Developing and Maintaining an FDA Compliant Complaint Handling Process

Presenter: Sarah Lacey Robbins | Rook Quality Systems - RookQS

In this on-demand webinar, recorded live on May 21, 2025, Sarah Lacey Robbins, Senior Quality Manager and Auditor at Rook Quality Systems, presented on how to develop and maintain an FDA-compliant complaint handling process for medical devices. She covered key FDA requirements and industry best practices, highlighting the importance of thorough complaint evaluation, investigation, and documentation. She emphasized the critical role of staff training and active management involvement in ensuring compliance. The presentation also addressed how to incorporate customer feedback into the complaint process and stressed the significance of proper documentation to avoid common findings during FDA inspections.

Full On-demand Recording

On-demand Chapters:

Sarah Lacey Robbins
Senior Quality Manager & Auditor | Rook Quality System

Sarah Lacey Robbins is a Senior Quality Manager at Rook Quality Systems, bringing over a decade of expertise in Quality Management, Regulatory Affairs, and Project Management within the medical device industry. She holds a Bachelor's degree in Chemistry from Winthrop University and has a proven track record of excellence, including multiple "0 Finding" FDA inspections. Sarah Lacey specializes in consulting for regulatory compliance across a broad spectrum of standards and regulations, including FDA, EU MDR, MDSAP, ISO, and IEC. Her deep knowledge extends to managing post-market quality activities such as CAPA, audit responses, and process improvements, making her a trusted leader in the field.