How to Prepare for and Manage Audits & Inspections Across Global Markets Panel Discussion

Moderated by
Jon D. Speer

MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME

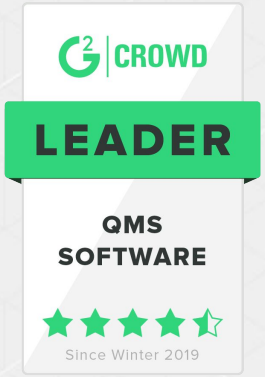
75
years industry experience

275k
podcast listeners

#1
blog and podcast in the industry

114k
look to us for the latest in quality

FEATURED IN



"Great eQMS Software..."

"The software is easy to use with little to no customization needed. It has been a great tool for developing our device through design control. The post-market additions have been amazing as well as tasks. **After using multiple types of eQMS software over the years, this is the best by far!"**

"My QMS is world class"
★★★★★

"Design controls lifesaver"
★★★★★

"One-stop shop"
★★★★★

"Fantastic product, even better team"
★★★★★

greenlight guru

Today's Agenda

- Introduce panelists
- Panel discussion on audits & inspections
- Audience Q&A

TODAY'S PANELISTS

Steve Niedelman - King & Spalding

Steven Niedelman serves as Lead Quality Systems and Compliance Consultant to the FDA & Life Sciences practice team at King & Spalding, LLP, specializing in regulatory, enforcement, and policy matters involving industries regulated by the U.S. Food and Drug Administration where he provides strategic advice, insight, and guidance to the medical device, pharmaceutical, biologics, tobacco and food industries. He assists firms with remediation programs, training, management oversight and responses to agency correspondence.

Mr. Niedelman retired from the Food and Drug Administration after a 34-year distinguished career where he served as Deputy Associate Commissioner for Regulatory Affairs and as Chief Operating Officer of the Office of Regulatory Affairs. He also served as the Director and Deputy Director of FDA's Office of Enforcement, where he also presided as Chairman of FDA's Compliance Policy Council. Before joining the Office of Enforcement, Mr. Niedelman spent nearly 24 years throughout the Office of Compliance at the Center for Devices and Radiological Health.

Colleen Hittle - ProVeritas Partners

Colleen Hittle has nearly 30 years of leadership in the healthcare and life sciences regulatory, clinical and compliance environment, providing expert support to companies regulated by the U.S. Food and Drug Administration (“FDA”) and global regulatory bodies.

Colleen has led global consulting teams that provide expertise to companies developing and marketing products in the medical device, health information technology, combination product, and drug and biologics industries. Former President, CEO, and owner of Anson Group, Colleen has served FDA-regulated companies ranging from the smallest start-ups to Fortune 20 industry leaders. Under her leadership, Anson Group was sold and successfully integrated into a $1B publicly traded global company.

A highly sought-after Strategic Advisor for mergers and acquisitions, she has led regulatory, quality system, and compliance diligence reviews for deals with a total value of over $30B. She has testified as an expert witness at FDA hearings and meetings and in civil and criminal litigation matters; led a multi-site investigation of allegations of compliance record falsification; provided primary leadership on engagements to remediate large-scale, complex U.S. and global regulatory agency enforcement actions; spearheaded a company-wide regulatory assessment for a Fortune 20 corporation seeking to expand into market sectors with substantially higher risk profiles; and interacted with regulatory agencies on behalf of manufacturers seeking to market new technologies and implement new regulatory requirements.

With a degree in Engineering from Purdue University, Colleen is a recognized expert in FDA regulatory and compliance strategies and an active participant in industry dialogue with the FDA. She has served on numerous industry, university, and civic non-profit boards, and is a regularly invited speaker and panel member at industry conferences.

George Zack - Two Harbors

George has been in leadership and contributor roles in quality, medical device regulation, information technology, software development and delivery, and process improvement for over two decades. George is a Co-founder and Principal at Two Harbors, a firm focused on helping organizations achieve greater business value and performance results above compliance and regulatory expectations. George's efforts include helping medical device manufacturers connect with FDA CDRH in the Case for Quality's Voluntary Improvement Program and the budding program for non-compliant device sits seeking to accelerate their process capabilities. George's experience in process and continuous improvement also includes value stream mapping engagements, Agile and other SDLC transformations, Six Sigma and enterprise tool implementations. George is certified (ASQ) Lead Auditor, a CMMI Professional and a CMMI Lead Appraiser Candidate. Outside of his efforts with Two Harbors, George is a volunteer assistant coach to the local high school cross country and distance running squad, and is active in various roles with the local Scout BSA Troop.

Sara Adams - Greenlight Guru

Sara Adams is a Medical Device Guru at Greenlight Guru and a Biomedical Engineer who began her career in the medical device industry in the post-manufacturing world. As an experienced Quality Engineer, she has been responsible for leading Corrective and Preventive Action (CAPA) investigations and implementations, process improvements, and leading supplier and regulatory audits. Sara believes Quality is the responsibility of all medical device professionals, regardless of role or function, and enjoys helping customers achieve a state of constant audit-readiness by establishing and leveraging their medical device QMS software to improve the quality of life for patients.

Norbert Stuiber - TÜV SÜD

Norbert is the Head of Sales & Strategic Marketing within the global division of Medical Health Services for TÜV SÜD Product Service Division. In his role he oversees the challenges and trends in the medical device industry concerning global regulatory requirements.

Norbert worked within TÜV SÜD as Lead Auditor for medical devices and as an expert on global regulations for medical devices.

Prior joining TÜV SÜD he managed the business unit “automated infusion systems” for B. Braun.

Norbert studied medical engineering and graduated with an MBA in Sales & Marketing

TODAY'S TOPIC:

Preparing for and managing audits and inspections, where FDA, NBs, and competent authorities use alternative inspection tools and methods (e.g. RRAs, virtual inspections, record requests, virtual walkthroughs, onsite hybrids).





Audience Q&A