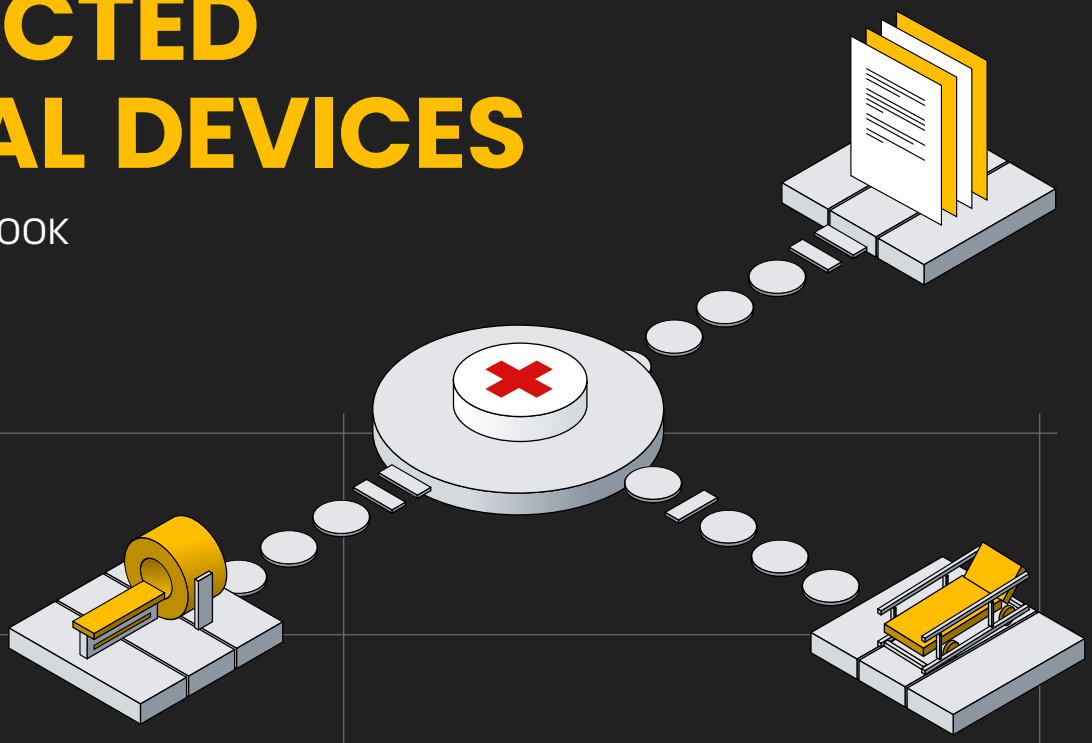
FIELD SERVICE INSIGHTS

NAVIGATING THE INTERSECTION OF INNOVATION AND REGULATION FOR CONNECTED MEDICAL DEVICES

A POST-WEBINAR EBOOK



CUMULOCITY

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This report summarizes a webinar exploring the intersection of innovation and regulation in the connected medical device industry.

Medical device manufacturers face key challenges in bringing connected devices to market, including data privacy concerns, cybersecurity risks, and the need to demonstrate value. Although the relationship between regulatory bodies and innovators has often been challenging, collaboration between the two could yield a more productive path forward, as well as better outcomes for patients.

Looking to the future, there will be significant developments in artificial intelligence (AI) and machine learning (ML), a growing emphasis on interoperability in connected medical devices, and stronger collaboration between regulators and manufacturers.

ABOUT THE CONTRIBUTORS

Moderator:
Patrick Dell
Field Vice President of Service Operations
Varian Medical Systems

Ricky Singh
VP, IoT Americas
Cumulocity

Chetan Makam
SVP, General Manager
Terumo Blood and Cell Technologies

Jatin Thakkar
General Manager, Global Services and Solutions
Carestream

CHALLENGES IN BRINGING CONNECTED MEDICAL DEVICES TO MARKET

The webinar participants highlighted several significant challenges faced by medical device manufacturers when introducing connected devices to the healthcare market.

The panelists emphasized the importance of ensuring the usefulness and actionability of collected data, as the value of connected devices lies in the insights they provide. This data is also critical to meeting regulatory reporting requirements, such as those established by regulations like HIPAA and GDPR.

Network security and data transmission issues also pose significant challenges, as hospitals and patients are often wary of connecting devices to their networks.

As such, cybersecurity risks and vulnerabilities are becoming growing concerns, especially given the increasing number of attacks on healthcare institutions. The panelists stressed the need for robust security measures and compliance checks for both host devices and transmission platforms.

Finally, patient safety emerged as a critical challenge, particularly in the context of life-critical medical devices such as infusion pumps and pacemakers. While organizations want to increase the speed at which their products come to market, rigorous testing is critical not only for compliance but also for patient safety and success.

KEY SUGGESTIONS

- → Develop comprehensive data privacy and security strategies that address both regulatory requirements and the concerns of customers and patients.
- → Develop and deploy a data governance strategy that will yield usable data from connected devices.

> *"In building a connected device ecosystem, the main concerns are data privacy, ownership, and regulations like HIPAA and GDPR. Additionally, there's the issue of device connectivity and data transmission security on shared networks, which makes hospitals and other customers nervous. However, once you overcome these challenges, all parties find the insights generated from that data valuable."*

Chetan Makam
SVP, General Manager
Terumo Blood and Cell Technologies

THE RELATIONSHIP BETWEEN REGULATORY FRAMEWORKS AND INNOVATION

According to the panelists, there is a complex relationship between regulatory compliance and innovation in medical devices. They noted that innovation and regulation are not necessarily at odds but can build upon each other.

Medical device manufacturers must fully understand regulatory boundaries and work collaboratively with regulatory agencies to successfully innovate and bring products to market. As regulations are constantly evolving, manufacturers must also stay aware of any new standards being introduced to address emerging technologies and data-related concerns.

The discussion revealed that regulatory bodies are increasingly recognizing the need to empower organizations to innovate, while also maintaining safety standards. Regulators are essentially learning alongside the industry, particularly in areas like connectivity and AI.

However, they also noted differences in regulatory approaches, with European regulators tending to be more conservative compared to their U.S. counterparts.

KEY SUGGESTIONS

- → Adopt a “regulatory-first” mindset that integrates compliance considerations into the innovation process from the outset.
- → Actively engage with regulatory bodies to foster mutual understanding and shape more innovation-friendly regulatory frameworks.

> *“I think the challenge is in the word innovation itself. You’re charting new boundaries, and it’s impossible to regulate something that you haven’t discovered a boundary for yet. I think innovation must lead, but regulation must progress at the same speed.”*

Ricky Singh
VP, IoT Americas
Cumulocity

THE EVOLUTION OF REGULATORY FRAMEWORKS FOR MEDICAL DEVICES

Regulatory bodies must continuously adapt their frameworks to keep pace with rapid technological advancements in connected medical devices. To do so, regulators are increasingly participating in industry conferences and seeking input from manufacturers to better understand new technologies. According to the panelists, this collaboration represents a new and positive approach to regulation, and it is helping to bridge the gap between innovation and compliance.

Still, the discussion emphasized the need for more flexible and agile regulatory approaches to address the accelerating pace of innovation. Panelists observed that regulatory cycles that once took years are now compressed into months or even weeks.

They also highlighted the challenges regulators face in defining boundaries for emerging technologies like AI and ML in medical devices. Moving forward, organizations should continue to educate and inform regulatory bodies about developments relating to these technologies.

KEY SUGGESTIONS

- → Advocate for and contribute to the development of more agile regulatory frameworks that can adapt quickly to technological advancements.
- → Invest in educating regulatory bodies about new technologies and their potential benefits to help shape more informed and balanced regulations.

> *"The next generation of people working inside regulatory bodies will bring a more well-rounded perspective because they will have embraced the tools we have today, such as AI. Regulation will be more participative because everyone has the same goal: better patient outcomes and improved healthcare. Regulators themselves need better tools and incentives to drive better frameworks inside their organizations."*

Ricky Singh
VP, IoT Americas
Cumulocity

THE FUTURE OF CONNECTED MEDICAL DEVICES

The panelists believe there will be significant advancements in connected medical devices over the next five to ten years, particularly in the realm of AI. Thanks to these developments, healthcare organizations will move beyond data collection toward using data collected from devices for insights generation and remote monitoring. There is now immense potential for devices to significantly impact patient care and life expectancy.

The discussion touched on the importance of interoperability and data sharing across different devices and systems to unlock the full potential of connected healthcare.

Automation also emerged as a key trend for the future. The panelists believe it could address skilled labor shortages and enhance the value of healthcare roles. There is a need for more technology-savvy professionals who can quickly adapt to new systems, both in manufacturing and healthcare.

Finally, connected devices will eventually enable seamless predictive maintenance and remote diagnostics over the next several years. Not only will this make devices safer and more reliable, but it will also empower healthcare providers to improve outcomes for their patients.

KEY SUGGESTIONS

- → Invest in developing AI and ML capabilities that can transform collected data into actionable insights for improved patient outcomes.
- → Focus on creating interoperable systems that can seamlessly share data across different devices and healthcare platforms to maximize the benefits of connected medical devices.

> *"We must develop organizational maturity and acumen around our data because new capabilities come out quickly. AI, cloud, and IoT technologies are now available to everyone, but our processes and governance mechanisms have not developed as quickly. Organizations and regulators must get up to speed so innovators can harness new capabilities as they emerge, while still maintaining governance and compliance standards."*

Jatin Thakkar
General Manager, Global Services and Solutions
Carestream

ABOUT THE AUTHORS

FIELD SERVICE INSIGHTS

Field Service Insights, the industry research and digital publishing arm of the Field Service conference series, delivers cutting-edge data and analysis on trends, challenges, and opportunities in the field service and customer support sectors. Through comprehensive research reports, webinars, and thought leadership initiatives, we empower senior-level field service leaders to make informed strategic decisions and stay ahead in the rapidly evolving service landscape. Our deep industry intelligence not only informs field service leaders but also connects innovative solution providers with key decision-makers, fostering a dynamic ecosystem that drives the future of service excellence in the field service space.

For more information, please visit **wbrinsights.com.**

CUMULOCITY

Cumulocity empowers manufacturers of industrial, commercial, and medical equipment to develop, deploy, and scale innovative digital services. Robust bulk device management capabilities, paired with expertise in API management, make it effortless to manage devices—from thousands to millions.

Our buy & build approach to IoT enables customers to address 80% of their product requirements with out-of-the-box solutions while customizing the remaining 20% to meet unique functionality needs and stand out in the market.

With advanced self-service capabilities, domain experts are able to drive innovation, create new products, while streamlining complex regulatory processes.

For more information, please visit **cumulocity.com.**