



Medmarc Risk Management Webinar Series

Webinar Summary

Medical Device Compliance: A Practical Perspective

Presenter: [Daniel Raymond](#) | Medical Device Executive Consultant | Founder, Springboard Solutions LLC

In this on-demand webinar, recorded on April 8, 2026, Daniel Raymond from Springboard Solutions shared his extensive experience working on complex medical devices, particularly proton radiation therapy systems, to explain the regulatory framework, costs, challenges, and approaches for medical device compliance. He discussed the Quality Management System Regulation (QMSR) under ISO 13485, emphasizing its impact on every business function and the significant compliance overhead costs. Dan covered pre-market approval and post-market surveillance phases, highlighting the importance of integrated business systems, risk management, and maintaining a culture of compliance from the top down. Key challenges included balancing technical and regulatory priorities, managing complex traceability, and dealing with supplier management and nonconformances. Dan also addressed new regulations, including the harmonization of FDA requirements with international standards and the shift to a risk-based inspection framework. The webinar concluded with a Q&A session in which Dan answered questions about regulatory challenges, key compliance topics, FDA meetings, MDSAP requirements, and AI software regulations in healthcare.

[Full On-demand Recording](#)

On-demand Chapters:

- [00:00](#) – Introduction - About the Speaker Daniel Raymond
- [07:50](#) – Regulatory Framework
- [10:03](#) – Cost of Compliance
- [12:11](#) – Challenges of Compliance
- [26:10](#) – Suggested Approach
- [39:54](#) – What's New – Regulations
- [41:50](#) – What's New – Inspections
- [43:30](#) – What's New - Your SOPs
- [44:11](#) – Q & A





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Daniel Raymond is the Founder and Principal Consultant of Springboard Solutions LLC, a medical device consulting firm formed in 2024. Daniel brings more than a decade of senior leadership experience in engineering, quality, and regulatory affairs, previously serving in dual roles as Vice President of Engineering and Director of Quality and Regulatory Affairs for a Class II proton radiation therapy system used in cancer treatment.

Daniel's background spans medical devices, industrial automation, telecom, and defense, providing a practical, cross-functional perspective on regulatory compliance and product development. Daniel was part of an executive 510(k) submission team, ISO 13485 implementations, and complex safety, risk, and EMI/EMC evaluations, while building and leading multidisciplinary teams.

Through Springboard Solutions, Daniel supports medical device companies across FDA QMSR requirements, quality systems, regulatory submissions, systems integration, and emerging AI-enabled compliance strategies—helping organizations align people, processes, tools, and technology to build sustainable, compliant operations that support long-term growth.