AUDIT DIVISION CONFERENCE

SEPTEMBER 23 - 24, 2026 | ROSEMONT, IL

Full Program

Rev.0 14SEP2026

Note from the Technical Program Chair

Welcome to the ASQ Audit Division's 32nd Conference! I am honored and excited to reprise my role this year as Technical Program Chair.

We are pleased to again be collaborating with the ASQ Food, Drug & Cosmetics Division. They will have one full track of seven sessions (Tracks E and J) across both days of the conference. Please support both the FDC Division and the Audit Division by visiting our booths in the sponsor area.

This year's theme is *Future Ready: Empowering Auditors, Transforming Tomorrow*, and our technical program is ripe with topics that will prepare auditors for new technologies, new standard revisions, and new ways of thinking. You will find the full program with abstracts for all sessions in the following pages, and you'll be able to learn more about our fantastic speakers as well.

Your feedback is invaluable to our speakers. You will receive a survey after each session, so please let us know the speakers and topics you'd like to see at future conferences. Perhaps we'll hear from you with a session proposal at our call for speakers next year!

Our other program elements include four keynote presentations by renowned speakers, who will definitely get you thinking. Our generous sponsors, without whom such a conference would not be possible, will also be highlighted on our main stage and positioned throughout our Sponsor Hallway, available for conversation and networking throughout these busy two days.

Please also be sure to join us at our signature Gala event starting at 6:30pm on Wednesday evening in the Cassatt Ballroom. There will be lots of food, music, dancing, a photo booth, and karaoke!

Presentation slide decks will be uploaded to myASQ in the Audit Division community shortly after the conference ends. We will make an announcement via our socials once they are available.

Lastly, this conference would not have been possible without all the volunteers who made it all happen. My sincerest appreciation goes out to the ASQ Audit Division Conference Business Team, our Session Managers, the FDC for partnering with us, the Loews Chicago O'Hare Hotel for their day-by-day assistance with our planning, and all of you who made the decision to attend this year. Our goal is to continue bringing you a valuable experience through thought leadership, and – let's face it – an intimate and fun opportunity to meet and network with other auditors.

In closing, thank you very much for attending the 2026 ASQ Audit Division Conference. I sincerely hope you continue to find benefit, knowledge, and yes – FUN – with us this year!

Sincerely,

Please use our conference hashtag when posting to LinkedIn!

#ASQAuditCon

Katie Keller

2025-2026 Audit Division Conference
Technical Program Chair
2026-2027 Division Chair-Elect

Audit Division Bingo

What Is It? How Does It Work?

When you check in for the conference, you should receive an Audit Division Bingo Card in your conference bag. Please go to the registration desk if you did not receive one.

Just like normal bingo, you will need to mark off the squares on your card to make a bingo. With Audit Division Bingo, the only bingo that counts will be a cover-all. That means you will need to mark off every square on the card!

The squares will be assigned to our generous Sponsors and to some of the amazing ASQ Member Leaders who are present at this year's conference. You will need to visit the Sponsor booths, find the Member Leaders, and ask them to check off the squares on your bingo card. When you have all the squares filled, turn in your card at the registration desk to be entered into a raffle for prizes!

HINT: You can check the photos of the Member Leaders on the looping slide deck before the keynotes and at lunchtime to find them more easily!

AUDIT DIVISION CONFERENCE

ASQ SEPTEMBER 23 - 24, 2026 | ROSEMONT, IL

BINGO CARD

GMP Trends	**Andrew Davison** ASQ Audit Division Chair	Food, Drug, & Cosmetic Division — Visit the ASQ FDC Division Booth and show that you follow the FDC on LinkedIn!	Q3 Integrative Solutions
SGS	Audit Division — Visit the ASQ Audit Division Booth and show that you follow the Audit Division on LinkedIn!	QSG Quality Support Group	**Kristen Wagner** ASQ Audit Division Social Media Co-Chair (myASQ)
Compliance Group	**Katie Keller** ASQ Audit Division Chair-Elect; Conference Technical Program Chair		**Danielle Hestermann** ASQ Audit Division myASQ Engagement Chair
Nancy Pasquan ASQ Audit Division Conference Registration Chair	Quality Auditing	2026 ASQ Audit Division **Paul Gauthier Award winner**	FocalCXM
Food Smart Strategies — The Food Safety Experts	**Bill Hackett** ASQ Audit Division WCQI Technical Program Chair	Exemplar Global	**BJ Johnson** ASQ Audit Division Technical Standards Chair

Rules are easy!
1. Visit our sponsors to have them sign their square.
2. Find our Audit Division leaders to have them sign their square.
3. Turn in your card when you have it fully signed off. It's a cover-all!
4. Be entered into the drawing for a prize! Drawing will be Thursday around 11:45am. Must be present to win.
5. Completed Card Drop-off locations: Audit Division Booth OR Conference Registration Desk.

Name: _____

Phone #: _____

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Conference Overview

Wednesday, September 23, 2025	
6:30a	Registration Opens
8:00a – 9:25a	Opening, Morning Announcements, Guest Speaker, Keynote & Sponsor Presentation
9:25a – 9:40a	Break
9:40a – 10:30a	Concurrent Sessions
10:30a – 10:50a	Break
10:50a – 11:40a	Concurrent Sessions
11:40a – 12:00p	Break
12:00p – 1:20p	Midday Announcements, Lunch, Paul Gauthier Award Presentation, Keynote & Sponsor Presentation
1:20p – 1:30p	Break
1:30p – 2:20p	Concurrent Sessions
2:20p – 2:40p	Break
2:40p – 3:30p	Concurrent Sessions
3:30p – 3:50p	Break
3:50p – 4:40p	Concurrent Sessions
4:40p – 6:30p	No Programming
6:30p – 10:00p	Gala

Thursday, September 24, 2025	
7:00a	Registration Opens
8:00a – 9:25a	Opening, Morning Announcements, Keynote & Sponsor Presentation
9:25a – 9:40a	Break
9:40a – 10:30a	Concurrent Sessions
10:30a – 10:50a	Break
10:50a – 11:40a	Concurrent Sessions
11:40a – 11:50a	Break
11:50a – 1:30p	Sponsor Bingo Winners/Prizes, Announcements, Lunch & Keynote
1:30p	End of Conference

Registration Desk Hours:

Tuesday, September 22, 2026	7:00a – 8:00a
Tuesday, September 22, 2026	1:00p – 5:30p
Wednesday, September 23, 2026	6:30a – 4:40p
Thursday, September 24, 2026	7:00a – 8:00a

Pre-Conference Tutorials

Business Acumen for Quality Professionals: 10 Tips That Deliver

½ Day Course: Tuesday, September 22, 2026, 8:00a – 12:00p
Instructor: Rai Chowdhary
Location: Tate

Course Description:

A 2022 CQI Workforce Study revealed that fewer than two in five quality professionals felt highly valued by other teams. Quality is often perceived as the department of “failed engineers” or the “police.” These stereotypes are not anomalies; they are indicators of dysfunctions that have quietly eroded the profession’s vitality over decades. Unchecked, this can put your career at risk.

In this Tutorial, you’ll learn practical tips that deliver:

- How to reframe quality outcomes in business terms executives understand
- Ways to connect compliance work to cost savings, risk reduction, and growth
- Strategies to elevate your role from auditor to strategic partner

You’ll walk away with tips and techniques to influence decisions, elevate your visibility, and accelerate your career growth. Join us to gain the business acumen that transforms your trajectory, secures your seat at the decision-making table, and strengthens your earning potential as you learn the language of the business — and the C-Suite.

Five compelling reasons to attend:

1. Experience real world examples and hands-on practice during the session
2. Gain insights you will not in formal quality training
3. Boost your influence at work – and sharpen your skills in personal life
4. Become ***the bridge*** that connects quality with business impact

Instructor Bio:

Rai is an award-winning speaker and relentless learner who continues to expand his portfolio of knowledge, skills, and abilities. He brings over 40 years of diverse experience across automotive, aerospace, life sciences, food products, and service industries. His undergraduate studies included Mechanical and Production Engineering, with graduate study in Materials Science. He holds several ASQ Certifications: CSQP, Six Sigma Black Belt, CQE, and CMQ/OE. Rai is also a Lead Auditor for ISO 9001, 13485, and 27001.
He has led / participated / witnessed hundreds of audits starting in 1995 covering a broad range of industries and regulations; he serves on standards development committees (ISO TC 176, among others). Rai was recognized as “Expert on WG 28 for the development of ISO/TS 10020:2022” (Organizational Change Management).

Your Audit Report: False Assurance or Stamp of Authenticity

½ Day Course: Tuesday, September 22, 2026, 1:00pm – 5:00pm
Instructor: Rai Chowdhary
Location: Tate

Course Description:

When quality auditors sign off on an audit report, they are attesting to the accuracy of what was checked. Yet too often, critical questions about **data integrity and data quality** are left unasked. Just examining a chart, table, or report is seldom adequate. This gap undermines the very foundation of the audit process.
In this tutorial, you'll learn how to:

- Identify the right questions to probe the integrity and accuracy of data presented during audits
- Recognize red flags in data collection, reporting, and analysis
- Strengthen your audit conclusions with evidence that stands up to scrutiny

Consequences of Missing Data Integrity Checks

- **False assurance:** Audit reports may appear compliant while hiding systemic issues.
- **Regulatory risk:** In industries like medical devices, pharma, and manufacturing, overlooked data flaws can trigger FDA findings, EU MDR nonconformities, costly recalls, and in some cases harm to society via preventable accidents.
- **Business impact:** Poor data quality leads to misguided decisions, wasted resources, and erosion of customer trust.
- **Career credibility:** Auditors who fail to challenge data integrity risk being seen as "rubber-stamping" rather than safeguarding compliance and value.

Auditors are guardians of trust - Five Key Reasons to Attend:

1) Understand how QMS standards and regulations demand evidence-based auditing. ISO 9001, 13485, IATF 16949, AS 9100D, TL 9000 and many regulations such as FDA 21 CFR 820, EUMDR, and USDA lean toward the use of evidence to support conformance or compliance.
2) Evidence without data is just an opinion – which is subjective. Learn to ask the right questions.
3) Learn to spot how concealment, falsification and cherry picking of data takes place; it occurs more widely than you would believe.
4) Develop questioning techniques that uncover weaknesses in data collection, accuracy, and integrity — before they derail corrective and preventive actions.
5) Protect organizational integrity, your professional credibility, the trust society places in quality, and in you.

Instructor Bio:

Rai is an award-winning speaker and relentless learner who continues to expand his portfolio of knowledge, skills, and abilities. He brings over 40 years of diverse experience across automotive, aerospace, life sciences, food products, and service industries. His undergraduate studies included Mechanical and Production Engineering, with graduate study in Materials Science. He holds several ASQ Certifications: CSQP, Six Sigma Black Belt, CQE, and CMQ/OE. Rai is also a Lead Auditor for ISO 9001, 13485, and 27001.
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Structured Root Cause Analysis: Empowering Auditors to Drive System-Level Improvements

Full Day Course: Tuesday, September 22, 2026, 8:00am – 5:00pm
Instructor: Denis Devos
Location: Avedon A

Course Description:

We are pleased to offer this one-day tutorial to professional third-party auditors and internal auditors alike. Root Cause Analysis (RCA) enables a structured approach to identifying and eliminating the underlying causes of nonconformities, rather than focusing only on symptoms. RCA helps auditors guide organizations toward sustainable corrective actions that prevent recurrence. Tools such as the 5 Whys, Logic Trees, and Fishbone diagrams provide clarity in complex processes, ensuring that issues are traced back to systemic weaknesses rather than isolated mistakes. Auditees often lack the RCA tools to respond to complex, system-level nonconformances and require assistance and coaching from their auditors to find true root causes. This tutorial will give auditors the background they need to provide coaching to auditees and also assess the sufficiency of Corrective Action responses they receive in response to their findings.

Instructor Bio:

Denis Devos is a professional engineer with a long career providing QMS training and advisory services. He is a Fellow of the ASQ and is a recognized expert in the application of the ISO 9001, IATF 16949 and ISO 14001 Standards. Denis was the developer of the Risk is the Compass risk-based audit model in 2001. He works with clients in a variety of industries, providing internal audit services and training for QA practitioners and internal auditors. Denis has been a regular contributor to the Audit Division conference for over 20 years in a row. He is the recipient of the 2024 ASQ Audit Division's Paul Gauthier Award.

GxP for Supplier and Internal Audits

Full Day Course: Tuesday, September 22, 2026, 8:00am – 5:00pm
Instructor: James Shore
Location: Avedon B

Course Description:

Looking to sharpen your auditing skills or earn points toward recertification? Whether you're new to auditing or simply need a refresher, this dynamic one-day course is designed for professionals who want to enhance their effectiveness in both supplier and internal audits.

Led by an expert with over 30 years of industry experience, this class offers practical insights and proven techniques to conduct efficient, impactful audits that meet GxP standards. You'll learn how to apply the principles of auditing to both internal operations and external suppliers, gaining tools and strategies you can use immediately in your role.

Don’t miss this opportunity to level up your auditing expertise in just one day!

Agenda Overview

- Session 1: Introduction to Internal and Supplier Auditing
- Session 2: Key Components of Internal and Supplier Audits
- Session 3: The Audit Process
- Session 4: Common Findings and Issues
- Session 5: Effective Internal and Supplier Relationship Management
- Session 6: Best Practices and Industry Standards
- Session 7: Conclusion and Wrap-Up

Instructor Bio:

James Shore is the founder of Quality Lean Solutions, specializing in Quality Systems, auditing, and regulatory compliance for the medical device and life sciences industries. With more than 30 years of hands-on experience in manufacturing, plastics, machining, and quality engineering, he has built and implemented multiple Quality Management Systems and led organizations through successful FDA, ISO 13485, MDSAP, and customer audits.

James is a frequent instructor for ASQ divisions and industry groups, known for delivering simple, sustainable, and practical training rooted in real-world experience. His approach blends risk-based thinking, Lean principles, and auditor expectations to help organizations strengthen compliance without unnecessary bureaucracy.

Prior to entering the medical device and quality professions, James served in the United States Marine Corps, completing a distinguished career as a Gunnery Sergeant (E-7) and helicopter Crew Chief. His military background reinforces his commitment to leadership, discipline, accountability, and mission-focused execution, the same principles he brings to every audit, project, and training engagement.

Advanced Problem Solving: Applying the 8D Methodology to Strengthen Corrective Action Performance

Full Day Course: Tuesday, September 22, 2026, 8:00am – 5:00pm
Instructor: Angelo Scangas
Location: Warhol A

Course Description:

Corrective action continues to be one of the most frequent and persistent findings during certification audits across industries. This full-day, interactive workshop provides participants with a practical and disciplined approach to problem solving using the 8D methodology. Attendees will explore why corrective action processes fail, how auditors evaluate effectiveness, and what organizations can do to permanently eliminate systemic issues. Through structured exercises, real-world examples, and group application activities, participants will learn how to define problems accurately, verify root causes, develop robust corrective actions, and implement sustainable controls. Whether you are an auditor, quality professional, or improvement leader, this workshop equips you with actionable tools to reduce recurring nonconformities and strengthen your organization's problem-solving culture.

Brief Workshop Outline (8 Hours)

1. Introduction & Workshop Overview (30 min)
- Importance of effective problem solving in quality systems
- Why corrective action remains a top certification-audit finding
- Expectations from auditors regarding corrective action effectiveness

2. Overview of 8D Methodology (45 min)
- History and purpose of the 8 Disciplines
- How 8D aligns with ISO 13485 / QMSR / ISO 9001 / AS9100 / IATF 16949 corrective action requirements
- Key success factors for using 8D

3. D1–D2: Team Formation & Problem Definition (1 hr)
- Building an effective cross-functional team
- Defining the problem clearly using data
- Tools: 5W2H, problem statements, scoping boundaries
- Group exercise: Writing a precise problem statement

4. D3: Interim Containment Actions (45 min)
- Purpose of containment vs. corrective action
- Common audit findings related to ineffective containment
- Exercise: Evaluating good vs. weak containment actions

5. D4: Root Cause Analysis (1.5 hrs)
- Distinguishing symptoms from causes
- Tools: 5 Why, Fishbone, causal factor charts
- Auditor expectations for demonstrating root-cause verification
- Group case study: Conducting RCA on a sample scenario

6. D5–D6: Corrective Action Development & Implementation (1.25 hrs)
- Converting root cause into systemic corrective action
- Preventing recurrence: process changes, mistake-proofing, controls
- Linking actions to risks and organizational processes
- Exercise: Developing corrective actions from RCA outputs

7. D7–D8: Verification, Validation & Closure (45 min)
- Measuring effectiveness of corrective actions
- Audit evidence requirements for closure

- Preventing “recycled” nonconformities
- Lessons learned and institutionalization of improvements

8. Integrating 8D Into the Organization (30 min)

- Embedding problem-solving into culture and daily management
- Training, coaching, and leadership support
- Examples of high-performing corrective action systems

9. Final Group Exercise & Discussion (30 min)

- Teams complete a mini 8D on a provided case
- Peer review and auditor-style feedback
- Q&A and next steps

Instructor Bio:

Angelo Scangas is President of Quality Support Group, Inc., an International Consulting and Training organization. Angelo has a B.S. in Chemical Engineering, M.S. in Manufacturing Engineering, and an MBA. Angelo is a senior member of the American Society for Quality and a long-time member leader of the ASQ Audit Division.

Angelo has more than 30 years of experience in the Medical Device, Consumer, Electronic, Healthcare, and Chemical Industries working in product development, manufacturing, quality assurance, and process improvement.

ISO 9001 Revision Requirements (USA Style)

Full Day Course: Tuesday, September 22, 2026, 8:00am – 5:00pm
Instructor: Paul Russell
Location: Warhol B

Course Description:

This 1-day pre-conference tutorial covers the changes in the upcoming ISO 9001:2026 revision. While most of the standard remains similar to ISO 9001:2015, there are some sub-clause movements and wording updates. The session will explain what’s new, what’s changed, and how it could impact your organization. Attendees should have a basic understanding of the current ISO 9001 requirements to fully benefit. The goal is to build confidence in navigating the revision—no need to worry, we’ll tackle it together.

Instructor Bio:

Paul Russell has been a Certified Quality Auditor since 2008 and is Managing Director for QualityWBT Center for Education and the JP Russell Learning Center. For 24 years, Paul Russell has worked with Web-based training and blended learning classes approved by the American Society for Quality. He is a voting member of the United States Technical Advisory Group (US TAG) ISO/TC 176 for Quality Management Systems standards. For over 10 years, Paul worked in the health industry. He has spent crazy fun times throughout the 21st Century getting to know ISO 9001, ISO 13485, 21 CFR 606, 21 CFR 640, 21 CFR 860, and 21 CFR 1300-1317.

Keynote Speakers

Day 1 – Opening Keynote
Wednesday, September 23, 2026
Jd Marhevko

Auditor Evolution! From Compliance to Strategic Catalyst

In an era defined by rapid technological disruption, global supply chain volatility, and rising expectations for transparency, auditors stand at a pivotal moment. We will explore how auditors can evolve from compliance stewards into strategic catalysts—professionals who not only assess quality but actively shape organizational resilience and innovation.

Attendees will gain insight into the emerging capabilities, mindsets, and tools required to thrive in a future where data, automation, and cross-functional collaboration redefine what “good” looks like. We will challenge you to embrace new competencies in order to elevate your influence, and lead organizations toward smarter, more adaptive quality systems.

Jd is a VP of Quality for ZF Groups Electronics & ADAS Division. Jd has been a senior executive in several companies including Borg Warner, Delphi, Accuride, Eaton, etc. in roles of Operations, Quality, and Lean. She has helped companies transform from bankruptcy to best in class with 3rd Party recognition from the AME (Association of Manufacturing Excellence) and Industry Week. In 2020, Jd was inducted into the inaugural USA’s Women in Manufacturing (WiM) Hall of Fame. Jd is an ASQ Fellow, Shainin Medalist, CMQ/OE, CQE, CSSBB and MBB. In 2018, she was recognized by Crain’s as a notable Woman in Manufacturing. She holds a BSE and MSA. Jd has co-authored several books and articles on Lean and Quality Systems; most notably, Accuride Corporation’s Lean Management 50-50-20, as well as a small vignette depicting their family’s journey with autism, A Sample Size of One.

Day 1 – Midday Keynote
Wednesday, September 23, 2026
Michael Fank

Riding the Next Wave: How Auditors Can Lead Through Disruption

Every major leap in history created fear… until people learned to ride the wave. From the steam engine to 3D animation, Mike Fank shares surprising stories of how technology has always pushed professionals to grow, not disappear.
Today’s wave is AI. Instead of resisting it, Mike shows quality professionals how to harness it. Auditors will walk away with three simple AI tools they can use immediately, plus a clear mindset shift for leading their organizations through the next decade of change.

Mike Fank is an Operational Excellence Leader and consultant who helps organizations align quality with business strategy to achieve lasting results. With more than a decade of experience in quality and process improvement, Mike has guided teams across manufacturing and service industries to simplify systems, eliminate inefficiencies, and strengthen performance.

As the founder of Upside Down Excellence, Mike focuses on bridging quality and business so that quality becomes a natural part of how organizations operate and grow. His approach helps quality to make meaningful improvements and business leaders to understand the value of their quality team. He blends Lean, Six Sigma, and human-centered problem-solving with a strong emphasis on building systems people want to use.

Mike is a Certified Manager of Quality and Organizational Excellence, a Lean Six Sigma Black Belt, and a long-standing ASQ Senior Member and Mentor. He has developed corporate audit standards, designed training programs, and advised leadership teams on how to build efficient, sustainable systems that free people to focus on what they do best—solving problems and driving innovation.

Driven by the belief that “a bad system can be held together by good people, and vice versa,” Mike’s work centers on creating simplicity, accountability, and alignment between people, processes, and strategy. His vision is a world where quality and business practices are one and the same.

Day 2 – Morning Keynote
Thursday, September 24, 2026
Loralyn Ledenbach

Tales From the Road – Learnings from a Career of Performing and Undergoing Audits

In order to get the best results from an audit, one that truly discovers actionable performance items, it requires not only technical knowledge, but emotional intelligence (EI). Working with different personality types and being able to “read the room” is an essential skill for anyone performing and/or undergoing an audit.

With a career spanning more than 40 years at a large, multi-national consumer goods company, Lori has had to facilitate a wide variety of audits from both sides. Lori will share her stories from the field that illustrate the importance of a good EI quotient and help attendees learn how to develop their own EI skills.

Loralyn (Lori) Ledenbach is President of Ledenbach Food Safety, LLC, having recently retired as Associate Director for Food Safety at Kraft Heinz North America. During her 43+ years at the company, she has performed multiple supplier audits and provided corporate support during customer and FFSC 22000 audits of Kraft Heinz. She led the Kraft Foods global HACCP team, then Kraft Heinz NA HACCP team. Currently she is a Trainer of Trainers for Preventive Controls for Human Foods in support of the FDA’s Food Safety Modernization Act, and provides training, food safety risk assessment, and HACCP support for companies. She is a Fellow and Honorary Life Member of the International Association for Food Protection.

Day 2 – Midday Keynote
Thursday, September 24, 2026
Michael D. Ford

A Life of Abundance: Yes, You Can!

Many people see their work, their lives and the entire world as viewed from both ends of the following spectrum:

SCARCITY <----------> ABUNDANCE

This is not just a glass-half-full or half-empty approach, but rather, recognition that there is more than enough available. There's an awesome array of possibilities for all of us—so much that there's no reason to ever use language which negates those possibilities. What would happen if, when we expressed our vision of the future, we consistently used the word "AND" followed by the ways we'll make it happen, instead of the word "BUT" connected to the idea's unlikely success?

The facilitator is a devout disciple of the power of positive thinking, engaging life's challenges with a "can do" attitude. Quoting Henry Ford, "whether you think you can or think you can't, you're right." Let's believe we can! Living life with this kind of enthusiasm needs references, resources, and tools, which we can all carry with us 24/7. Come and see how simple (yet profound) they are and the amazing amount of power to choose your own direction that each of us holds within us!

Michael D. Ford, M.S.I.S.E., CFPIM, CSCP, CLTD, CTSC, CMQ/OE, CQA, CRE, CQE, ACPF, CPSM, CSSGB, is an Earth-to-Earth Sustainable Supply Network Expert with TQM Works Consulting. He provides innovative solutions based on forty years of experience in retail, distribution, manufacturing, training, and consulting. His work history includes software implementation, business planning, inventory control, distribution planning, and corporate training. This includes a broad range of experience in manufacturing from engineer-to-order to make-to-stock, as well as distribution, non-profits, service, and Department of Defense.

Ford has presented at over 400 industry events throughout the U.S., Canada, Japan, Nigeria, South Africa, Australia, Saudi Arabia, The Netherlands, and United Arab Emirates. He has provided over 7,500 hours of classroom training, averaging 4.5/5.0 on evaluations. He has taught accredited and continuing education courses for multiple Penn State and State University of NY campuses. He has delivered on-site training at BAE, Lockheed Martin, IBM, Raymond Corp, Universal, Pfizer and many others.

Ford has created online content using learning management systems (LMS) such as Blackboard, Angel, Canvas, and Brightspace. He has facilitated live virtual training (LVT), asynchronous, and hybrid formats. He has authored scripts for online courses, journal articles, newsletters, and blogs.

Ford combines his technical expertise with personal skills, to develop a unique "outside the box" approach to life's challenges. He is a charismatic speaker who specializes in delivering training that is edutaining.

Concurrent Sessions / Technical Program
Wednesday, September 23, 2026

Session: A1
Date/Time: Wednesday, September 23, 2026; 9:40am
Location: Avedon A
Session Speaker: Aditya Desai & Dani Hestermann
Session Title: Holistic Approach to Prepare Auditors for the Future

Session Summary:
Technologies and tools continue to emerge, and auditors must evolve to remain valuable. This presentation explores how a holistic approach can truly empower auditors and prepare them for a rapidly evolving future. We'll dive into several aspects auditors can use to develop, including Continuous Learning, Collaboration, Catalysts for Change, and Cultivation and Care. We'll demonstrate how these can be applied and review practical applications auditors can implement. Auditors will learn approaches to bring back to their organizations for assessing and applying to their audit programs. They can use these techniques to build on their skills and knowledge to improve and sustain their competencies to remain relevant in a rapidly changing environment.

Speaker Bio:
Aditya Desai is a quality leader with 14+ years in life sciences, holding ASQ CQA & CMDA certifications. He is a manager of Quality Assurance at Grifols and chairs the local ASQ section. His expertise includes change control, audits, document management, regulatory compliance, and validation. Aditya values self-awareness, gratitude, and coaching in his leadership.
Dani Hestermann is the Founder and CEO of The Quality Maven where she provides expert ISO9001 and Quality Management Solutions for manufacturers. She has over 20 years of experience leading audit teams and ISO9001 programs and helping manufacturers implement, improve, and optimize their quality management systems.

Session: B1
Date/Time: Wednesday, September 23, 2026; 9:40am
Location: Avedon B
Session Speaker: Jennifer Stepniowski
Session Title: Social Audits: Strengthening Ethical Practices Across Global Supply Chains

Session Summary:
As global supply chains continue to grow in complexity, organizations face pressure to manage social responsibility risks while maintaining operational resilience. Research shows that major supply chain disruptions can reduce revenues by 5–20% and link strong environmental, social, and governance

(ESG) performance to lower cost of capital and stronger long-term financial results. Social audits provide a practical framework for addressing these risks by translating ethical commitments into measurable, actionable processes.

This session examines how widely used frameworks, such as SA8000, ISO 26000, and SMETA, support organizations in assessing labor practices, strengthening transparency, and driving continuous improvement across supplier networks. Participants will gain insight into how these complementary approaches can be integrated into existing quality and supplier management systems to reduce disruptions, mitigate reputational exposure, and build stakeholder confidence.

The session will also highlight the critical role of auditor competency, leadership engagement, and structured follow-up in ensuring meaningful outcomes beyond compliance. Designed for quality and supplier management professionals, this discussion connects established quality principles with emerging ESG expectations, demonstrating how social audits can strengthen both ethical performance and long-term business resilience.

Speaker Bio:

Jennifer Stepniowski is a global quality leader with over two decades of experience developing and executing quality systems and initiatives across diverse industries. As an ASQ Fellow, CMQ/OE, and certified auditor for IATF 16949 and ISO 9001, Jennifer has extensive experience building global audit programs, quality analytics, and continuous improvement cultures. She is a frequent industry speaker and contributor focused on advancing practical, scalable approaches to quality and supply chain resilience. She is currently the Social Responsibility Vice Chair of the Audit Division and Chair of ASQ's Fellow Think Tank for Social Responsibility.

Session: C1
Date/Time: Wednesday, September 23, 2026; 9:40am
Location: Cassatt A
Session Speaker: Kellan Ilse
Session Title: Future Ready: The AI-Enabled Auditor

Session Summary:

AI is rapidly becoming part of the environment auditors operate in. While adoption by auditors remains limited today, these tools are beginning to show clear potential to support how audits are performed.

AI has the ability to make auditors more effective. It can assist with reviewing large volumes of information, identifying patterns and potential risks, organizing evidence, and improving the structure and clarity of audit outputs. While these capabilities are still emerging, they represent a meaningful opportunity to enhance audit performance when applied appropriately.

This session focuses on practical exposure. Through live walkthroughs, attendees will see how emerging AI tools can support core audit activities, including planning, information review, interview capture, and reporting. Examples will reflect how these tools are being used in adjacent functions and early audit-related use cases. Attendees will leave with a clearer understanding of how AI may intersect with their work and how to begin preparing in a practical, measured way.

Speaker Bio:

Kellan has 20+ years of experience in the pharma, med device, and biotech industries, working in both small startups and in Fortune 100. His early career focused on wound closure & cardiovascular

devices using innovative technologies including drug coatings, animal origin materials, bioabsorbable polymers, and combination products. He's earned several ASQ Certifications, become an Exemplar Global Lead Auditor and crisscrossed the globe, conducting hundreds of audits in 15 countries.

Session: D1
Date/Time: Wednesday, September 23, 2026; 9:40am
Location: Cassatt B
Session Speaker: Michael D. Ford
Session Title: Quality Auditing as Investigative Analysis: Break Out Your Inner Sleuth!

Session Summary:
Quality auditing can be considered both an art and a science. The science may be focused on detailed data analysis, examining spreadsheets, dashboard reports, and statistical studies. Left brain methodologies focused on number crunching.
The art reflects the human element, the right brain aspects including Emotional Intelligence. The ability to read people during formal interviews and casual conversations. Inference from language, voice, facial expressions and body language. Seeking clues that aren't as obvious as the results of a hypothesis test. Join facilitator Michael Ford for a demonstration of detective skills that will help you uncover the clues to improved quality audits!

Participants will attain the following learning objectives:

- Most data analysis merely reflect B.S. Statistics (that's not Bachelor of Science!)
- Auditors are detectives inferring conclusions from verbal and nonverbal clues
- Artifacts may provide more information than data
- The ability to read people is a powerful skill set

The facilitator will include case study examples from his personal and professional life experiences, using a humorous storytelling approach to engage the audience in participative discussion.

Speaker Bio:

Michael D. Ford, an Earth-to-Earth Sustainable Supply Network expert, brings more than 40 years of experience across retail, distribution, manufacturing, training, and consulting. With deep expertise in supply chain, operations, software implementation, and business planning, he has worked with organizations ranging from manufacturers and nonprofits to the Department of Defense. A sought-after speaker, Ford has presented at more than 400 industry events worldwide and delivered over 7,500 hours of training. He creates engaging classroom, virtual, and online learning experiences, authors educational content, and is recognized for his practical, innovative, and highly engaging, edutaining approach to solving complex business challenges worldwide.

Session: E1 (FDC Track)
Date/Time: Wednesday, September 23, 2026; 9:40am
Location: Tate
Session Speaker: Jennifer DuCree
Session Title: Food Safety Culture as a Strategic Asset: Driving Excellence Beyond Audits

Session Summary:
In today's food and beverage industry, increasing regulatory demands and consumer expectations have made food safety culture a strategic imperative. Organizations that embed food safety into their core values move beyond reactive compliance toward proactive risk management, stronger decision-making and greater stakeholder trust. Key drivers include leadership commitment, employee engagement, cross-functional collaboration and continuous improvement. This session will highlight practical strategies and real-world examples demonstrating how a strong food safety culture can reduce risk, improve operational performance and strengthen brand reputation, providing attendees with actionable insights to elevate both compliance and business success.

Speaker Bio:
Jennifer is Regional QAFS Director at F&S Fresh Foods, bringing over 25 years of quality and food safety leadership across diverse sectors. She previously served as Senior Manager, Crisis and Risk Management at RQA, Inc., where the content for this presentation was developed. Her experience includes leadership roles with Diageo, Anthony Marano Company, Glanbia Performance Nutrition, and Ingredion. Jennifer holds an MS in Management and Organizational Behavior, a BS in Biology and maintains multiple advanced industry certifications including CFSQA, PCQI Lead Instructor, and FSVP.

Session: A2
Date/Time: Wednesday, September 23, 2026; 10:50am
Location: Avedon A
Session Speaker: Kathy Lyall
Session Title: The Future of Quality Auditing: Insights from a Futurist on the Evolving Role of Auditors

Session Summary:
Years ago at WCQI, a futurist keynote speaker used data and trends to explore possible futures of industry and work—most of which have since come true. That experience was profound for the speaker and inspires this session.
Futurists analyze trends, patterns, and emerging technologies to anticipate what could happen and help organizations prepare. Drawing on 25 years of auditing experience and advances in AI, data analytics, and automation, this session offers an optimistic view of how the auditing profession will evolve. While some fear AI will eliminate roles, automation will reshape—not replace—auditors, increasing impact. Participants will gain practical strategies and real-world examples to apply immediately, along with actionable takeaways. The future of quality auditing is bright, and this session equips auditors to lead that transformation.

Speaker Bio:
Kathy Lyall is Head of Global Supplier Quality Processes and Systems at Philips. She's an ASQ Fellow and was named "Quality Professional of the Year" by Quality Magazine in 2020. She holds a Bachelor's degree in Industrial Engineering and two Master's degrees in Engineering Management and Regulatory Affairs. She maintains five ASQ Certifications. Kathy is a past-chair of ASQ section #1003 Battle Creek/Kalamazoo and the Hromi Medal Committee. She's currently a member of Section #1001 Grand Rapids and serves on the ASQ Board of Directors.

Session: B2
Date/Time: Wednesday, September 23, 2026; 10:50am
Location: Avedon B
Session Speaker: James Shore
Session Title: How Do I Validate This QMS Software?

Session Summary:
Software validation remains one of the most common challenges faced by auditors and Quality professionals. Whether evaluating an Excel tool used for production decisions, calibration software, or an enterprise eQMS system, the question is always the same: "How do I validate *this*?"
This session provides a simple, practical, and risk-based framework for determining the *appropriate* level of validation for any software application. Rather than promoting one-size-fits-all templates, the session focuses on intended use, complexity, and risk to product or patient safety. Attendees will see real examples of how to apply impact assessments, user requirements, test strategies, traceability, and documentation expectations that align with FDA, ISO, Customer, and industry standards.
Speaker Bio:
James Shore is the founder of Quality Lean Solutions, specializing in Quality Systems, auditing, and regulatory compliance for the medical device and life sciences industries. With more than 30 years of hands-on experience in manufacturing, plastics, machining, and quality engineering, he has built and implemented multiple Quality Management Systems and led organizations through successful FDA, ISO 13485, MDSAP, and customer audits. James is a frequent instructor for ASQ divisions and industry groups, known for delivering simple, sustainable, and practical training rooted in real-world experience.

Session: C2
Date/Time: Wednesday, September 23, 2026; 10:50am
Location: Cassatt A
Session Speaker: George Kwiecinski
Session Title: AI-Powered Regulatory Intelligence and Auditing: What the Future Brings

Session Summary:
AI is changing how auditors work, but most organizations are still figuring out where to start. This session cuts through the hype and shows you what is real, what is coming, and how to get ahead of

it.
What you will learn:
1. Where AI Fits in Auditing Today – From automated monitoring to predictive risk scoring, we will cover the tools and trends reshaping how audits are planned and executed.
2. Real-World Data Meets Regulatory Intelligence — How healthcare data ecosystems (claims, clinical, real-world evidence) are converging with FDA compliance data to give auditors a more complete picture of supplier and facility risk.
3. The Research Behind It — George will share findings from newly published research analyzing 10 years of FDA foreign inspection data, including an AI model trained on over 50,000 FDA observations that helps auditors write clearer, less biased findings.
4. What is Next — Dr. Kleczyk will discuss emerging trends in enterprise AI strategy, data governance, and responsible AI adoption, and what auditors need to know to stay future-ready.
You will leave with a clear understanding of how AI is being applied in regulatory auditing right now, and practical steps to bring these tools into your own practice.

Speaker Bio:

George Kwiecinski is CEO of Global Key Solutions Corp, developer of KeyPedia, an AI platform built on 1.5M+ FDA data points, and a published researcher in the Journal of Pharmaceutical Innovation.

Session: D2
Date/Time: Wednesday, September 23, 2026; 10:50am
Location: Cassatt B
Session Speaker: Jd Marhevko
Session Title: Calibrating Humans. Attribute Agreement Analysis (AAA)

Session Summary:

Whether in the design lab, product testing, or in the work environment, quality professionals typically use methods to assess the “goodness” of something by using one of the five senses of sight, smell, touch, taste, or hearing. From doctors looking into ears, to smelling a gas leak, to tasting wine, to thumping on a melon, most of us have used our senses to measure one thing or another.
As auditors, the ultimate question is, how do we know if the teams are getting accurate results? What risks might they bear if their assessments are incorrect? Attend this session to understand this specialty as to how humans can be calibrated through Attribute Agreement Analysis (AAA) so that teams can make an effective decision. Attendees will gain a clear understanding of how to design and develop an AAA assessment and then evaluate the data to ensure that they can get an effective result.

Speaker Bio:

Jd is a VP of Quality for the Electronics and ADAS Division of the ZF Group, with 40 years of progressive executive leadership in multiple industries including automotive, military, aerospace, food, etc. She is a USA Women in Manufacturing Hall of Famer and holds several honors including a Shainin Medal and is an ASQ Fellow. She transformed several organizations from bankruptcy to best in class performance: In one business, 4 sites were honored by the Association of Manufacturing Excellence as being Best in Class in industry. Jd has co-authored several books and articles on Lean and Quality. She is an adjunct professor for UM.

Session: E2 (FDC Track)
Date/Time: Wednesday, September 23, 2026; 10:50am
Location: Tate
Session Speaker: Nish Abeysiriwardena
Session Title: Medical Device Product Development: What an Auditor Should Look for in Every Stage

Session Summary:
Auditors are often the only barrier between “good enough” and “safe enough” in medical devices—but many never see the real pressures and shortcuts inside product development.
In this interactive, hands-on session, you’ll walk through a realistic medical device lifecycle—hardware, embedded software, and software—from concept and design through prototyping, verification, validation, and transfer to manufacturing. You’ll review authentic-style artifacts, timelines, and decision points instead of theory and checklists.
You'll sharpen your ability to spot the silent signals of risk that traditional audits miss, including:

- Non-negotiable timelines that quietly erode design rigor
- Weak onboarding that leaves engineers blind to key quality and regulatory expectations
- Gaps in traceability among user needs, requirements, and validation
- Superficial reviews masked by signatures and time stamps
- Incomplete tollgate reviews and unapproved deliverables pushed forward

You'll leave with concrete questions, red flags, and patterns to look for so your future audits reveal hidden weaknesses before they become findings, recalls, or patient harm.

Speaker Bio:
Nish Abeysiriwardena, BSEE, MSEE, MBA, PMP, CSSGB, SM IEEE is a MedTech R&D and Quality leader with experience spanning General Electric, Intel, Curtiss-Wright Defense Solutions and GN Group. He has led the development of MedTech, Defense, Industrial Automation & Embedded computing solutions for 25+ years.

Session: A3
Date/Time: Wednesday, September 23, 2026; 1:30pm
Location: Avedon A
Session Speaker: Manish Dnyaneshwar
Session Title: Future-Ready Audits: Risk-Based Validation of AI, Software, and Automation in GxP Environments

Session Summary:
This session shows how auditors can assess AI-enabled systems, computerized systems, and automation using a practical, risk-based approach grounded in GxP expectations. Drawing from real pharmaceutical manufacturing and validation experience, the presentation will translate evolving requirements into audit-ready questions, evidence expectations, and common gap areas. Attendees will learn how to review data integrity, change control, audit trails, vendor oversight, model governance, and lifecycle validation for modern digital systems. The session will provide a usable audit framework, examples of what works, and actionable takeaways for auditing future-ready quality systems.

Speaker Bio:
Manish Baviskar is a validation and quality professional with experience in pharmaceutical manufacturing, computerized systems, equipment qualification, and AI-enabled quality applications. He leads validation, audit readiness, and risk-based compliance activities for regulated systems in cGMP environments. His background includes software, automation, utilities, and equipment validation, along with invited lectures and publications on AI and validation in the pharmaceutical industry.

Session: B3
Date/Time: Wednesday, September 23, 2026; 1:30pm
Location: Avedon B
Session Speaker: Rai Chowdhary
Session Title: Are You Future Ready – *Financially?*: Applying the Quality Auditor's Mindset

Session Summary:
As auditors, we are trained to identify risk, evaluate evidence, challenge assumptions, and improve performance. Every day, we apply these skills to protect the organizations we serve. Isn't it strange that many of us never apply the same disciplined thinking to one of the most important projects we will ever manage—our own financial future?
This interactive session demonstrates how the principles of auditing can be applied beyond the workplace to improve personal financial outcomes. Rather than offering investment advice, I will present a practical framework for evaluating financial goals, identifying risks, assessing evidence, monitoring performance, and making informed decisions using the same critical thinking skills we already possess. Through an engaging case study and practical real-world examples, participants will discover how audit principles can be applied to retirement planning, investment decisions, and long-term wealth creation.
Participants will leave with a simple framework they can immediately apply to their own financial lives. More importantly, they will discover that the skills we use every day to transform organizations can also transform tomorrow by securing our own financial future.
Speaker Bio:
Rai is an award-winning speaker, lifelong learner, and quality professional with more than 40 years of experience spanning automotive, aerospace, life sciences, food products, and service industries. With academic backgrounds in Mechanical and Production Engineering and Materials Science, he brings deep technical and operational expertise. Rai holds multiple ASQ certifications, including CSQP, CQE, CMQ/OE, and Six Sigma Black Belt, and he serves as a Lead Auditor for ISO 9001, ISO 13485, and ISO 27001. Since 1995, he has participated in hundreds of audits and contributes to international standards development, including ISO TC 176 and ISO/TS 10020:2022.

Session: C3
Date/Time: Wednesday, September 23, 2026; 1:30pm
Location: Cassatt A
Session Speaker: Amanda Lyon
Session Title: Auditing Smarter with Copilot: Applying Generative AI Without Losing Trust

Session Summary:
Audit preparation is essential to audit quality, but it is often manual, time-consuming, and heavily reliant on individual auditor experience. As organizations adopt Copilot and Generative AI capabilities, many struggle to move beyond isolated prompts to solutions that are trusted, governed, and repeatable. This session shares a real-world case study of how Generative AI was implemented within an internal Audit Academy to support—not replace—professional audit judgment. Attendees will learn how AI was applied to high-effort preparation activities such as summarizing procedures, building SIPOCs, identifying risks, and generating ISO-aligned audit questions, while operating within a controlled and governed environment. The session focuses on lessons learned transitioning from ad-hoc AI usage to a structured approach using standardized templates, approved knowledge sources, and purpose-built Copilot agents. Key topics include improving consistency across auditors, capturing experienced auditor knowledge, reducing preparation time, and avoiding common pitfalls such as hallucinations, over-automation, and erosion of accountability. Attendees will leave with practical guidance on what to automate, what must remain human-led, and how to design AI-enabled solutions auditors and stakeholders can trust.

Speaker Bio:
Amanda Lyon is a Corporate Quality professional with Applied Materials, where she leads process audits and supports auditor development through the Audit Academy. Her work focuses on improving audit effectiveness, consistency, and efficiency through the responsible application of Generative AI to audit preparation activities, including procedure analysis, SIPOC development, and ISO aligned audit question development. She has hands on experience designing governed AI solutions that enhance, rather than replace, professional judgment.

Session: D3
Date/Time: Wednesday, September 23, 2026; 1:30pm
Location: Cassatt B
Session Speaker: Paul Russell
Session Title: Open-Ended Requirements: More Keep Coming, How Do I Audit Them?

Session Summary:
This century started with many prescriptive requirements in the ISO 9001 standard. Back then, it was still easy to place checkmarks on one's checklists if the requirement was being satisfied. Fast forward twenty-five years, there have been three revisions of the ISO 9001 standard. Each revision shaved away some rigidness. As time goes on, more open-ended requirements are created to allow organizations to figure out for themselves how they satisfy requirements. While great news for

organizations, the new overall feeling of uncertainty tends to overshadow an auditor's old techniques. Do not worry, these are the days for auditors' techniques to really shine! Auditing open ended requirements makes one more of an auditor and less of an inspector. This session presents a brief history of quality requirements, compares prescriptive versus open-ended requirements, and demonstrates an effective process to utilize when one comes face-to-face with an open-ended requirement.

Speaker Bio:

Paul Russell (CQA) performed internal audits in the health industry to maintain Food and Drug Administration (FDA) and European Union (EU) compliance for over 45 blood bank locations, five blood manufacturing facilities, and over 31 blood mobiles. Paul performed pharmacy audits in the Midwest/Northeast/Mid-Atlantic/South regions of the United States to maintain Drug Enforcement Agency (DEA) and FDA compliance and pharmacy-specific adherence to the drug laws of 21 states and one District. He has taught face-to-face classes in Lead Auditor, Internal Auditor, as well as a company-wide current Good Manufacturing Practices (GMP) corrective action.

Session: E3 (FDC Track)
Date/Time: Wednesday, September 23, 2026; 1:30pm
Location: Tate
Session Speaker: Cathleen Howick
Session Title: Auditing for FSMA Intentional Adulteration Rule

Session Summary:

The FSMA Intentional Adulteration (IA) Rule was finalized on May 27, 2016, with full compliance for all covered facilities being required by July 26, 2019. However, with the onset of the COVID pandemic, the Agency's initial enforcement was limited to quick checks without issuing citations. Full, comprehensive enforcement began in Sept 2024 and, as FDA transitions from education to enforcement, audit expectations are rapidly evolving. To remain inspection ready, protect brand equity, and reduce operational and security risk, the industry must modernize and future proof their IA audit framework.

This presentation outlines why the current approach—focused heavily on documentation reviews and static mitigation strategies—is no longer sufficient. It recommends a set of practical, scalable enhancements that auditors should look for in a robust, comprehensive food defense program that would ensure alignment with FDA's enforcement trajectory.

Speaker Bio:

Cathleen Howick has over 30 years of experience in the dietary supplement industry. Her work has included almost all aspects of Quality Control and Quality Assurance, including microbiologist, quality engineer, site compliance lead, and corporate auditor. She has a BS in Biology from Loyola Marymount University and a Master's in Regulatory Science with an emphasis in Food Safety from Arizona State University. Cathleen is a Certified Quality Auditor and Certified HACCP Auditor. She is also an FSPCA lead instructor for Preventive Controls for Human Food, Foreign Supplier Verification Programs, and Intentional Adulteration.

Session: A4
Date/Time: Wednesday, September 23, 2026; 2:40pm
Location: Avedon A
Session Speaker: Shwetha Jayachandran
Session Title: Audit Smarter: Practical AI Techniques for Everyday Auditing

Session Summary:
Tagline: Simple, ready-to-use workflows and digital tools for auditors
Building on insights from ASQ's AI in Auditing conference, this session goes beyond theory. Drawing on 3 years of experience developing tool-centric audit workflows, you will learn how to integrate AI into your everyday audits to make decisions faster, more consistent, and more reliable. Through practical demonstrations and applied techniques, you'll discover how to frame sharper questions, detect patterns more efficiently, and validate information effectively.
You will also explore practical methods to track risks, organize audit evidence, and maintain consistency across audits, enhancing your overall audit workflow and digital competency. At the end of the session, you will get a practical AI-Auditing checklist and audit prep condensation prompts, designed to help you generate the right questions and answers from the preparation stage through reporting and CAPA management.
By the close of the session, you will leave with hands-on strategies, templates, and actionable steps that make AI and analytics approachable and practical for daily auditing work. This session equips auditors to confidently bridge traditional audit practices with modern, data-driven techniques, preparing them for the next generation of audit challenges.
Speaker Bio:
Shwetha Jayachandran is a Quality Auditor in Knoxville, Tennessee, with 3 years of experience in internal and external audits across OTC, dietary supplements, and food industries. She works at Melaleuca: Wellness Company, focusing on audit readiness, validation, and quality systems while partnering with cross-functional teams to enhance compliance. An ASQ member since 2023, She holds a Master's in Chemical Engineering from University of California, Davis, and is trained in Foreign Supplier Verification and FSPCA. She has completed ASQ audit courses, and AI-focused conferences to help auditors apply practical, proactive quality practices.

Session: B4
Date/Time: Wednesday, September 23, 2026; 2:40pm
Location: Avedon B
Session Speaker: Heather Wade
Session Title: Demystifying Calibration Accreditation Scopes

Session Summary:
Calibration service customers often understand that they need records of their calibrations, a "sticker and a cert." Customers may even know that they need to get an accredited calibration because that is how they were instructed. However, they may have never learned what that means and what is

necessary to get the accredited calibration they actually need. For the well-intentioned and untrained person, calibration service decisions are often made based on price, timeliness, location, and ease, but missing the most important detail - are they getting the accredited calibration data *actually* needed? They may search for what labs are “ISO/IEC 17025-accredited” but not evaluate any further if the calibration provider *is accredited for* their needed parameters, ranges, and accuracies. This presentation is to provide everyday-language and guidance to learn how to search, read, interpret, and compare accreditation scopes so one may make the best use of their money, resources, and time and make sure they receive the calibration they need.

Learning Objectives:

1) the basics of what is ISO/IEC 17025-accredited calibration and its advantages,
2) how to search and review accredited calibration scopes and apply across multiple accreditation bodies,
3) the basics of reading and interpreting accredited calibration certificates

Speaker Bio:

Heather A. Wade, ASQ-CCT, ASQ-CQA is a recognized metrology subject matter expert & internationally sought presenter where she excels at presenting useful and easy-to-implement practices. She is Editor of the ASQ Metrology Handbook, 3rd Edition, Past Chair of ASQ Measurement Quality Division, and Quality Magazine's 2026 Quality Professional of the Year. She is an A2LA ISO/IEC 17025 Lead & Technical accreditation assessor for calibration labs and chemical, biological, and mechanical test labs. She brings all her 30+ years of professional experience together to provide “Pain Relief for Measurement Headaches” to clients and audiences everywhere.

Session: C4
Date/Time: Wednesday, September 23, 2026; 2:40pm
Location: Cassatt A
Session Speaker: Angelo Scangas
Session Title: Auditing Risk Assessment Quality – Not Just the Scoring!

Session Summary:

Internal auditors frequently review risk assessments, yet many audits stop at confirming that risks were identified and scored according to an approved methodology. This approach provides limited assurance over whether risk assessments truly reflect the organization's risk exposure.

This presentation examines how auditors can move beyond numeric scoring to assess the quality of risk assessments themselves. It highlights recurring issues such as generic risk definitions, inconsistent application of scoring criteria, overreliance on subjective judgment, and weak consideration of control effectiveness. The session introduces practical audit techniques for challenging assumptions, validating scoring logic, and assessing whether risk assessment outputs meaningfully inform management action.

Participants will leave with a structured framework for auditing risk assessment quality—enabling audit teams to provide more insightful conclusions, support better risk prioritization, and elevate their role as trusted advisors in risk governance.

Speaker Bio:
Angelo is with Quality Support Group, a TUV Rheinland Company, an International Consulting and Training organization. Angelo has a B.S. in Chemical Engineering, M.S. in Manufacturing Engineering and an MBA. Angelo is a senior member of the American Society for Quality and member of the ASQ Audit Division. Angelo has more than 30 years of experience working in product development, manufacturing engineering, quality engineering, quality assurance and process improvement.

Session: D4
Date/Time: Wednesday, September 23, 2026; 2:40pm
Location: Cassatt B
Session Speaker: Lance B. Coleman
Session Title: ISO 9001:2026 – What's Next?

Session Summary:
ISO 9001:2026 will be released in Fall. Every clause of the standard and even the Annex will be impacted. Changes to the new revision of ISO 9001 are many and diverse. In some cases, details are added for requirements such as "*which* requirements will be addressed through the quality management system" or "the addition of three bullets to the planning of changes subclause". The importance of culture and ethics is emphasized where not previously mentioned directly. Risks and opportunities are split out into their own sub-clauses to better explore each concept. As always, language has been cleaned up to provide clarity and there are changes in document structure to both align with the ISO harmonized structure and to provide a more logical flow.
And of course, there is "the next big thing" to be mindful of per the standard - understanding the effect of climate change on business operations. The requirement that was actually introduced in the Climate Change Amendment to ISO 9001:2015 published in February of 2024.
How will your organization prepare to successfully meet these and other new requirements of ISO 9001:2026? Attend this session to successfully start you on your journey.
Speaker Bio:
Lance B. Coleman is an ASQ Fellow as well as a Certified Quality Engineer, Quality Auditor, Supplier Quality Professional, and Six Sigma Green Belt. He is also an Exemplar Global certified ISO 9001:2015 Lead QMS Auditor. Lance is the author of "Managing Organizational Risk Using the Supplier Audit Program (Quality Press 2018)", "Advanced Quality Auditing: An Auditor's Review of Risk Management, Lean Improvement and Data Analysis (Quality Press 2015)", and co-author of the QMS Auditor Memory Jogger. He is a member of TAG 176 which is charged with revising ISO 9001, and he is the editor of the 5th and 6th editions of the ASQ CQA Handbook.

Session: E4 (FDC Track)
Date/Time: Wednesday, September 23, 2026; 2:40pm
Location: Tate
Session Speaker: Balazs Bozsik
Session Title: How To Communicate with Your Conformity Assessment Body

Session Summary:
This session provides practical guidance for effectively communicating with your Conformity Assessment Body (CAB) throughout the certification lifecycle. It explains the nature of the CAB–client relationship, emphasizing that a CAB is a third party and a regulated supplier whose decisions rely on clear, complete regulatory and quality information. Participants learn what to expect before the CAP process, including the value of early engagement and permissible levels of technical dialogue. The session outlines contractual essentials, professional communication during audits and technical documentation assessments, and structured handling of nonconformities. Finally, it highlights best practices for ongoing communication between projects, timely notification of significant changes, and managing personnel or performance issues constructively.

Speaker Bio:
Balazs Bozsik is the Technical Director for the Medical-, Pharma- and Cosmetic audit teams of SGS North America. As a mechanical engineer, he gained industrial experience in manufacturing technology and design engineering in the medical (X-ray diagnostic devices), automotive, and consumer lighting industries. Prior to joining SGS 5 years ago, he worked for another TIC organization for over 14 years, including his roles as global MDSAP Program Manager, certification officer, product specialist focusing on active medical devices and medical software, as well as medical auditor for all major certification schemes.

Session: A5
Date/Time: Wednesday, September 23, 2026; 3:50pm
Location: Avedon A
Session Speaker: Laura Halleck
Session Title: Auditing the “Gray Areas”: How to Evaluate Effectiveness (Not Just Conformance)

Session Summary:
Audits often confirm that processes are followed but fail to determine whether those processes actually work. This session explores how auditors can move beyond checklist-based compliance and confidently evaluate effectiveness in the “gray areas” of management systems, including corrective action, management review, and risk management. Attendees will learn a practical framework for assessing whether processes achieve intended results, reduce risk, and drive performance improvement over time.
Through real-world case studies and interactive exercises, participants will identify common indicators of ineffective systems—such as repeat issues, superficial root cause analysis, and “green” metrics that mask deeper problems. The session provides actionable tools, high-impact audit questions, and

techniques for transforming audit findings into meaningful business insights. Attendees will leave equipped to deliver audits that not only verify conformance but also influence organizational performance and decision-making.

Speaker Bio:

Laura is a Senior Consultant and Certified Quality Auditor with over 25 years of experience in quality management and process improvement across the automotive and aerospace/defense industries. She plays an active role in shaping the future of quality as a US expert on the international committee revising ISO 9002 and as a member of the US Technical Advisory Group to ISO/TC176.

Laura also contributed to the revision of the recently published ISO guidance document *Integrated Management Systems - A Practical Guide*. Her experience includes implementing and auditing management systems aligned with ISO 9001, AS9100, IATF 16949, and ISO 13485.

Session: B5
Date/Time: Wednesday, September 23, 2026; 3:50pm
Location: Avedon B
Session Speaker: Christy Furlan
Session Title: Identifying and Avoiding Lean's 10(?) Wastes in Audits

Session Summary:

Waste can creep into auditing processes in unexpected ways, hampering auditors, auditees, and the results of the audit as a whole. In this session, we will go over Dr. Taiichi Ohno's original 7 Wastes of Lean Manufacturing (Transportation, Inventory, Motion, Waiting, Overproduction, Overprocessing, and Defects) and an additional 3 wastes that have been suggested since his innovation. We will discuss how these wastes may show up in auditing processes and what we can do to combat them before, during, and after audits.

Speaker Bio:

Christy Furlan is an ASQ Certified Quality Auditor, Certified Supplier Quality Professional, and Certified Quality Process Analyst with over 14 years of experience as a quality assurance professional and over 12 years of experience as an auditor. She has been working at Asahi Kasei Bioprocess America, Inc. (AKBA) since 2011 and is currently the Assistant Manager of the Quality Assurance department there. Christy is also a Lead Auditor for AKBA, focusing on supplier auditing, internal auditing, and training new auditors. Outside of work, Christy loves role-playing games like Dungeons & Dragons, board games, knitting, and travel.

Session: C5
Date/Time: Wednesday, September 23, 2026; 3:50pm
Location: Cassatt A
Session Speaker: Attrayee Chakraborty
Session Title: Empowering Auditors with Agentic AI: Build, Validate, and Audit with Confidence

Session Summary:
As organizations race to adopt agentic AI for operational efficiency, auditing professionals are uniquely positioned to lead this transformation responsibly. This hands-on session explores how audit teams can leverage Copilot Studio and Copilot 365 Lite to build custom AI agents and multi-agent interactions, using natural language — no coding required — and connect them to relevant data sources to automate and streamline quality workflows.
Beyond building agents, this session addresses a critical gap: how to validate and audit agents using established Computer System Assurance/Validation (CSA/CSV) practices. Attendees will walk away with a practical framework for ensuring agents perform as intended, meet regulatory and organizational standards, and are validated appropriately to ensure they meet compliance requirements and establish user trust.
Session Learnings:

1. How to build AI agents in-house using Copilot Studio and Copilot 365 Lite with natural language prompts and data source integrations, without relying on AI vendors for Quality Management Systems (QMS)
2. How to define intended use, risk level, and risk identification. Validate use cases against intended behavior, including test protocols and acceptance criteria using established CSA/CSV processes
3. How to use agents to audit internal documents against established standards by linking reference documents and compliance frameworks that can facilitate auditors and ensure proactive approaches.

Speaker Bio:
Attrayee “Atty” Chakraborty is an award-winning Quality Systems Engineer in digital healthcare and a recognized leader in AI, quality, and regulatory affairs. She has spoken at more than 30 national and international conferences on AI in healthcare regulations and practical use of AI in organizations. Atty serves as President and Board member of the Boston Congress of Public Health and Vice Chair for Newsletters and Publications for the ASQ Medical Device Division. Her honors include the 2026 AAMI Young Professional Award, 2025 RAPS Rising Star Award, and 2025 Quality Rookie Award.

Session: D5
Date/Time: Wednesday, September 23, 2026; 3:50pm
Location: Cassatt B
Session Speaker: Dan Cannon
Session Title: Benchmarking Internal Audit Duration: Are We Auditing Enough?

Session Summary:
Are organizations dedicating enough time to internal audits to make them effective? This session examines the risks and underlying causes of under-resourced internal audit programs, using survey data from internal auditors, third-party auditors, organizational leaders, quality managers, and certification bodies.
Designed for auditing professionals, the session compares auditor perceptions with real-world data, including a study of internal audit duration versus certification body recertification audit time. The findings highlight a consistent gap—organizations often underinvest in internal audits while relying on certification body audits, which are intended only as sampling activities.
Attendees will gain practical insight into how insufficient audit time impacts audit effectiveness, audit outcomes, and auditor experience, along with actionable strategies to better scope, plan, and advocate for internal audit programs that drive meaningful improvement—not just compliance.
Speaker Bio:
Dan Cannon is a quality and regulatory consultant with over 25 years of QMS experience. The majority of his career has been spent in industry quality leadership roles and CB management prior to transitioning into consulting. He has led and supported internal audit programs from both the practitioner and external auditor perspective. His experience spans ISO 9001, AS9100, ISO 13485, Regulatory Affairs, ISO 27001, and ISO/IEC 17021-1/17025/17065. Dan currently focuses on helping organizations strengthen effectiveness through Fractional Quality Management with an emphasis on positioning internal audits as a driver of performance.

Session: E5 (FDC Track)
Date/Time: Wednesday, September 23, 2026; 3:50pm
Location: Tate
Session Speaker: Steven Ault
Session Title: Cosmetic Manufacturer Auditing: Update on MoCRA Compliance and Auditing Trends

Session Summary:
As of March 2026, the Modernization of Cosmetics Regulation Act (MoCRA) has transitioned from an initial alignment phase into a period of active enforcement and oversight. The FDA is now conducting systematic inspections and audits, shifting away from "soft enforcement" toward formal actions such as warning letters and mandatory recalls.
Significant compliance gaps remain in Registration & Listing, Safety Substantiation, and Adverse Event Reporting. Emerging Auditing & Enforcement Trends by the FDA include focus on Facility &

R&D Inspections, Remote Regulatory Assessments (RRAs), Fragrance Allergen Disclosure, Digital & Social Media Surveillance, and Supply Chain Scrutiny. Top Compliance Challenges include State-Level Conflicts, Small Business Costs and Rulemaking Delays. Auditors now must measure facilities against mandatory GMP standards that the FDA is currently finalizing, which are expected to align with international standards like ISO 22716.

Speaker Bio:

Steven Ault is currently enjoying semi-retirement as Principal of SJA Quality Consulting, LLC. As a previous full-time and current contract auditor with NSF, he performed hundreds of cGMP and Product Certification audits for Dietary Supplement and Cosmetic manufacturers. Steve has been in the dietary supplement/CPG industry for over 30 years and has extensive experience in product development, food safety, quality assurance, and regulatory affairs across nutritional, personal care, and OTC products. He holds BS, MS, and PhD degrees in Biology, and is an ASQ Certified Quality Auditor, HACCP certified, and PCQI.

Session: F1
Date/Time: Thursday, September 24, 2026; 9:40am
Location: Avedon A
Session Speaker: Melody Scott
Session Title: Third-Party Verification as a Strategic Asset for GMP Quality Systems

Session Summary:

Internal and regulatory audits play a critical role in GMP oversight—but they often miss systemic risks due to bias, limited scope, or infrequent inspections. This session explores how third-party verification can bridge these gaps and serve as a strategic asset for strengthening quality systems. Through real-world case studies, attendees will examine recurring failures in data integrity, material control, laboratory practices, and supplier oversight that were uncovered only through independent audits. The session highlights how high-quality, risk-based third-party audits—paired with product verification—can drive scientific decision-making, improve CAPA effectiveness, and transform quality culture. Participants will gain actionable insights to enhance audit programs, mitigate risk, and build more resilient, future-ready GMP systems.

Speaker Bio:

Dr. Melody Scott is a Senior GMP Auditor at the U.S. Pharmacopeia, where she leads global verification audits and manages audit teams across pharmaceutical, dietary supplement, and excipient industries. A Certified Quality Auditor, she specializes in GMP compliance, data integrity, and risk-based quality systems. Dr. Scott has supported international regulatory initiatives through USP's PQM+ program and previously led Quality Control operations at Becton Dickinson Diagnostics Systems. She holds a Ph.D. in Medical Biochemistry and a B.S. in Biochemistry and Molecular Biology.

Session: G1
Date/Time: Thursday, September 24, 2026; 9:40am
Location: Avedon B
Session Speaker: Kristin Schuler
Session Title: From Reactive Audits to Preventive Control: Risk-Tiered Contract Governance Model

Session Summary:
Auditors frequently encounter findings that trace back to poorly structured supplier agreements. Yet contracts are rarely designed with audit strategy in mind. This session presents a case study of how a regulated healthcare organization reframed contracts from legal formalities into structured risk-control mechanisms. Faced with hundreds of supplier agreements and limited audit resources, the quality function developed a classification model aligning supplier risk, material criticality, and regulatory exposure to defined contract requirements. The framework enabled targeted reviews, standardized audit clauses, and stronger cross-functional alignment with Legal and Supply Chain.
Attendees will learn how to:

- Build a contract risk decision tree tied to audit strategy
- Reduce review burden through a short-form vs. full-review decision matrix
- Use contract data to inform audit planning

Speaker Bio:
Kristin Shuler is a Quality Systems leader with over 20 years of experience in regulated pharmaceutical, API, and healthcare environments. She has led global eQMS implementations, validation programs, supplier governance frameworks, and audit strategy aligned to FDA, ISO, and GxP requirements. She is a former validation engineer for national data integrity and computer system validation and now focuses on designing risk-tiered governance models that strengthen compliance while reducing unnecessary audit burden. She holds a B.S. in Chemical Engineering from Purdue University and ASQ Certifications for CSQP and CMQ/OE.

Session: H1
Date/Time: Thursday, September 24, 2026; 9:40am
Location: Cassatt A
Session Speaker: BJ Johnson & Urmi Vidyarthi
Session Title: Navigating the New Regulatory Landscape: EU MDR 2.0 & US QMSR

Session Summary:
Significant regulatory changes are reshaping the medical device landscape in both the United States and the European Union. This session provides a concise overview of recent updates from the U.S. FDA under the Quality Management System Regulation (QMSR) and the evolving expectations of the EU Medical Device Regulation (MDR).

Participants will gain insight into how these changes impact medical device manufacturers, including quality system alignment, documentation requirements, risk management expectations, and regulatory inspection readiness.

Speaker Bio:

BJ has more than 25 years of experience in the medical device industry, spanning microbiology, quality systems, manufacturing, and regulatory oversight. Her career includes service as an FDA investigator and leadership roles across multiple device manufacturers. An ASQ Certified Quality Auditor since 2001, she currently serves as Vice President of Global Transformation at Medline.

Urmi is a biomedical engineer with over 20 years of experience in medical device quality, validation, and regulatory compliance. She has led quality system improvements across complex device environments and provides practical expertise in sustainable compliance strategies. Currently a Project Manager with DEKRA, she also serves as a Lead MDSAP and Notified Body auditor.

Session: I1
Date/Time: Thursday, September 24, 2026; 9:40am
Location: Cassatt B
Session Speaker: Denis Devos
Session Title: A First Look at ISO 9001:2026

Session Summary:

After 11 years, the new sixth edition of ISO 9001 will be published in mid-2026. This presentation will explain the evolutionary changes to the standard along with commentary and Denis' guidance on approaches for implementation. Highlights include new requirements for a Culture of Quality, Ethical Behavior, Decoupling of Risk-Based-Thinking and Opportunity-Based-Thinking, and ISO 9001's first ever Annex A which will give guidance on understanding the requirements. Join us on September 24 and bring your questions!

Speaker Bio:

Denis Devos is a professional engineer with a long career providing QMS training and advisory services. He is a Fellow of the ASQ and is a recognized expert in the application of the ISO 9001, IATF 16949 and ISO 14001 Standards. Denis was the developer of the Risk is the Compass risk-based audit model in 2001. He works with clients in a variety of industries, providing internal audit services and training for QA practitioners and internal auditors. Denis has been a regular contributor to the Audit Division conference for over 20 years in a row. He is the recipient of the 2024 ASQ Audit Division's Paul Gauthier Award.

Session: J1 (FDC Track)
Date/Time: Thursday, September 24, 2026; 9:40am
Location: Tate
Session Speaker: Shelly Blackwell
Session Title: Who Owns Quality? Auditing Considerations for OWN Label Distributors Dietary Supplements

Session Summary:
Own Label Distributors (OLD) in the dietary supplement and OTC industries often question their responsibilities for complying with current Good Manufacturing Practices (cGMP's) required by FDA regulations. They sometimes incorrectly think that GMP responsibilities fall on the Contract Manufacturing Organization (CMO) alone. However, recent FDA enforcement has emphasized that brand owners, or "Own Label Distributors" (OLD's) are ultimately responsible for the quality of their products, even when the products are manufactured by a CMO. This session will provide an overview of the cGMP requirements of an Own Label Distributor and specific considerations when auditing such an organization.

Speaker Bio:
Shelly Blackwell has over 25 years of quality and compliance experience in regulated environments. After starting her career as a Microbiologist, she gained expert knowledge of domestic and international regulations while holding senior leadership positions in the dietary supplement, pharmaceutical, and medical device industries. She has led FDA and other regulatory inspections throughout her career and is also a lead auditor herself, auditing manufacturers all over the world. Shelly holds certifications from the American Society for Quality and the Institute of Food Technology and has a Biology degree from James Madison University.

Session: F2
Date/Time: Thursday, September 24, 2026; 10:50am
Location: Avedon A
Session Speaker: Denholm Kendall
Session Title: Data Quality – Auditing the Digital Factory

Session Summary:
When performing quality audits of processes for physical products, there is a maxim: "Never lose sight of the product". What if the product is Data? How do you perform an audit of Data?
In today's data-driven business environment, the quality of data plays a critical role in the success of organizations. Data is the lifeblood that powers various aspects of business operations. However, the abundance of data also presents challenges, as poor data quality can lead to inaccurate insights, wasted resources, and financial losses. Having high-quality data is crucial as it affects decision-making, operational efficiency, and overall business success. Regular assessment and management of Data Quality are necessary to ensure its reliability and usability. Auditing data quality must happen before you trust any AI output. To leverage the full potential of data, it is essential to recognize that quality of

decisions is strongly dependent on the quality of data. Merely acknowledging this fact is not enough; it is crucial to measure the quality of data and take action to improve it, thereby ensuring tangible results.

Topics covered:

- What is Data Quality?
- Data Quality Dimensions
- Data Quality Management, PDSA
- Correcting Data Quality Issues
- Cost of Poor Quality Data
- Culture, Data Literacy

Speaker Bio:

Denholm Kendall is an Applied Science Engineering Technologist, a Certified Lean Six Sigma Black Belt, an ASQ CQA, CQE, CMQ/OE, and is a senior member of ASQ. He is an ISO 9001 Quality Management Systems expert who builds Quality Management Systems from the ground up and leads companies to successful certification to ISO 9001. He is an expert in evaluating, measuring, and monitoring supplier performance and suppliers' business processes and practices to reduce cost, mitigate risk and drive continuous improvement. He has co-authored the article “Part Manufacturer Assessment Process” in *Quality and Reliability Engineering International* magazine.

Session: G2
Date/Time: Thursday, September 24, 2026; 10:50am
Location: Avedon B
Session Speaker: Derek Purdy
Session Title: Playing Defense: Strategies for Avoiding, Containing, and Resisting Audit Findings

Session Summary:

How capable an auditor are you, anyway? As a contract manufacturer, the presenter's company experiences audits almost monthly, carried out by individuals whose acumen in this regard…may vary. As a result, we have had to develop strategies for dealing with overzealous auditors, argumentative auditors, lazy auditors, auditors with a “god complex,” audit findings written up as nonconformances when they should—at best—be opportunities for improvement, audit findings completely without merit, and the like.

Come join us to find out what kinds of fences and firewalls we've had to erect. Hear from one who sits on the other side of the audit table. Seeing how we've dealt with the not-so-great (while keeping things polite and professional) might just make you a better auditor. In short, if you want to be the best, then learn from the rest!

Speaker Bio:
Derek Purdy is VP of Quality at Stellartech Research Corporation. He has over 30 years of professional experience focused primarily on medical devices. His expertise includes quality management, operations, and compliance. Prior to Stellartech, Derek served in various roles at other medical device companies; he also worked in glass manufacturing and served for eight years in the U.S. Navy as a Nuclear Surface Warfare Officer.
Derek holds CQE and CQIA certifications with ASQ. He served as Membership Chair and Vice Chair of ASQ Section 0613. His letters include a BS in Mathematics, a Masters in Engineering Management, and an MBA.

Session: H2
Date/Time: Thursday, September 24, 2026; 10:50am
Location: Cassatt A
Session Speaker: Srividya Narayanan & Lavanya Ramnath
Session Title: Step-by-Step Audit of Digital Twin-Controlled Robotic Assembly Systems

Session Summary:
Medical device manufacturers are deploying digital twin technology to virtually commission robotic assembly lines before physical installation, reducing commissioning time by 30-50%. But how do auditors verify these virtual systems? What documentation proves a digitally validated process meets FDA 21 CFR Part 820 requirements?
This live demonstration session walks auditors step-by-step through the audit process for digital twin-controlled robotic systems. Using actual digital twin simulation software (screen share), attendees will learn:

- What to audit in virtual commissioning documentation (design specs, test protocols, validation reports)
- How to verify software-hardware integration before physical production begins
- Which FDA requirements apply to digitally validated automated systems (IQ/OQ/PQ for virtual environments)
- Red flags to watch for (incomplete testing, missing risk assessments, inadequate change control)

The session includes a live walkthrough of a medical device manufacturer's digital twin commissioning project, showing exactly where auditors should probe. Attendees receive a downloadable Digital Twin Audit Checklist with 25+ verification steps covering CAD model validation, simulation testing, control logic verification, and documentation requirements.
No digital twin expertise required—come ready to learn by watching!
Speaker Bio:
Srividya Narayanan is a Regulatory Affairs Specialist at Asahi Intecc USA, supporting FDA submissions for cardiovascular medical devices. She holds a Master's in Regulatory Affairs from Northeastern University and specializes in AI/ML-enabled devices and regulatory compliance. A frequent conference presenter, she is known for translating complex technical and regulatory concepts into practical audit frameworks.

Lavanya Ramnath is a regulatory affairs professional with more than eight years of experience guiding medical devices, SaMD, and digital health technologies through FDA, EU MDR, and global regulatory pathways. She specializes in regulatory strategies for innovative diabetes and cardiovascular technologies and holds an M.S. in Medical Device and Diagnostic Engineering from USC.

Session: I2
Date/Time: Thursday, September 24, 2026; 10:50am
Location: Cassatt B
Session Speaker: Whitney Davis
Session Title: Beyond Compliance: Future-Ready Auditing for Risk and Safety in the QMSR – ISO 9001:2026 Era

Session Summary:

As regulatory expectations, organizational complexity, and operational risks continue to evolve, auditors must move beyond simply verifying compliance. This session explores how emerging frameworks, including FDA's QMSR and the anticipated ISO 9001:2026 revisions, are driving a shift toward resilience-based assurance.

Participants will learn how to evaluate whether audit programs provide strategic insight that helps organizations anticipate change, manage risk, and sustain performance. The session introduces the Audit Impact Continuum, a practical model for assessing audit maturity and organizational value, along with the R.E.A.D.Y.™ Framework for evaluating resilience through Risk Awareness, Emerging Threat Identification, Adaptability, Decision-Making, and Organizational Learning.

Drawing on real-world examples from regulated industries, attendees will discover how resilience-focused auditing can strengthen management review, improve safety culture, enhance organizational learning, and identify vulnerabilities before they become failures. Participants will leave with practical tools and implementation guidance for transforming audit programs into proactive drivers of risk intelligence and organizational resilience.

Learning Objectives:

- Understand the forces driving the shift to resilience-based auditing
- Assess audit effectiveness using the Audit Impact Continuum
- Apply the R.E.A.D.Y.™ Framework to evaluate organizational resilience
- Develop a roadmap for creating future-ready audit programs that support better risk visibility and decision-making

Speaker Bio:

Whitney Davis, MBA, is a senior quality and regulatory executive with nearly 40 years of experience in the medical device, pharmaceutical, laboratory, and industrial sectors. A Certified Quality Auditor, Six Sigma Black Belt, and ISO Lead Auditor, she specializes in quality systems, regulatory compliance, and organizational resilience. Whitney is the creator of the Future-Ready Auditor, R.E.A.D.Y.™ Framework, and Audit Impact Continuum models, which help organizations strengthen risk intelligence, organizational learning, and executive decision-making. An active ASQ member, she is passionate about advancing the auditing profession and developing the next generation of quality leaders.

Session: J2 (FDC Track)
Date/Time: Thursday, September 24, 2026; 10:50am
Location: Tate
Session Speaker: Balazs Bozsik
Session Title: Standards for EU Medical Device Regulatory Compliance

Session Summary:
This session provides a clear and practical introduction to the role of technical standards in demonstrating conformity with the EU MDR's General Safety and Performance Requirements (GSPRs). Participants will explore where standards come from, how they evolve through international, European, and national processes, and why harmonized standards—when available—offer a presumption of conformity under MDR Article 8. The presentation breaks down how standards represent the state of the art and how they support consistent interpretation of regulatory expectations, while also highlighting what manufacturers must do when harmonized standards are unavailable, outdated, or contain gaps. Designed for quality and regulatory professionals of varying experience levels, this session reinforces foundational knowledge essential for ensuring safe, effective, and compliant medical devices.

Speaker Bio:
Balazs Bozsik is the Technical Director for the Medical-, Pharma- and Cosmetic audit teams of SGS North America. As a mechanical engineer, he gained industrial experience in manufacturing technology and design engineering in the medical (X-ray diagnostic devices), automotive, and consumer lighting industries. Prior to joining SGS 5 years ago, he worked for another TIC organization for over 14 years, including his roles as global MDSAP Program Manager, certification officer, product specialist focusing on active medical devices and medical software, as well as medical auditor for all major certification schemes.

END PROGRAM