



Medmarc Risk Management Webinar Series

Webinar Summary

Mastering Your Next Audit Proven Strategies for Success

Presenter: Kyle Rose | Founder/President of Rook Quality Systems

During the on-demand webinar, recorded live on June 26, 2024, Kyle Rose from Rook Quality Systems (RQS) shared his extensive experience in auditing and simplifying quality systems to reduce burden and improve compliance. Kyle discussed the importance of being prepared for FDA audits and the potential consequences of failing one, such as warning letters or company closure. He emphasized the need to have all necessary documentation and processes in place and to review marketing materials for unsupported claims. Kyle wraps up the session with a FAQ segment that is a terrific time saver if you are unable to attend the entire session.

[Full On-demand Recording](#)

On-demand Chapters:

- [00:00](#) - Intro About the Speaker; Kyle Rose Rook Quality Systems Reshoring Institute
- [01:51](#) - About Rook Quality Systems (RQS)
- [03:42](#) - FDA Inspections
- [04:15](#) - Understanding what happens during an FDA Medical Device QMS Inspection
- [09:50](#) - FDA QSIT Methodology
- [12:17](#) - What FDA Inspectors look for
- [25:34](#) - What happens at the conclusion of an FDA Inspection/Audit
- [28:54](#) - ISO Audits
- [29:31](#) - What is an ISO audit?
- [31:35](#) - Who is subject to ISO audits?
- [35:01](#) - Different types of ISO audits
- [43:20](#) - How to prepare for an ISO audit
- [47:37](#) - Conducting an ISO audit
- [48:44](#) - What happens after an ISO audit?
- [50:55](#) - FAQs and Closing



MEDMARC
Treated Fairly

Medmarc.com



Kyle Rose | Founder/President 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.

