



Medmarc Risk Management Webinar Series

Webinar Summary

Wearable and Home-use Devices: Quality Management System

Presenter: Kyle Rose | CEO of Rook Quality Systems

During the on-demand webinar, recorded live on May 13, 2026, Kyle Rose from Rook Quality Systems (RQS) discussed the unique challenges wearable and home-use devices present, including their use by non-professional users in unpredictable environments, the integration of hardware, electronics, software, and cloud connectivity, and the need for strong cybersecurity measures. He emphasized the importance of risk management, software lifecycle processes, usability engineering, and post-market surveillance in developing compliant QMS. Kyle also highlighted the need for efficient documentation and processes that can scale with a company's growth, and he provided practical steps for startups to address compliance gaps and prepare for regulatory submissions. The webinar concluded with a discussion on when to implement Electronic QMS (EQMS) and best practices for startups at different stages of development.

Full On-demand Recording

On-demand Chapters:

00:00 - Intro About the Speaker; Kyle Rose Rook Quality Systems Reshoring Institute

05:48 - About Rook Quality Systems (RQS)

10:47 - Why wearables and home-use devices are a different QMS challenge

23:23 - The QMS requirements you cannot skip

42:51 - How to find and close compliance gaps

45:49 - Building a QMS that scales with your company

50:56 - FAQs and Closing





Kyle Rose | CEO of Rook Quality Systems **info@rookqs.com**

Kyle is a Medical Device expert specializing in the development of efficient Quality Systems for small and startup medical device companies. Kyle founded Rook Quality Systems in 2012 to enable clients to implement compliant Quality Management Systems (QMSs) and to ensure that clients can efficiently produce effective and reliable medical devices. Rook has been overseeing overall quality strategy and ensuring compliance through documentation and auditing services for nearly a decade.

Kyle is a certified quality auditor (CQA) and has regulatory and submission experience for a variety of markets including FDA, CE Mark, Health Canada, and CFDA. Kyle encourages the simplification of Quality Systems to reduce the quality burden and improve compliance through training and efficient QS design.

