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:

Kyle Rose | Founder/President of Rook Quality Systems
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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.