> *Anusha Gangadhara, IQVIA*

IQVIA's global management system optimizes processes within and across safety, regulatory, and quality layers.

IQVIA's safety, regulatory, and quality solution interconnects functions within companies' safety, regulatory, and quality management systems by combining people, processes, and technology, surrounding them with high-quality data, and underpinning all system interactions with regulatory intelligence.

Figure 3. IQVIA's interconnected change management system



The key objective is to sharpen MedTech companies' focus on patient safety by recognizing up front what the impact of intended product changes would be across different markets, correcting biases that may be due to ingrained ways of working or a lack of familiarity with local regulations, and bringing balance and transparency to internal decision making. The aim of IQVIA's solution is to increase value generation for companies that use it and reduce their compliance risk.

> A key thing for us as an industry is making sure that the changes we implement help deliver safe and effective products in a more timely manner.
>
> *Michael King, IQVIA*

CONCLUSION

As technology advances and medical devices evolve through successive technology improvements, MedTech companies need to master change management in a heterogeneous, continuously updating regulatory environment. To achieve this goal, they need rugged, reliable, and interconnected change management systems that facilitate regulatory intelligence sharing, cross-functional alignment, and efficiency while preserving a focus on patient safety, market access, and commercial success.

"Intelligence-driven systems will become more needful as time goes forward and as boundaries in healthcare solutions start to blur between medical devices, pharmaceuticals, biotechnology, and maybe other technologies we've not yet considered," Mr. King said. "That will impact not just the change process, but the underlying regulations."

BIOGRAPHIES

Anusha Gangadhara

Business System Analyst, IQVIA

With close to a decade of technology experience in the healthcare platform and medical device industry, Anusha is part of the RIM Smart Product Management team at IQVIA. She drives the mapping of business needs to technical requirements and leads business critical engagements in defining RIM Smart Solutions for MedTech. Prior to IQVIA, she worked as a regulatory and quality engineer at Philips Healthcare and before that spearheaded global product launches at two startups—Consure Medical and Sohum Innovation Lab. Anusha holds a Master's in electrical engineering from National University of Singapore with rigorous hands-on experience in the medical device and technology development process from the Stanford-Singapore Biodesign program.

Michael 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.

Jason Berning

Associate Business Development Director, Regulatory Technology Solutions, IQVIA

Jason Berning has more than 10 years of experience in Regulatory Technologies in various roles that include: consulting, product management, and sales. As an Associate Dir. of Business Development at IQVIA, Jason focuses on bringing transformational Regulatory Technology and Consulting solutions to his customers. He has worked with a wide variety of pharma companies of various sizes and is passionately optimistic about the digitalization of regulatory affairs.