ASQ Audit Division Conference Program

ARTIFICIAL INTELLIGENCE IN AUDITING

Navigating the New Era

September 10th and 11th, 2025 - Reno, NV

August 11, 2025

Dear Conference Attendees,

It is both a privilege and an honor to welcome you to the **31st Annual Audit Division Conference**. This gathering is a vibrant celebration of the people, ideas, and passion that make our *society*, our *community*, and the *audit profession* thrive. Here, curiosity meets expertise, connections deepen, and the future of audit — and our broader mission of advancing quality — is taking shape before our eyes.

This year's program is truly inspiring. Together, we are engaging in bold ideas and important skills through sessions such as *The Current Realities and Future Potential for AI in Auditing*, *What Auditors Miss in an AI and Data-Driven World: 25 Things to Check*, *Risk is the Compass™ – A Process Approach Auditing Model Using Risks and Control*, *The 3Rs of Calibration*, and *AI in Action: Enhancing Risk-Based Audit Planning*. These sessions are an opportunity to learn from one another, share experiences, and strengthen the bonds that hold our professional community together.

This extraordinary conference is possible because of the dedication and talent of:

- **Andrew Davison – Conference Chair**
- **Katie Keller – Technical Program**
- **Nancy Pasquan – Registration**
- **Susanne Burke – Registration / Arrangements**
- **Kristen Wagner – A/V and IT**
- **Tatiana Miranda – FDC Representative**
- **Bill Hackett – Session Manager**
- **Santosh Mishra – Attendee Satisfaction Survey / Session Manager**

Your creativity, commitment, and attention to detail have shaped this conference into an experience that will leave a lasting impact on all who attend.

Looking Ahead

The future of our society and the audit profession is filled with possibility. Technological advancements, evolving business landscapes, and new ways of connecting will continue to shape how we come together and grow. But our true strength will always be rooted in integrity, collaboration, community, and our shared dedication to making a positive difference. The energy and relationships built here are the fuel for the next chapter of our work together.

To all attendees: your curiosity, openness, and willingness to connect are what make ASQ such a strong and vibrant community. Let the connections you make here grow into partnerships. Let the knowledge you gain inspire action. And let the shared experience of this conference remind you that, together, we are stronger and more impactful than any of us could be alone.

Thank you for being part of this extraordinary community.

With pride, gratitude, and great optimism,

Sid Bhatnagar, Chief Executive Officer
American Society for Quality

Note from the Technical Program Chair

Welcome to the ASQ Audit Division's 31st Conference! It is my first year as the Technical Program Chair, and I must say I am extremely excited for the fascinating topics our session speakers are presenting.

We are thrilled to 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. They will also have a booth in our sponsor area. Please support them by attending their sessions and visiting them at their booth.

The overall conference program represents the efforts of many people. I want to express gratitude to the members of the Conference Team, Keynote Speakers, Pre-Conference Tutorial Instructors, Session Speakers, Sponsors, conference volunteers, ASQ Headquarters, and the Staff of the Peppermill Resort.

The purpose of this conference is to provide premiere opportunities for learning, networking, knowledge-sharing, professional development, and career growth. Additionally, our conference always offers entertaining activities for all to partake in.

Be sure to take a close look at the following program for the details of each session. We have a great lineup with many sessions covering AI in Auditing, our theme for this year's conference.

In addition to sessions, we will also have four – you read that right! – *four* keynote speakers, and a number of networking breaks for you to interact with our generous sponsors. The sponsor area will

be right next to the session rooms, so be sure to get your bingo card signed!

Finally, please join us at our signature Gala event starting at 6:30pm on Wednesday evening in the Capri Ballroom. There will be lots of food, music, a photo booth, and maybe even some karaoke!

You will receive a survey after each session, so please give us your honest feedback and let us know the speakers and topics you'd like to see at future conferences.

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

In closing, thank you very much for attending the 2025 ASQ Audit Division Conference, and I sincerely hope you have some fun takeaways and "Aha!" moments during this year's sessions!

Sincerely,

Katie Keller

2025 Audit Division Conference Technical Program Chair

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 and find the Member Leaders 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 lunch!

Thank you to our generous sponsors!!

SGS

JP RUSSELL LEARNING CENTER
Delivering quality online training since 2000

Quality Support Group

QUALITY AUDITING

FOOD SMART STRATEGIES™
The Food Safety Experts

BPA Solutions

EASE

Boston Scientific
Advancing science for life™

Prodle

Thank you to our Gift-in-Kind sponsors!

QIMacros®
Quality Improvement Software for Excel

GOALQPC
home of the MEMORY JOGGER

Conference Overview

Wednesday, September 10, 2025	
7:30a – 8:00a	Coffee
8:00a – 8:10a	Opening, Morning Announcements
8:10a – 9:00a	Morning Keynote
9:00a – 9:15a	Pre-Conference Announcements
9:15a – 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 – 12:10p	Midday Announcements, Lunch starts
12:10p – 1:00p	Midday Keynote
1:00p 1:10p	Announcements
1:10p – 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 11, 2025	
7:30a – 8:00a	Coffee
8:00a – 8:10a	Morning Announcements
8:10a – 9:00a	Morning Keynote
9:00a – 9:15a	Announcements
9:15a – 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 – 12:15p	Midday Announcements, Lunch starts
12:15p – 1:00p	Midday Keynote
1:00p – 1:30p	Lunch continues
1:30p – 1:45p	End-of-Conference Announcements
1:45p – 3:00p	No Programming
3:00p – 4:00p	Annual Audit Division Business Meeting

Pre-Conference Tutorials

Risk Management / FMEA Auditing – Best Practices

½ Day Course: Tuesday, September 9, 2025, 8:00a – 12:00p
Instructor: Angelo Scangas
Location: Naples 1

Course Description:

Auditors continue to struggle with effective and efficient audit execution of Risk Assessments/FMEAs. Common deficiencies include an over-reliance on checklists and inadequate understanding of the documentation risk assessments, including linkage of audit procedures to the risks they are designed to address. So, what exactly does that mean? In plain English, this means the auditor needs to:

- Understand where within the company's quality / business system are the highest product / process risks
- Tailor his or her audit program to evaluate risk management effectiveness
- Understand the purpose and structure of FMEAs (or other risk assessment tools)
- Know how to audit the Severity, Occurrence and Detectability criteria
- Evaluate the effectiveness of the mitigations to reduce risk
- Audit for value

Expected Takeaways:

You'll learn to:

- Determine the right time to audit risk assessments
- Identify the critical requirements for the product or process to be included in a risk assessment
- Identify and classify potential failure modes
- Evaluate potential failure mode severity
- Evaluate potential causes of the failures

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, an 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 (Webinar Chair).

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.

The 3Rs of Calibration; Reading, Writing, and Reviewing Accreditation Scopes, Service Requests and Calibration Certificates

½ Day Course: Tuesday, September 9, 2025, 1:00pm – 5:00pm
Instructor: Heather Wade
Location: Naples 1

Course Description:

Personnel who must manage measurement & test equipment can feel overwhelmed knowing how to find appropriate calibration vendors, what to ask for when seeking measurement & test equipment calibration, and then how to read the calibration certificate. Often, this frustration arises because they were never trained how to do these activities.

This session is appropriate for consumers and suppliers of calibration services. This tutorial will include hands-on exercises for attendees to practice searching for and interpreting ISO/IEC 17025 calibration scopes of accreditation, comparing and interpreting scopes of accreditation, and reviewing and interpreting calibration certificates to meet their requirements.

Please bring your laptops and any examples of calibration certificates with which you'd like to practice. Examples will also be provided for hands-on activities.

Learning Objectives:

At the end of this 4-hour tutorial, participants will know:

1) How to search for appropriate calibration vendors and understanding scopes of accreditation
2) What to communicate to calibration vendors so you get what you need the first time
3) To read and interpret calibration certificates and use the data to reduce your risks and ensure better measurements.

Instructor Bio:

Heather A. Wade, ASQ-CCT, ASQ-CQA is a recognized metrology subject matter expert & internationally sought presenter. She excels at presenting useful and easy-to-implement practices. She is Editor of ASQ's Metrology Handbook, 3rd Edition. She is Past Chair of ASQ Measurement Quality Division. A graduate of University of Michigan with a B.S. in Biology, Heather has worked as a microbiologist, filter test specialist, laboratory compliance officer, extraction chemist, and analytical chemist before moving full-time into metrology. She brings all her 30+ years of professional experience together to provide “Pain Relief for Measurement Headaches”.

What Auditors Miss in an AI and Data Driven World: 25 Things to Check

Full Day Course: Tuesday, September 9, 2025, 8:00am – 5:00pm
Instructor: Rai Chowdhary
Location: Naples 2

Course Description:

Just about all QMS standards - ISO 9001, 13485, IATF 16949, AS 9100D, TL 9000 and many regulations such as FDA 21 CFR 820, EUMDR, and USDA, are leaning toward the use of evidence to support conformance or compliance. Additionally, reliance on data and statistical methods is also emphasized. Today's data driven world is also increasingly permeated with AI.

As it is, the pace of data generation is astounding, and it is only going to accelerate. According to one source*, the amount of data created, captured, copied, and consumed worldwide from 2010 to 2025 is estimated to increase by 90x. Are the auditors of today and auditors of the future prepared for such upheaval?

Join us for a unique, timely, and engaging event as Rai shares his know-how on 25 things every auditor should look for when examining evidence, data, its analysis, and the use of AI by firms. Here are the key takeaways:

1. The chain from events, evidence, and situations to data, its analysis, reporting, presentation interpretation – and errors in the same. Understand how error propagation can severely compromise analyses and information.
2. Practice with numerous audit case studies and develop / create the right questions to ask in each case.
3. In class practice on (using Excel on your laptop) data sets provided by Rai and develop the ability to spot the right areas / process steps where audits will be most effective.
4. Understand key points from the above standards that are applicable to data, analytics, and how to check for potential nonconformances when AI is used.
5. Learn 25 things you can do to boost immunity against flawed evidence data errors at your organization.

Instructor Bio:

Rai is a 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 and 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).

GxP for Supplier and Internal Audits

Full Day Course: Tuesday, September 9, 2025, 8:00am – 5:00pm
Instructor: Jim Shore
Location: Naples 3

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 "Gunny" Shore is the Chief Quality Officer at Quality Lean Solutions. He offers over 30 years of quality and supplier management experience working in medical devices, semiconductors, aerospace, and defense (Titan Medical, Lake Region, Nypro Healthcare, Boston Scientific, Aspect Medical, ACMI, Brooks Automation, and Raytheon). Quality Lean Solutions provides Simple Sustainable Solutions™ to companies in the medical device and high-tech industries by providing value-added auditing services, lean manufacturing, development of quality management systems, assisting with the EU Medical Device Regulation transitions, and performing inspections to the American Association of Tissue Banks standard. Shore's professional certifications include ASQ Certified Six Sigma Black Belt, ASQ Certified Quality Manager/Operations Excellence, ASQ Certified Quality Auditor, and Certified Mechanical Inspector, and he is an ASQ Senior Member. He is a Certified Welding Inspector and Test Supervisor for the American Welding Society and Co-author of the book entitled "Proactive Supplier Quality Management in the Medical Device Industry," which is published by Quality Press. (100% of the royalties are donated to Veteran service organizations). Shore served his country in the United States Marine Corps for 15 years as a Helicopter Crew Chief/door Gunner and was Honorably Discharged at the rank of Gunnery Sergeant (E-7).

Risk is the Compass™ – A Process Approach Auditing Model Using Risks and Controls

Full Day Course: Tuesday, September 9, 2025, 8:00am – 5:00pm
Instructor: Denis Devos
Location: Naples 4

Course Description:

We are pleased to offer this one-day tutorial to professional third-party auditors and internal auditors alike. Texts and training sessions always talk about considering risks during an audit but stop short of offering a template to assist in audit planning and preparation. Our session will introduce auditors to an auditing approach which includes process risks along with their corresponding enablers, or process controls. Topics will include the potential impact of AI in the preparation and conducting of audits. Many auditors find themselves unable to perform a QMS audit beyond written procedures and checklists. Hands-on workshops will teach simple techniques to help auditors see that Risk is the Compass for charting their course through a challenging audit.

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, the former Chair of the ASQ Quality Management Division 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 is a regular contributor to the Audit Division Conference, having shared his insights and expertise with us for over 15 years in a row. He also contributed to the published ASQ Certified Quality Auditor Handbook, Fifth Edition.

FSPCA IA Conducting Vulnerability Assessments Participant Course

Full Day Course: Tuesday, September 9, 2025, 8:00am – 5:00pm
Instructor: Cathleen Howick
Location: Naples 5

Course Description:

This course will provide participants with the knowledge to implement the requirements of conducting a vulnerability assessment under the Mitigation Strategies to Protect Food Against Intentional Adulteration (IA) regulation of the U.S. Food and Drug Administration (FDA). This regulation is one of a number of regulations and guidance that implement the provisions of the 2011 Food Safety Modernization Act (FSMA).

The Mitigation Strategies to Protect Food Against Intentional Adulteration regulation (referred to as the IA rule) is aimed at preventing intentional adulteration from acts intended to cause wide-scale public

health harm, including acts of terrorism targeting the food supply. The regulation requires that certain activities must be completed by a “food defense qualified individual” who has successfully completed training in the conduct of a vulnerability assessment (21 CFR 121.4). This course developed by the FSPCA is the “standardized curriculum” recognized by FDA; successfully completing this course is one way to meet the requirements for a “food defense qualified individual” responsible for conducting a vulnerability assessment.

The IA rule does not specify a particular method that you must use to conduct your vulnerability assessment. Two potential methods that can be used are the Key Activity Type (KAT) and/or the Three Fundamental Elements methods. If you conduct your vulnerability assessment using the KAT method with no modifications, you should consider completing the FSPCA IA Conducting Vulnerability Assessments Using Key Activity Types course and may not need the training provided in this course. However, if you use any modifications to the KAT method or plan to use the Three Fundamental Elements method, then this course would provide valuable insights**.**

Upon successful completion, you will receive an official FSPCA Food Defense "Qualified Individual" certificate issued by IFPTI, $60 additional fee.

Requirements:

- Participants must have access to the FSPCA IAVA Participant Manual and Exercise Workbook. Hardcopies of FSPCA Participants manuals are available for purchase through the FSPCA Bookstore (https://bookstorefspca.ifpti.org/index.php/iava.html) or on Amazon.com (https://a.co/d/1HUgU9J).

Recommendations

- As this course covers the portion of the Rule specific to conducting vulnerability assessments, participants should have a basic understanding of the IA rule. Strongly recommend attending the free FSPCA Overview of the IA Rule Course https://www.fspca.net/ia-rule.
- Strongly recommend bringing a computer / tablet / device to work on the exercises required to complete this course.

Instructor Bio:

Cathleen Howick, MS. FSPCA PCQI 2.0, FSVP & IAVA L.I. 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 microbiology, quality engineering, 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 Vulnerability Assessments.

Keynote Speakers

Day 1 – Opening Keynote
Wednesday, September 10, 2025
Rai Chowdhary

AI and Quality Audits – A Reality Check

AI holds great promise for the quality profession. It will become extremely valuable as models get refined, and more information becomes available. Rai has been experimenting and discovering the bright (and not so bright) side of using AI. He will share several of his key experiences using AI in audits, and a few from AI applications to quality at large. Along the way he has developed key approaches to validate AI responses, and methods to spot and steer around inaccurate information.

Rai is a 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 and 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).

Day 1 – Midday Keynote
Wednesday, September 10, 2025
Lisa El-Shall

Ensuring Consumer Safety through Robust Auditing Practices

In an era where regulatory landscapes are continuously evolving and uncertainty prevails; the role of auditors has never been more crucial. Auditors serve a critical function as the first line of defense or protection for consumers, especially amidst the recent developments at the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA). This keynote will highlight the integral role auditors play in maintaining the integrity and safety of consumer products. Their vigilance ensures that companies adhere to regulatory standards and best practices, thereby safeguarding public health. This session will provide several recent examples from the food, drug and

cosmetics industries to illustrate the pivotal role auditors can play in raising awareness of risks and potentially avoiding recalls and enforcement actions.

Lisa El-Shall is the Senior Director of Pharmaceutical and Medical Device Consulting Services at EAS Consulting Group. She brings a wealth of experience, having previously led R&D Quality groups at Pfizer and GSK, with global responsibility in areas ranging from new product development and clinical supply production to study oversight and business development quality.
Lisa has a proven track record in establishing and maintaining regulatory inspection compliance and fit-for-purpose standards. She also serves on the Board of Directors of ASQ, is a Certified Quality Auditor, and holds a B.S. in Chemistry from UNC Chapel Hill and an M.S. in Biochemistry from UCLA.

Day 2 – Morning Keynote
Thursday, September 11, 2025
Denis Devos

Everything I Know About Lean I Learned from My Grandmother

It's no surprise that many Lean concepts are rooted in common-sense and simplicity. I've recently realized that my wise old grandmother taught me a lot of the key tenets of Lean when I was just a child. In this tribute to grandmothers everywhere, we will acknowledge their crucial role in teaching us to work hard, be organized, not be wasteful, and face our problems head on.

Denis Devos is a professional engineer with a long career providing QMS training and advisory services. He is a Fellow of the ASQ, the former Chair of the ASQ Quality Management Division 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 is a regular contributor to the Audit Division Conference, having shared his insights and expertise with us for over 15 years in a row. He also contributed to the published ASQ Certified Quality Auditor Handbook, Fifth Edition.

Day 2 – Special Guest Speaker
Thursday, September 11, 2025
Colonel (ret) J. Craig Flowers

Colonel (ret) J. Craig Flowers is a 4th generation native Texan originally from San Antonio. His 25+ years in our military encompassed nearly a decade overseas, including three years in The Kingdom of Morocco as a diplomat and military attaché. His final military assignment was at West Point where he taught and later served as a Director of Cadet Activities and Assistant Baseball Coach for the record-setting Army West Point Black Knights.

Craig attended Texas Christian University earning a degree in Economics while playing baseball for the Horned Frogs. He earned an M.A. from Kansas University and is fluent in French. He trained, specialized, and operated in the field of Military Intelligence.

Founder of The Sideline Leadership CO., he serves Educators, NCAA & High School Coaches, Police Departments, CEOs and their staff on Character, Culture and Leader Development.

As a keynote speaker, Leader Development coach, and emcee, he incorporates humor while sharing anecdotes from experiences in the Army, the outdoors, raising daughters and 30+ years of marriage while serving alongside our nation's most elite leaders in sports and industry.

He recently co-authored "A Colonel and A Cowboy", a #1 Best Selling book that has reached thousands across the country.

Concurrent Sessions / Technical Program
Wednesday, September 10, 2025

Session: A1
Date/Time: Wednesday, September 10, 2025; 9:40am
Location: Naples 1
Session Speaker: Balazs Bozsik
Session Title: The Current Realities and Future Potential for AI Application in Auditing

Session Summary:
This introductory course walks the audience through the current possibilities and various aspects of limitations of utilizing AI technologies for quality auditing. We'll discuss technological, legal, ethical, and general regulatory constraints and assess the degree to which these are currently immovable obstacles or doable challenges to solve.
In the second half of the session, as case studies to spark ideas and raise awareness of already existing AI-supported solutions, we discuss currently-known implementations and future initiatives or just ideas in this field.
Since each attendee may be at a different stage of their AI journey, we leave time for Q&A.
Speaker Bio:
Balazs Bozsik has been the Technical Director for the medical audit team of SGS North America for 3.5 years, where he is managing the auditing aspect of SGS's notified and approved body certification services. Prior to joining SGS, 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 (including AI), as well as medical auditor for all major certification schemes.

Session: B1
Date/Time: Wednesday, September 10, 2025; 9:40am
Location: Naples 2
Session Speaker: Aditya Desai
Session Title: Unsung Heroes of Audit – Role of Support Team for Successful Outcome

Session Summary:
This session will showcase key ingredients needed for a successful audit-hosting program recipe. Participants will gain an understanding of the roles within the audit support team, including war/back-room members, the scribe, and the gatekeeper. This session will highlight effective strategies and tactics for managing external audits conducted by regulatory agencies or customers. It will emphasize the importance of the support team's behavior in achieving a successful audit outcome. Additionally, the session will address common challenges faced by the team and offer practical solutions to

overcome them without disrupting the audit flow. Examples of how AI applications can enhance efficiency will also be shared. Attendees will leave with practical approaches to implement improvements within their own companies. By participating in this session, you will acquire valuable insights that ensure your audit processes are both efficient and effective.

Speaker Bio:

"Quality Finds You" aptly describes Aditya Desai, who holds an MS in Pharmaceutical Science, specializing in Quality, Regulatory, and Validation. With 13+ years of experience in the life-science industry, Aditya has led various audits in the US and Internationally. As a strategic and visionary leader, he currently serves as QA Manager at Grifols, overseeing Change & Document Control processes and leading a global team for new document management system implementation. He chairs his local ASQ Section, fostering a quality community for learning and growth. Committed to gratitude, balance, and mental health wellness, Aditya is here to share his insights and learnings for a successful audit program.

Session: C1
Date/Time: Wednesday, September 10, 2025; 9:40am
Location: Naples 3
Session Speaker: Joy Toney
Session Title: Is AI Putting My Organization At Risk?

Session Summary:

In today's evolving world, one of Internal Audit's main functions is not only to ensure regulatory compliance from the business but also just as importantly manage risk for the business. As professionals, we have an obligation to ensure that solutions our organizations develop or deploy, especially those involving AI, promote benefits to not only the organization but also society and do not cause harm to constituents, society, or the environment.

In this session, we will explore Internal Audit's role to understand potential and realized risks of developing and deploying AI initiatives in the ecosystem. Attendees will be exposed to the use of risk management frameworks to identify and mitigate these risks and drive sustainable outcomes as well as the situational applicability of ethics in the profession. Case studies and statistics will be cited from various real-world communities. While some cases discussed will be resolved with implemented remediations, others will be on-going with the opportunity to explore potential solutions.

Speaker Bio:

Joy Toney serves as a Senior Program Consultant for AIM for Change, LLC. Joy's career successes are mapped over 20+ years of professional experience in non-profit, consumer services, and transportation. Joy enjoys utilizing her skills in responsible AI, process improvement, software development, information security, quality assurance, project management, and organizational change management. She's a CISSP, CCSP, CST, SHRM-CP, Prosci Certified Change Practitioner and CompTIA Pentest+ certified.

Session: D1
Date/Time: Wednesday, September 10, 2025; 9:40am
Location: Naples 4
Session Speaker: Edwin Bills
Session Title: Auditing Medical Device Quality Systems – Risk Management

Session Summary:
In this session we will present important information on the state of medical device risk management in accordance with ISO 14971 that will be helpful for auditors of medical device quality systems. We will address misconceptions of the requirements and misuse of the tools in conducting medical device risk management. We will also point to the connections between ISO 14971:2019 and the Medical Device Quality System ISO 13485:2016.

Speaker Bio:

- Medical Device Industry 1988-present
- Corporate Product Risk Manager
- Director, Quality and Regulatory
- Medical Device and Combination Product Consultant
- 25-year member of ISO TC 210 JWG1 medical device risk management committee
- Adjunct instructor, Quality Science Education, The Wistar Institute, and LaSalle University thru Pathways for Patient Health
- ASQ Fellow; CQE; CQA; CMQ/OE; RAPS RAC
- AAMI Instructor, Quality Systems; Risk Management
- Technical Advisor-Gessnet / Advisory Board Member-Prodct
- Co-editor of Lifecycle Risk Management for Healthcare Products, PDA
- Author of articles and book chapters and frequent Presenter

---

Session: E1 (FDC Track)
Date/Time: Wednesday, September 10, 2025; 9:40am
Location: Naples 5
Session Speaker: Rosemarie Christopher
Session Title: Future-Proofing Your Auditing Career in the New Workplace

Session Summary:
Food SMART Strategies International has built a strong reputation over the past decade by providing customized solutions for small businesses and startups to comply with the Food Safety Modernization Act (FSMA) and stay audit-ready year-round. We offer innovative, web-based training tools that ensure ongoing learning, accessible on any device, anytime, anywhere. These tools help establish a strong food safety culture, meeting FSMA requirements. Our vision is to foster a thriving ecosystem of small businesses that bring innovative, safe food products to market, win consumer trust, and enrich their communities.

3 Takeaways:

- Think critically about Audits- Personalization
- Create a structured audit prep process – Collaboration and Partnering
- Skilling: Training; re-training and upskilling – Lifetime Continuous Improvement

Speaker Bio:

Rosemarie Christopher is President of Food SMART Strategies International Incorporated, an Audit Prep Services company with a custom training app for workers in all small to mid-sized Food companies and Farms. Rosemarie earned her M.A. in Corporate Communications from University of Southern California (USC), B.A. in Anthropology from University of California Los Angeles (UCLA), and A.A. in Liberal Arts from Northampton County Community College (NCCC). Rosemarie is also a graduate Alum of the Goldman Sachs 10K Small Business program (out of Babson College).

Session: A2

Date/Time: Wednesday, September 10, 2025; 10:50am
Location: Naples 1
Session Speaker: Heather Wade
Session Title: Giving Engaging Presentations and Avoiding Death-By-PowerPoint

Session Summary:

We have all been in *that* meeting or presentation where we cringe because the presenter is reading the slides word-for-word, we miss what the presenter is saying because we are busy reading the slide or tune out because we cannot read the novel-length text on the slides. We grow frustrated when a presentation is missing expectations, connection, and flow.

No one is a born storyteller or presenter. The fear of public speaking is a stronger fear than death. How do we overcome this so we can develop and deliver our presentations to effectively deliver our messages and keep the attendees engaged and interested? What are tools, techniques, and resources that can help us improve our presentations and be more effective in our meetings? Join this engaging presentation to learn these tools, techniques, and resources so you can more effectively deliver your messages.

Learning Objectives: At the end of this presentation, attendees will

1) Learn tools & resources to make your presentations more engaging so that people remember your message,
2) Learn about resources to help you improve your presentation speaking skills.

Speaker Bio:

Heather A. Wade, ASQ-CCT, ASQ-CQA is a recognized metrology subject matter expert & internationally sought presenter. She excels at presenting useful and easy-to-implement practices. She is Editor of ASQ's Metrology Handbook, 3rd Edition. She is Past Chair of ASQ Measurement Quality Division. A graduate of University of Michigan with a B.S. in Biology, Heather has worked as a microbiologist, filter test specialist, laboratory compliance officer, extraction chemist, and analytical chemist before moving full-time into metrology. She brings all her 30+ years of professional experience together to provide “Pain Relief for Measurement Headaches”.

Session: B2
Date/Time: Wednesday, September 10, 2025; 10:50am
Location: Naples 2
Session Speaker: Rachel Ryll
Session Title: Leading Audit Transformation: Change Management Strategies for AI Integration

Session Summary:
The auditing profession is evolving rapidly, and AI is playing a key role in shaping its future. However, successful adoption depends on effective change management. Auditors must not only understand AI-driven tools but also navigate the organizational transitions required to implement them.
This session will explore:

- Strategies for Managing Change in Auditing: How to introduce AI-powered technologies while ensuring stakeholder buy-in
- Overcoming Resistance: Addressing common concerns among teams hesitant to embrace AI in audit processes
- AI in Audit Planning and Execution: Practical ways to integrate AI without disrupting existing methodologies
- Balancing Automation and Human Oversight: Maintaining audit integrity while leveraging AI for efficiency
- Real-World Case Studies: Success stories demonstrating how organizations have adopted AI without compromising audit quality

Attendees will gain insights into change management frameworks that help audit teams and organizations transition smoothly into an AI-enhanced environment.
Speaker Bio:
Rachel Ryll is a seasoned executive with over 20 years of experience in the life sciences and medical device sectors, specializing in global quality assurance, regulatory compliance, risk management, and change management. As the founder of Reliance Quality and Regulatory Consulting, she helps organizations navigate complex regulatory landscapes, mitigate risks, and drive transformational change.

Session: C2
Date/Time: Wednesday, September 10, 2025; 10:50am
Location: Naples 3
Session Speaker: Christy Furlan
Session Title: Reviewing Auditees' Corrective Action Responses to Findings

Session Summary:
You have completed your audit, issued your audit report, and finally received your auditee's responses to your audit findings. But how do you ensure that those responses are up to snuff? How do you assess their root cause analyses and action plans? And, if their responses do not meet your needs, how do you push back and get your auditee to course correct and change their plans?

This session aims to answer these questions with guidelines for reviewing all sections of auditee finding responses, from root cause analyses to corrections to corrective and preventive action plans. We will also engage in some interactive practice with these skills by reviewing and determining how to react to sample auditee finding responses.

Speaker Bio:

Christy Furlan is an ASQ Certified Quality Auditor, Certified Supplier Quality Professional, and Certified Quality Process Analyst with over 13 years of experience as a quality assurance professional and over 11 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, and travel.

Session: D2
Date/Time: Wednesday, September 10, 2025; 10:50am
Location: Naples 4
Session Speaker: Danielle Hestermann
Session Title: Is ISO 9001 Still Relevant? – A Closer Look at the Review Process and How It Remains Pertinent

Session Summary:

It's been nearly 10 years since ISO9001 was last updated and there have been a lot of changes over that decade. Given all that's changed, is the standard still pertinent to today's businesses? How do we ensure it remains relevant? The technical community has heard these concerns and is in the process of updating ISO9001. We'll take a deep dive into the review process to explore how ISO9001 remains applicable. We'll examine how the standard is reviewed and how new technologies such as AI and climate change are considered. We'll answer the pressing question of why ISO9001 is still on the 2015 revision and conclude by exploring the revision history and what to expect next.

Speaker Bio:

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. She is currently chair of the Fox Valley ASQ section and a member of TAG176, the US Technical Advisory Group to ISO for Quality Management standards.

Session: E2 (FDC Track)
Date/Time: Wednesday, September 10, 2025; 10:50am
Location: Naples 5
Session Speaker: Steve Ault
Session Title: Cosmetic Auditing Under MoCRA: The Before and After

Session Summary:
Enactment of the Modernization of Cosmetic Regulation Act (MoCRA), signed into law in December 2022, and final cGMP regulations are expected in 2025, which bring new perspectives and challenges to auditing cosmetic manufacturers. This session aims to share current experiences faced during audits as we approach MoCRA due dates and beyond. Topics and Key Implementation Timelines to be discussed include:

- Facility Registration and Product Listing – currently required
- Adverse Event Reporting – currently required
- Labeling and Allergen Transparency
- Safety Substantiation
- Good Manufacturing Practices – expected end of 2025
- Review of the most common nonconformances encountered during cosmetic manufacturer audits.

Speaker Bio:
Steven Ault is currently enjoying semi-retirement as Principal of SJA Quality Consulting, LLC. Most recently, he was an auditor with NSF for over 9 years, where he performed cGMP and Product Certification audits for Dietary Supplement and Cosmetic manufacturers. Steve has been in the dietary supplement/CPG industry for 30 years and has broad scientific and technical expertise with 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 a ASQ Certified Quality Auditor, HACCP certified, and PCQI.

Session: A3
Date/Time: Wednesday, September 10, 2025; 1:30pm
Location: Naples 1
Session Speaker: Attrayee Chakraborty
Session Title: Leveraging AI in Auditing: Step-By-Step Prompt Generation for Audit Checklists

Session Summary:
This live demonstration showcases how AI tools like Perplexity (an open-source research assistant) streamline MDSAP audit checklist creation. Attendees will see real-time examples of crafting prompts (e.g., “Generate MDSAP audit questions for CAPA under ISO 13485”) and refining outputs to align with regulatory requirements.
Key highlights:

- Checklist Automation: Convert complex regulatory text (e.g., FDA 21 CFR Part 820, ISO 14971) into actionable audit questions, ensuring compliance with MDSAP's harmonized framework.
- Cross-Mapping: Dynamically linked questions to multiple standards and customize templates based on organizational risk profiles.
- AI Scribes: I will be showing features of AI tools like Otter.ai or built-in Zoom/Teams AI features reducing manual note-taking that can support audit scribes.

The session reveals strategies to cut checklist development time by 30–50% while enhancing rigor. Limitations, such as requiring human validation to ensure accuracy and audit integrity, are also addressed. Ideal for medical device auditors and quality teams seeking efficiency without compromising compliance.

Speaker Bio:

Attrayee (Atty) Chakraborty is a Quality Systems Engineer at Analog Devices (ADI), a Fortune 500 semiconductor leader, specializing in regulatory and quality management for digital healthcare and medical devices. With experience spanning startups and major corporations in India and the U.S., she is dedicated to advancing healthcare quality. Winner of the 2025 Quality Rookie Award, Atty has presented at 20+ global conferences on AI in healthcare, drug misinformation, and regulatory topics. She contributes to FDA-recognized AIGHI and IEEE P3396 AI standards and is recognized as an AI community leader by the RAPS.

Session: B3
Date/Time: Wednesday, September 10, 2025; 1:30pm
Location: Naples 2
Session Speaker: Rachel Ryll
Session Title: AI-Driven Change Management: A Smarter Approach to Transformation

Session Summary:

Managing change effectively requires a structured approach—and Artificial Intelligence is a game-changer in helping leaders analyze impact, identify risks, and streamline implementation. By leveraging AI-driven prompting techniques, organizations can navigate transitions more efficiently, making informed decisions at every stage.

This session will cover:

1. Assessing the Impact of Change with AI (10-15 min)
    a. Using AI-driven analysis to evaluate how changes will affect different stakeholders
    b. Prompting AI to generate impact assessments based on historical data and trends
2. Identifying Risks Before They Escalate (10-15 min)
    a. Using AI to scan patterns and uncover hidden risks in organizational change
    b. Prompting AI to predict potential challenges and recommend mitigation strategies
3. Creating a Comprehensive Change Management Plan (10-15 min)
    a. Leveraging AI-powered tools to draft structured transition plans
    b. Using AI prompts to refine communication strategies for smooth adoption
4. Supporting Implementation with AI-Driven Execution (10-15 min)
    a. How AI can help monitor processes to ensure effectiveness of implementation

Speaker Bio:
Rachel Ryll is a seasoned executive with over 20 years of experience in the life sciences and medical device sectors, specializing in global quality assurance, regulatory compliance, risk management, and change management. As the founder of Reliance Quality and Regulatory Consulting, she helps organizations navigate complex regulatory landscapes, mitigate risks, and drive transformational change.

Session: C3
Date/Time: Wednesday, September 10, 2025; 1:30pm
Location: Naples 3
Session Speaker: Paul Russell
Session Title: Auditor Cookbook Page One: A Recipe for a Delicious Nonconformity

Session Summary:
New auditors want to make a solid impression with management, but sometimes they have a rocky start due to writing ineffective or unclear audit findings. The Audit Division can assist! This session will help sharpen an auditor's nonconformity writing discussing real life past examples of what was written versus what needed to be written. Also, the slight differences between internal and external non-conformities will be discussed. Attendees new to auditing, or looking for a refresher, will leave this 50-minute session with a better understanding of what an effective nonconformity can look like and pitfalls to avoid along the way.
Speaker Bio:
Paul Russell is Managing Director for QualityWBT Center for Education and the JP Russell Learning Center. For 23 years, Paul (ASQ CQA) has worked with online, blended, and public classes approved by the American Society for Quality. Paul performed audits in the health industry to maintain Food and Drug Administration and European Union compliance for over 45 blood bank locations and five blood manufacturing facilities. Paul has performed pharmacy audits in many regions of the US to maintain Drug Enforcement Agency and FDA compliance as well as pharmacy-specific adherence to the drug laws of 21 states and one District.

Session: D3
Date/Time: Wednesday, September 10, 2025; 1:30pm
Location: Naples 4
Session Speaker: Sanath Hegde
Session Title: Transitioning to Smart and Objective Audits with AI

Session Summary:
This session will explore best practices, technologies, and tools for optimizing audit management and reporting. We'll then examine how these foundational elements enable objective AI-driven audits and

demonstrate how AI can serve as an intelligent copilot throughout the complete audit lifecycle, including root cause analysis and corrective and preventive action (CAPA) implementation.

Speaker Bio:

Sanath is a lead innovator at Prodle, where he drives AI-powered solutions for compliance auditing and manufacturing quality management. With over 25 years of experience in product management and engineering, he consistently delivers impactful products that reduce total cost of ownership and accelerate time-to-value. His work focuses on intelligent automation across core compliance functions, including document control, audits, CAPA, and risk management.

Session: E3 (FDC Track)
Date/Time: Wednesday, September 10, 2025; 1:30pm
Location: Naples 5
Session Speaker: Balazs Bozsik
Session Title: Medical Auditing Masterclass

Session Summary:

In this session the attendees can learn about tips, tricks and best practices performing first- (internal-), second- (typically supplier-) and third-party audits of medical device organizations' integrated management systems. Audit planning and preparation, various aspects of the audit execution, and a few established methods for reporting and following up on audit results will be covered. As far as it impacts the practical aspects implementation, the principles (including threats to impartiality and proper handling of findings) and broader context of medical audits (e.g., contractual and regulatory compliance, product conformity, audits supporting a global quality and regulatory strategy) will also be mentioned. The session will include interactive Q&A.

Speaker Bio:

Balazs Bozsik has been the Technical Director for the medical audit team of SGS North America for 3.5 years, where he's managing the auditing aspect of SGS' notified and approved body certification services. Prior to joining SGS, 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: A4
Date/Time: Wednesday, September 10, 2025; 2:40pm
Location: Naples 1
Session Speaker: Heather Wade
Session Title: ISO 9001 vs. ISO/IEC 17025

Session Summary:

For ISO 9001 auditors, understanding ISO/IEC 17025 can strike fear and avoidance. For ISO/IEC 17025, one of the Quality Management System options is to use your ISO 9001 Registration, as long

as the ISO/IEC 17025 requirements are also met. In this presentation, we will look at the common Management System requirements between ISO 9001 & ISO/IEC 17025. We will also do a high-level view of ISO/IEC 17025 technical requirements.

Learning Objectives: At the end of this presentation, attendees will:

1. Be able to describe the target audiences of ISO 9001 and of ISO/IEC 17025
2. Be able to identify the common Management System requirements between ISO 9001 & ISO/IEC 17025
3. Be able to identify the unique Management System requirements of ISO/IEC 17025

Speaker Bio:

Heather A. Wade, ASQ-CCT, ASQ-CQA is a recognized metrology subject matter expert & internationally sought presenter. She excels at presenting useful and easy-to-implement practices. She is Editor of ASQ's Metrology Handbook, 3rd Edition. She is Past Chair of ASQ Measurement Quality Division. A graduate of University of Michigan with a B.S. in Biology, Heather has worked as a microbiologist, filter test specialist, laboratory compliance officer, extraction chemist, and analytical chemist before moving full-time into metrology. She brings all her 30+ years of professional experience together to provide “Pain Relief for Measurement Headaches”.

Session: B4
Date/Time: Wednesday, September 10, 2025; 2:40pm
Location: Naples 2
Session Speaker: Tony George
Session Title: The Four-Step Process of Quality Auditing: Ensuring Continuous Improvement

Session Summary:

This presentation will introduce quality auditing and its role in continuous improvement. It will cover a four-step audit process involving the Client/Sponsor, Auditor, and Auditee:

1. Planning – defining purpose, scope, and tools
2. Conducting – gathering evidence and conducting interviews
3. Reporting – developing and closing the report
4. Follow-up – verifying corrective actions

The session will also align this process with the PDCA cycle and highlight the importance of audits in continuous improvement. Join us to enhance your skills as an internal, organizational, or supplier auditor.

Speaker Bio:

Tony George is a Quality Engineer at Master Meter, Inc., with over 22 years of experience in quality roles, including Quality Manager and Internal & Supplier Quality Auditor. He has worked in industries such as packaging, plastic injection molding, and water management technology. A Senior Member of ASQ, Tony has served in various positions on the Ft Worth Section Leadership Committee and holds ASQ CQA, CSQP, and CQIA certifications. He is also a retired US Army National Guard Officer and holds a BS in Industrial Engineering and Management from North Dakota State University.

Session: C4 (back-to-back with C5)
Date/Time: Wednesday, September 10, 2025; 2:40pm
Location: Naples 3
Session Speaker: BJ Johnson
Session Title: Recent Audit Standard Updates from the Vice Chair of US TAG 302 (Part 1)

Session Summary:
This session will be led by the Vice-Chair of the U.S. Technical Advisory Group (TAG) which serves as the national mirror committee to ISO Project Committee 302, responsible for revising ISO 19011 – the international standard that provides guidelines for auditing management systems. The primary purpose of U.S. TAGs is to develop U.S. consensus positions and comments on activities and ballots which include the approval, reaffirmation, revision, and withdrawal of ISO standards. The session will include an update on the status of the audit/assessment standards that have been developed or revised recently, including information on key dates, issues, and key players involved for ISO 19011 and:

- IAF MD 4:2025 – Mandatory Document for the Use of Information and Communication Technology (ICT) for Conformity Assessment Purposes (formerly Audit/Assessment Purposes) and a related proposed ID XX
- ISO/IEC TS 17012:2024 – Guidelines for the use of remote auditing methods in auditing management systems
- ISO/IEC 27006-1:2024 – Requirements for bodies providing audit and certification of information security management systems
- ISO/IEC 42006:20XX – Requirements for bodies providing audit and certification of artificial intelligence management systems
- ISO/IEC 42007 – High-level framework guidance development of Conformity Assessment schemes for AI system

Speaker Bio:
BJ Johnson began her career over 25 years ago as a microbiologist working on medical devices manufactured out of human and animal tissues. She has worked at companies that manufactured medical devices from bandages to permanent implants. BJ worked at the FDA as a consumer safety officer (investigator) and in the medical device quality organizations at several medical device companies. BJ has been an ASQ Certified Quality Auditor since 2001 and currently is working as a Project Manager for DEKRA.

Session: D4
Date/Time: Wednesday, September 10, 2025; 2:40pm
Location: Naples 4
Session Speaker: Edwin Bills
Session Title: Preparing for the Upcoming New FDA QMSR

Session Summary:
This session will discuss the upcoming US FDA Quality Management System Regulation which takes effect on February 2, 2026. We will discuss what the manufacturer should do to get ready for this new regulation which replaces the current Quality System Regulation. There are some misconceptions such as, "if I already have a Quality System based on ISO 13485, I am already compliant". That is not true, nor will an ISO 13485 Certificate cover FDA requirements or prevent FDA inspections of your facility.

Speaker Bio:

- Medical Device Industry 1988-present
- Corporate Product Risk Manager
- Director, Quality and Regulatory
- Medical Device and Combination Product Consultant
- 25-year member of ISO TC 210 JWG1 medical device risk management committee
- Adjunct instructor, Quality Science Education, The Wistar Institute, and LaSalle University thru Pathways for Patient Health
- ASQ Fellow; CQE; CQA; CMQ/OE; RAPS RAC
- AAMI Instructor, Quality Systems; Risk Management
- Technical Advisor-Gessnet / Advisory Board Member-Prodct
- Co-editor Lifecycle Risk Management for Healthcare Products, PDA
- Author of articles and book chapters and frequent Presenter

---

Session: E4 (FDC Track)
Date/Time: Wednesday, September 10, 2025; 2:40pm
Location: Naples 5
Session Speaker: Sarah Collins
Session Title: NSF:2024: Dietary Supplement GMP Nonconformances Report Overview

Session Summary:
As a global leader in nutrition and wellness Good Manufacturing Practices (GMP) certification, NSF is committed to helping understand the root causes of GMP audit noncompliances. NSF facilitated the development of the NSF/ANSI 455 GMP certification standards, including: NSF/ANSI 455-2 – Dietary Supplements, NSF/ANSI 455-3 – Cosmetics, and NSF/ANSI 455-4 – Over-the-counter Products. We reviewed a full year of our GMP certification audit data to identify and categorize the most common

GMP nonconformances in our certification clients. In this session we will review the most common standard subsections for each of the four top categories of noncompliances.

Speaker Bio:

Sarah Collins has over 20 years of experience in manufacturing environments, specializing in quality management systems for dietary supplements. She has held various leadership roles, in both educational and industrial settings managing quality systems, compliance, and extensive training programs. Sarah's expertise includes staff and budget management, laboratory setup and maintenance, process analysis, and regulatory oversight. She holds a Certificate in Food Safety from USC and a Bachelor of Science in Industrial Technology from East Carolina University. Sarah is dedicated to ensuring high standards in the dietary supplements industry.

Session: A5
Date/Time: Wednesday, September 10, 2025; 3:50pm
Location: Naples 1
Session Speaker: Colleen McGuigan
Session Title: From Insider to Outsider: Building Organizational Familiarity as an External Auditor

Session Summary:

Transitioning from internal to external auditing changes everything – especially how you get to know a company you've never worked with before. This session explores practical and people-focused strategies to quickly and effectively familiarize yourself with an organization as an external auditor. We'll unpack real-world stories, share practical tools like pre-audit research checklists and facility walkthrough guides, and dive into soft skills that help build rapport with auditees from "Hello."

Whether you're preparing off-site, conducting the opening meeting, or walking the shop floor, you'll learn how to tune in to company culture, identify key information quickly, and build confidence in unfamiliar environments. You'll leave with actionable techniques and training ideas to support your development as an external auditor – without losing the strengths you've built as an internal one.

Speaker Bio:

Colleen McGuigan is an accomplished professional with over 30 years of extensive experience in the manufacturing and service industries, specializing in quality systems and auditing. She is an Exemplar Global Master Quality Management System Auditor, and an ASQ CQA.

Session: B5
Date/Time: Wednesday, September 10, 2025; 3:50pm
Location: Naples 2
Session Speaker: Aditya Desai
Session Title: GMP Manufacturing Through an Auditor's Eye

Session Summary:
This session will emphasize crucial areas to concentrate on when auditing a GMP manufacturing facility. Participants will gain insights into specific topics that are common concerns and observations for regulatory auditors. The session will uncover interesting tactics used by auditors to identify gaps, which professionals in the industry can then use as improvement opportunities. Key industry trends related to quality and data integrity issues will be discussed. Additionally, practical use cases for AI applications that auditors can implement will be provided. Attendees will be able to apply the knowledge gained from the session to effectively identify and assess gaps within their respective areas.

Speaker Bio:
"Quality Finds You" aptly describes Aditya Desai, who holds an MS in Pharmaceutical Science, specializing in Quality, Regulatory, and Validation. With 13+ years of experience in the life-science industry, Aditya has led various audits in the US and Internationally. As a strategic and visionary leader, he currently serves as QA Manager at Grifols, overseeing Change & Document Control processes and leading a global team for new document management system implementation. He chairs his local ASQ Section, fostering a quality community for learning and growth. Committed to gratitude, balance, and mental health wellness, Aditya is here to share his insights and learnings for a successful audit program.

Session: C5 (back-to-back with C4)
Date/Time: Wednesday, September 10, 2025; 3:50pm
Location: Naples 3
Session Speaker: BJ Johnson
Session Title: Recent Audit Standard Updates from the Vice Chair of US TAG 302 (Part 2)

Session Summary:
This session will be led by the Vice-Chair of the U.S. Technical Advisory Group (TAG) which serves as the national mirror committee to ISO Project Committee 302, responsible for revising ISO 19011 – the international standard that provides guidelines for auditing management systems. The primary purpose of U.S. TAGs is to develop U.S. consensus positions and comments on activities and ballots which include the approval, reaffirmation, revision, and withdrawal of ISO standards. The session will include an update on the status of the audit/assessment standards that have been developed or revised recently, including information on key dates, issues, and key players involved for ISO 19011 and:

- IAF MD 4:2025 – Mandatory Document for the Use of Information and Communication Technology (ICT) for Conformity Assessment Purposes (formerly Audit/Assessment Purposes) and a related proposed ID XX

- ISO/IEC TS 17012:2024 – Guidelines for the use of remote auditing methods in auditing management systems
- ISO/IEC 27006-1:2024 – Requirements for bodies providing audit and certification of information security management systems
- ISO/IEC 42006:20XX – Requirements for bodies providing audit and certification of artificial intelligence management systems
- ISO/IEC 42007 – High-level framework guidance development of Conformity Assessment schemes for AI system

Speaker Bio:
BJ Johnson began her career over 25 years ago as a microbiologist working on medical devices manufactured out of human and animal tissues. She has worked at companies that manufactured medical devices from bandages to permanent implants. BJ worked at the FDA as a consumer safety officer (investigator) and in the medical device quality organizations at several medical device companies. BJ has been an ASQ Certified Quality Auditor since 2001 and currently is working as a Project Manager for DEKRA.

Session: D5
Date/Time: Wednesday, September 10, 2025; 3:50pm
Location: Naples 4
Session Speaker: Laura Halleck
Session Title: AI in Action: Enhancing Risk-Based Audit Planning

Session Summary:
In this session, we will explore how AI can support risk-based audit planning, delivering more efficient, targeted, and effective audits. The presentation will begin with an introduction to risk-based thinking, emphasizing its importance in focusing resources on areas of higher risk to improve audit effectiveness and ensure quality system compliance. We will then discuss how to apply risk-based thinking directly to audit planning, ensuring that every audit is aligned with the organization's most critical risks.
Next, we will highlight the benefits of adopting a risk-based audit approach, such as improved efficiency, more focused audits, and better resource allocation. The core of the session will outline the steps to develop a risk-based audit plan, from risk identification to prioritization. Finally, we will demonstrate how AI can optimize the audit planning process by automating risk analysis, identifying patterns, and providing data-driven insights that enhance decision-making. This session is designed for audit program managers and consultants who perform internal audits on a contract basis, offering practical tools to integrate AI into risk-based audit planning, improving overall audit quality and efficiency.

Speaker Bio:
Laura is a Senior Consultant with Quality Support Group specializing in guiding organizations through quality management system implementation and certification, including training and internal auditing. Laura has over 20 years of experience in manufacturing, engineering, quality assurance and Six Sigma process improvement for the Automotive and Aerospace and Defense Industries. She is a member of ASQ and the US TAG to ISO/TC176 on ISO 9001.

Session: E5 (FDC Track)
Date/Time: Wednesday, September 10, 2025; 3:50pm
Location: Naples 5
Session Speaker: Bob Ferguson
Session Title: What You May Really See at a Food Plant – Lessons from Surveys and Interviews of >500 Food Safety Professionals

Session Summary:
We have all seen presentations and publications outlining what *should be* happening in a food plant's Food Safety Program. But we also all know that we don't live in a perfect world, so what is really happening? The Food Safety Insights program in Food Safety Magazine is designed to report on what is actually occurring in food processors' facilities and the practical difficulties and obstacles that food safety professionals face in running their programs. Based on surveys and interviews with more than 3000 food safety professionals since 2023, we'll present real-life lessons learned that auditors and anyone else involved in food production will want to hear about these practical issues.

Speaker Bio:
Bob Ferguson is the author of Food Safety Insights in every edition of Food Safety Magazine and is a co-host of the Food Safety Matters podcast. Bob has more than 40 years of experience in food diagnostics and laboratory businesses, is President of the Capital Area Food Protection Association (CAFPA) – the Washington DC Chapter of the International Association for Food Protection and a frequent attendee at national and international food safety meetings and conferences.

Session: F1
Date/Time: Thursday, September 11, 2025; 9:40am
Location: Naples 1
Session Speaker: Kellen Ilse
Session Title: AI in Quality Audits: Insights from Certification and Regulatory Stakeholders

Session Summary:
AI is expected to become a fixture in QMS auditing, but how is its adoption viewed by those responsible for oversight? This session presents emerging insights from Certification Bodies and Regulators using structured survey data and targeted interviews, this presentation will explore three key areas:

- Perception – How do these stakeholders view the use of AI tools in audits?
- Adoption – What AI-enabled tools or technologies are they currently using or evaluating within their own audit processes?
- Capability Building – How are they preparing and training their auditors to use or assess AI systems effectively?

Attendees will walk away with a clearer understanding of how oversight organizations are adapting to AI and how to succeed in this changing environment.

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 has earned several ASQ Certifications, become an Exemplar Global Lead Auditor and crisscrossed the globe, conducting hundreds of audits in 15 countries.

Session: G1
Date/Time: Thursday, September 11, 2025; 9:40am
Location: Naples 2
Session Speaker: Tatiana Miranda
Session Title: How I Have Streamlined My Audit Documentation with Microsoft 365 Copilot

Session Summary:
This hands-on, live practical session will explore how Microsoft 365 Copilot transformed my auditing process by enhancing efficiency and accuracy. Participants will learn my take on practical applications of Copilot in various Microsoft-based auditing tasks, specifically its use in Excel (i.e. checklists) and Word documents (i.e. reports), as well as addressing technical questions and support to make audit reports effective. Attendee's takeaways:

- Increased Efficiency: Learn how Copilot can automate tasks, allowing auditors to focus on more critical aspects of their work.
- Improved Accuracy: Discover how Copilot's intelligent suggestions can enhance data accuracy and the quality of audit reports.
- Enhanced Collaboration: Understand how Copilot facilitates real-time AI collaboration.

Speaker Bio:
Tatiana Miranda is a Sr. QA Manager-GMP Audits at Unilever Wellbeing. She partners with dietary supplement businesses and conducts GMP audits to ensure the suppliers' GMP compliance. She has experience in FSMA, FSVP, ISO, BRC, and NSF standards. Before Unilever, Tatiana was a Quality Engineer for Nutrilite, FSQA Manager with Sabra Dipping Co., and Quality Engineer for SAB-Miller Breweries. Tatiana has a B.S. in Food Engineering and an MS in Food Science. She is an ASQ Certified Food Safety & Quality Auditor, PCQI 2.0 Lead Instructor, HACCP Trainer by the IHA, and adjunct faculty at Chapman University (Orange, CA).

Session: H1
Date/Time: Thursday, September 11, 2025; 9:40am
Location: Naples 3
Session Speaker: Justin Mitchell
Session Title: Using Generative AI to Conduct Smarter, Safer Audits

Session Summary:

In today's evolving quality landscape, auditors are expected not just to understand Artificial Intelligence, but to lead conversations on its implementation. This session will showcase how generative AI models – like ChatGPT and others – can be applied directly to the audit process to streamline evidence gathering, accelerate clause-by-clause compliance validation, and provide real-time access to policy-aligned documentation.

- Part 1 of the session will demonstrate real-world applications of AI in auditing – such as conducting an ISO 9001 internal audit. Attendees will see how an AI system can interpret audit clauses, identify relevant internal compliance documents, and surface supporting evidence, complete with links and contextual summaries.
- Part 2 will address the critical underpinnings of responsible AI use. We'll explore technical considerations for securing AI implementations, including strategies for siloed deployments, restricting internet access, and controlling source data to maintain accuracy, compliance, and confidentiality.

Designed for auditors, quality leaders, and compliance professionals, this session will provide a practical and ethical framework for integrating AI into audit environments. Whether you're evaluating AI or implementing it, you'll leave with tools to speak knowledgeably with IT, advocate for safe AI use, and elevate your audit outcomes.

Speaker Bio:

Justin Mitchell is the CTO and co-owner of Consult2.Cloud, where he leads a team dedicated to integrating advanced technologies into quality management and auditing systems. Working with medium to large organizations – including those in the DOD and government sectors – Justin and his team design and secure cloud-based solutions tailored for high-compliance environments. As Chair-Elect of the ASQ Software Division, he also helps guide industry-wide AI initiatives. With over two decades of experience, Justin is known for translating complex AI and technology concepts into practical, actionable strategies that empower quality and audit professionals to innovate with confidence and security.

Session: I1
Date/Time: Thursday, September 11, 2025; 9:40am
Location: Naples 4
Session Speaker: Angelo Scangas
Session Title: Advanced Product Quality Planning (APQP) Rev.3 & Control Plan Rev.1 Overview

Session Summary:

A new APQP (Advanced Product Quality Planning) manual is here! The new version is more than a methodology; it's a commitment to excellence, ensuring that every product not only meets but exceeds customer expectations. It is updated to include higher automation, autonomous driving, and electrification. The updated standard provides steps and tools to avert quality issues, elevate customer satisfaction, and foster an environment of continuous improvement.

This presentation focuses on changes in the new APQP 3rd Edition and standalone Control Plan, emphasizing their impact on the future of product quality planning. Decoupling the two documents will also facilitate more timely updates as systems evolve and will emphasize the importance of Control Plans in product development.

During this session we will dive into the critical components of Advanced Product Quality Planning (APQP) and Control Plan (CP) and their pivotal role in the automotive industry. You will gain a comprehensive overview of APQP/CP methodologies and their significance in ensuring product quality and compliance.

Key topics include:

- Understanding APQP/CP: Dive deep into the core elements and fundamentals of APQP/CP.
- Revision Insights: Learn more about the new APQP revision 3 and Control Plan manuals.

Speaker Bio:

Angelo G. Scangas, President
Quality Support Group, Inc., Westford, MA 01960 / 978-430-7611
angelo@qualitysupportgroup.com

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 has more than 30 years of experience in the Medical Device, Automotive, Aerospace, Healthcare, and Chemical Industries working in quality systems, product development, manufacturing engineering, quality assurance, and process improvement.

Session: J1 (FDC Track)
Date/Time: Thursday, September 11, 2025; 9:40am
Location: Naples 5
Session Speaker: Jon Gawlak
Session Title: Common GMP Audit Findings

Session Summary:
Review of GMP Certification Audit Findings from drug products and OTC products. By attending this session, auditors will be aware of what the industry needs to focus on, based on these most common findings, and additionally, auditors can use these findings to update their audit checklists or to properly phrase their questions in their upcoming audits.

Speaker Bio:
Jon Gawlak has over 35 years of Quality and Project Management experience with over 29 years of leadership experience in the Pharmaceutical, Cosmetic, Personal Care, Dietary Supplements, Food, and Device industries.
Specialties: QA, QC, Supplier Qualification and Management, CMC, Quality Management, Project Management, Certification Auditing, Vendor Auditing, Internal Auditing, Analytical Testing, QC Laboratory Management

---

Session: F2
Date/Time: Thursday, September 11, 2025; 10:50am
Location: Naples 1
Session Speaker: Kristen Wagner
Session Title: Acquisitions: Give Me Chaos or Give Me Death (How Auditing Best Practices Secure a Successful Initial Launch)

Session Summary:
MedTech companies are increasingly turning to acquisitions to expand their product portfolios rather than relying solely on in-house R&D innovation. Even outside of MedTech, there are business models that grow principally by acquisition. Such acquisitions demonstrate their multi-billion-dollar value by enabling faster market entry, closure of portfolio gaps, and reduction of development spend.
This session will explore the dynamic and fast-paced world of Acquisitions from the perspective of a Supplier Quality Engineer. Attendees will learn how auditing best practices can be utilized to support a successful initial launch with a focus on patient safety, compliance, risk mitigation, and interpersonal communication.

Speaker Bio:
Kristen Wagner has an extensive background in Supplier Management, Quality, and Auditing within the Medical Device Industry, including sustaining, new product development, and acquisitions. Kristen is a Principal Supplier Quality Engineer at Boston Scientific and holds a Bachelor of Science in Materials Science and Engineering from the University of Minnesota. Beyond her professional role, Kristen is involved with the ASQ Audit Division, serving as Vice Chair – Social Media (MyASQ), and

Kitty Revolution, a volunteer-based no-kill rescue for cats, as an Event Coordinator. In her personal life, Kristen enjoys rock climbing and spending time with her cats Euridice, Apollo, and Macaroni.

Session: G2
Date/Time: Thursday, September 11, 2025; 10:50am
Location: Naples 2
Session Speaker: George Kwiecinski
Session Title: Transforming Technologies – New and Advanced Methods and Logic Using AI to Make Our Most Critical Quality Decisions

Session Summary:
Quality auditors face increasing complexity in their daily workflows, from identifying critical deviations to executing standard CAPA processes, corrective actions, and issuing ratings. While standards remain foundational, informed decisions now rely on a deeper integration of historical inspections, observations, and contextual data.
Today, both internal systems and publicly available datasets are undergoing a renaissance. New technologies, particularly AI and machine learning, are unlocking powerful use cases that go beyond compliance. These include predictive analytics, advanced risk modeling, and contextual decision support, enabling auditors to identify signals earlier, assess systemic risks more effectively, and prioritize actions more efficiently.
This session will explore how auditors can integrate AI-driven logic and emerging tools into their assessments. Attendees will learn how to harness new workflows, apply advanced logic frameworks, and interpret complex data sources to strengthen facility evaluations and improve audit outcomes. The discussion will bridge traditional quality systems with modern capabilities, offering auditors practical insights into making faster, more consistent, and more informed decisions in dynamic environments.
Speaker Bio:
George Kwiecinski is the current CEO of Global Key Solutions and an Engineer from New York, NY. He joined ASQ in 2021 and recently presented emerging technologies for audit decision-making during the May 2025 ASQ Audit Division webinar. With background and publications on the FDA's databases, he brings the unification of data and technology to the forefront of regulated manufacturing processes.

Session: H2
Date/Time: Thursday, September 11, 2025; 10:50am
Location: Naples 3
Session Speaker: Jim Shore
Session Title: Optimizing Supplier and Internal Audits with AI Intelligence

Session Summary:
Quality and Supply Chain Organizations have realized that traditional audit methods are time-consuming and reactive. They face growing regulatory demands and increasingly complex supply

chains with restrictive financial budgets. Can Artificial Intelligence (AI) offer a powerful compliance solution, transforming supplier and internal audits into proactive, data-driven processes?
This session will identify the areas and improvements that will improve audit efficiencies and how this can perform on-the-job training of auditors. We will also discuss some of the risk mitigation that must be taken.

Speaker Bio:

James “Gunny” Shore is the CQO at Quality Lean Solutions. He offers over 30 years of quality and supplier management experience working in medical devices, semiconductors, aerospace, and defense. Shore’s professional certifications include ASQ Certified SSBB, ASQ CQM/OE, ASQ CQA, and Certified Mechanical Inspector, and he is an ASQ Senior Member. He is a Certified Welding Inspector and Test Supervisor for the American Welding Society and Co-author of the book entitled “Proactive Supplier Quality Management in the Medical Device Industry,” published by Quality Press. Shore served in the U.S. Marine Corps for 15 years as a Helicopter Crew Chief/door Gunner and was Honorably Discharged at the rank of Gunnery Sergeant (E-7).

Session: I2
Date/Time: Thursday, September 11, 2025; 10:50am
Location: Naples 4
Session Speaker: Srividya Narayanan
Session Title: From Compliance to Resilience: Evolving Cybersecurity Audits for Medical Device Risk Management in the AI Era

Session Summary:

Modern cybersecurity audits for medical devices have transitioned from static compliance exercises to dynamic, risk-driven processes aligned with global regulatory frameworks like the FDA’s premarket guidance, EU MDR, and ISO 14971. This session explores how auditors can integrate AI-driven analytics and enterprise risk management (ERM) principles to address evolving threats to connected medical devices, which now account for 34% of healthcare cybersecurity incidents. The session will also address California’s CPPA mandates for annual audits of devices handling sensitive patient data, emphasizing how auditors can balance innovation with compliance in AI-powered diagnostic tools.

Speaker Bio:

Srividya Narayanan is a dedicated regulatory affairs professional with a background in dentistry, now specializing in medical devices and AI integration in health systems. She currently works with Culture Care Collective, where she contributes to AI-driven platforms to enhance community health worker interactions and provide automated guidance for clients. Her expertise includes FDA 510(k) submissions, EU MDR compliance, and quality system management. She is pursuing a Regulatory Affairs degree at Northeastern University and has a strong interest in leveraging AI/ML for healthcare and medical device oversight. In addition to her professional endeavors, she has led community outreach programs, published research, and she actively volunteers in health and fitness initiatives.

Session: J2 (FDC Track)
Date/Time: Thursday, September 11, 2025; 10:50am
Location: Naples 5
Session Speaker: Robert Thrash
Session Title: Changes to Food Safety Auditing

Session Summary:
The GFSI (Global Food Safety Initiative) is constantly evaluating food safety standards worldwide. In this session, we will review the most current food safety issues being discussed and evaluated by the GFSI.

Speaker Bio:
Robert Thrash began his auditing career in 1973 for KFC helping to develop their auditing processes. He has audited proprietary quality systems, food safety for processing plants, distribution, and animal welfare for poultry processing. In addition, Robert had been an auditor and a trainer for BRCGS, the world's largest GFSI audit scheme in the world.

END PROGRAM