Audit Division
Excellence Through Quality™

2023 ASQ Audit Division Conference Program

"The Future in Auditing"

at the Peppermill Resort Spa Casino in Reno, NV!

Our 29th ASQ Audit Division conference will deliver content that is of interest to a broad range of auditing and quality professionals. Please join us at the fabulous Peppermill Resort! The Audit Division has held our conference at this venue several times in the past and it has always been a crowd-pleaser. We have been given a room-block which offers a discounted rate.

The two days prior to the conference (Oct. 31 – Nov. 1), we are offering 2-day tutorial courses instructed by very experienced instructors who are well-known in the quality community. The cost of the pre-conference tutorials are in-addition to the cost of conference registration.

Our 2-day conference includes 3 keynotes speakers, 4 tracks of sessions to select from, Audit Jeopardy (fun!), meals, a Thursday night Gala with buffet, music and dancing, a bookstore, book signings and our program schedule gives you plenty of time to take advantage of the many networking opportunities you will have.

Register for the conference at: https://app.memberplanet.com/#/event/asqauditdivision/2023asqauditdivisionconference

The ASQ Audit Division would like to thank the **Peppermill Resort/Casino/Spa**, our **Sponsors**, **Keynote Speakers, Session Speakers**, **Preconference Workshop Instructors**, the **Staff at ASQ Headquarters**, the **Audit Division Member Leader Team** and the many **Volunteers** that make our conference a success!

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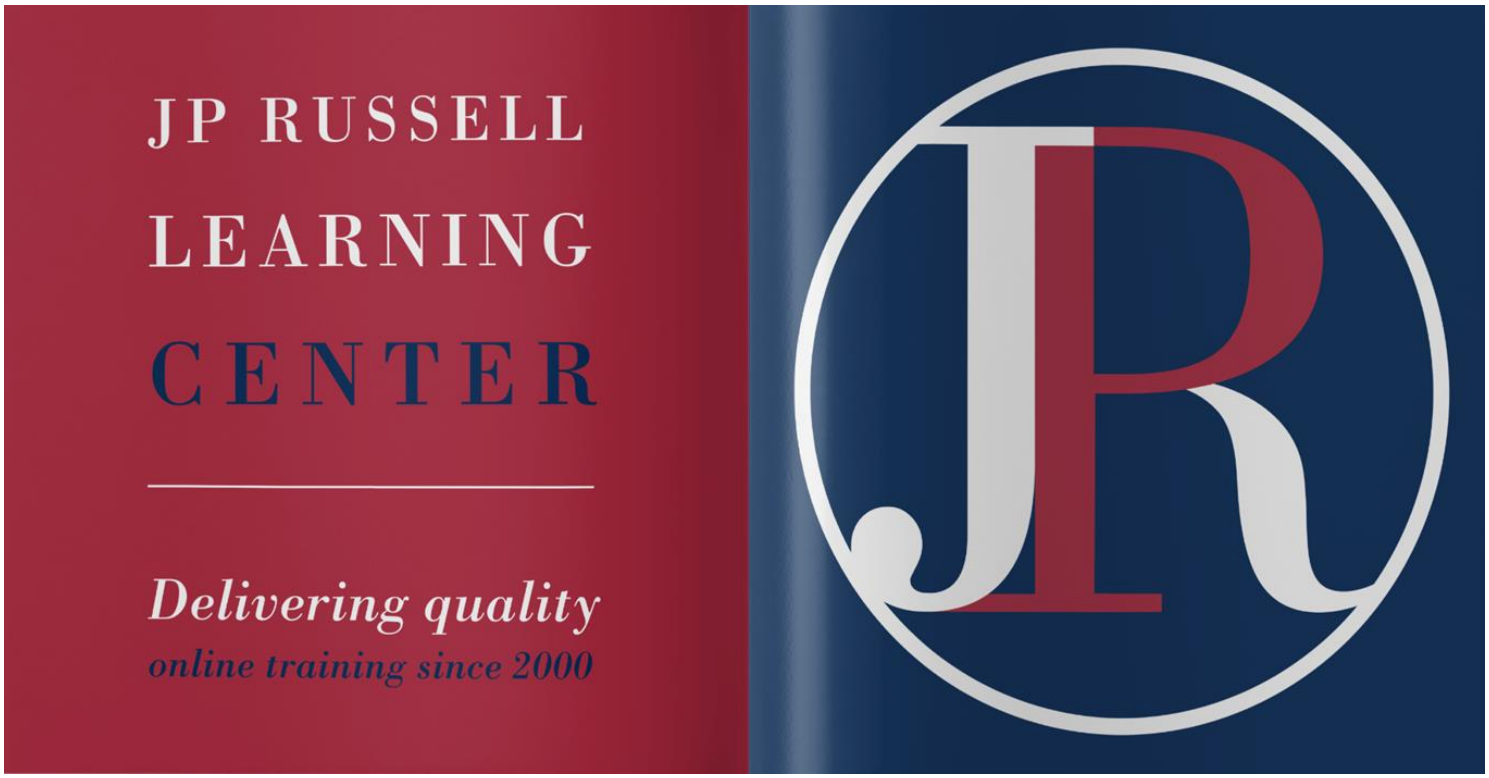

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Key to Performance Improvement

Rai Chowdhary – KPI System

ASQ Statistics Division

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Conference Overview

Tuesday, October 31	
8:00AM – 5:00PM	2-Day Preconference Tutorials Day 1

Wednesday, November 1	
8:00AM – 5:00PM	2-Day Preconference Tutorials Day 2
1:00PM – 5:00PM	Conference Registration and Conference Bookstore Open

Thursday, November 2	
8:00AM – 8:15AM	Welcome, Announcements, Keynote Introduction
8:15AM – 9:15AM	Keynote Speaker – Lance Coleman
9:15AM – 9:30AM	Break - snacks
9:30AM – 11:00AM	1.5-hour Sessions in Progress (4 to choose from)
11:00AM – 11:15AM	Break and Book Signing
11:15AM – 12:05AM	50-minute Sessions in Progress (4 to choose from)
12:30PM – 12:45PM	Lunch starts, Announcements, Keynote Introduction
12:45PM – 1:45PM	Keynote Speaker – Heather Wade
1:45PM – 2:00PM	Break and Book Signing
2:00PM – 3:30PM	1.5-hour Sessions in Progress (4 to choose from)
3:30PM – 3:45PM	Break - snacks
3:45PM – 4:35PM	50-minute Sessions in Progress (4 to choose from)
6:30PM	Gala Reception begins!
7:30PM – 10:00PM	Music and Dancing begin! (Decoy Band)

Friday, November 3	
8:00AM – 8:15AM	Welcome, Announcements, Keynote Introduction
8:15AM – 9:15AM	Keynote Speaker – Erin Urban
9:15AM – 9:30AM	Break - snacks
9:30AM – 11:00AM	1.5-hour Sessions in Progress (4 to choose from)
11:00AM – 11:15AM	Break and Book Signing
11:15AM – 12:05AM	50-minute Sessions in Progress (4 to choose from)
12:30PM – 12:45PM	Lunch starts, Announcements, Audit Jeopardy Host Introduction
12:45PM – 1:45PM	Audit Jeopardy – Hosted by Susan Gorveatte
3:00PM – 4:00PM	Annual Audit Division Business Meeting

Pre-Conference Tutorials

Using Supplier Audits to Strengthen the Partnership

2-Day Course: Tuesday Oct. 31 – Wednesday Nov. 1

Instructor: Denise Robitaille

ASQ Member Pricing: $800

Non-ASQ Member Pricing: $950

Course Description:
The level of excellence we bring to our customer relations is directly linked to the integrity of our supply chains. Without reliable suppliers, companies can't meet customer expectations. One of the most effective tools in the development and maintenance of a robust supply chain is the audit. What suppliers do you audit? How often? Who uses the results of your report? This workshop will cover selection methods, audit schedules, checklists, remote auditing, planning and conducting the audits, make-up of the audit team, the report, corrective actions, follow-up and much more. It will include exercises and opportunities to discuss best practices.

Instructor Bio:
Denise Robitaille has authored over a dozen books on quality topics, including: Remote Auditing: A Quick and Simple Guide for Management System Auditors and Managing Supplier-Related Processes.

Denise has participated internationally in standards development for over 20 years. She has served in a variety of roles, including chair of PC302, (project committee that revised the ISO 19011 guidance standard on auditing quality management systems) and is the current chair of TC176/SC1 that maintains ISO 9000. She is a Fellow of the American Society for Quality and a certified lead assessor.

She has conducted hundreds of trainings on multiple topics. Denise is internationally recognized for her work and is a frequent speaker at conferences.

ISO 13485/FDA QSR Internal Auditing

2-Day Course: Tuesday Oct. 31 – Wednesday Nov. 1

Instructor: Angelo Scangas

ASQ Member Pricing: $800

Non-ASQ Member Pricing: $950

Course Description:
This course is designed for Internal Auditors, Quality Assurance Managers, ISO 13485:2016 Implementation Team Members, Management Representatives, and individuals who wish to learn how to perform an audit to ISO 13485.

Through training, participants will learn to:

- Describe the ISO 13485 Medical Device Quality Management System (QMS) – Requirements for Regulatory Purposes standard and development process
- Understand medical device QMS terms
- Describe the intent and requirements of ISO 13485:2016
- Determine the objective evidence needed to demonstrate conformity to ISO 13485:2016
- Apply the process approach and Plan-Do-Check-Act (PDCA) methodology
- Describe the relationship between ISO 13485:2016 and applicable regulatory requirements
- Apply the principles, processes, and methods of auditing
- Demonstrate the activities involved in preparing for an audit
- Determine an effective audit in the context of the auditee's organizational situation
- Apply effective audit skills and practice personal behaviors necessary for an effective and efficient conduct of a management system audit

Day 1 Course Introductions and Objectives

- Lecture: Overview, Auditing and the Standard Requirements
- Lecture: Discuss process-approach and metrics-driven audits
- Exercise: Construct a process map (inputs, outputs, measures) and assign ISO 13485 / FDA CFR 21 part 820 requirements)
- Lecture: Discuss the requirements/principles of ISO 13485/FDA CFR 21 Part 820 and how to integrate in a successful audit program

Day 2 Review of Day One Activities

- Lecture: Review the ISO 13485:2003 / FDA CFR 21 part 820 requirements
- Discuss implications to your company
- Lecture: The Audit Process (planning, performing and reporting an audit)
- Lecture: Preparing/Planning the audit – key criteria of a process audit
- Exercise: Developing an Audit Checklist
- Lecture: Conducting a process-based and metrics-driven audit
- Exercise: Auditing the Organization Case Study Scenarios
- Lecture: Audit report – key elements and documentation requirements
- Lecture: Audit Nonconformance
- Exercise: Auditing the Evidence Sample Documents and Records

Instructor Bio:
Angelo 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 a 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.

Writing Effective Audit Reports

2-Day Course: Tuesday Oct. 31 – Wednesday Nov. 1

Instructor: Denis Devos

ASQ Member Pricing: $800

Non-ASQ Member Pricing: $950

Course Description:
This two-day course is for novice and experienced auditors who are looking to increase the effectiveness of their audit reports. Many organizations feel like their internal audits do not get the management visibility and attention that they deserve. A more professional approach to internal audit reporting can help to improve this condition. A common shortcoming of many audit reports is that they are only a list of nonconformances and do not accurately reflect everything that was examined during the audit, leading the reader to wonder if all processes and requirements were examined. Participants will learn how to write effective non-conformance reports and Opportunities for Improvement and how to compile it together into a comprehensive audit report that is easy to read and understand. This course is ideal for both new and experienced internal auditors. Every organization has compliance obligations that it must manage effectively.

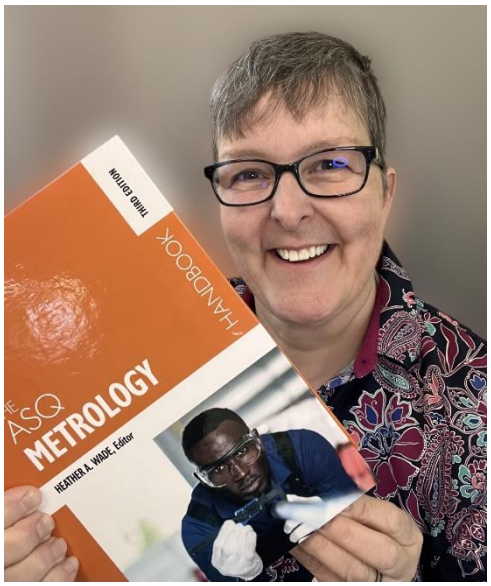
Instructor Bio:
Denis Devos is a professional engineer with a long career providing QMS training and advisory services. He is a Fellow of the ASQ, the current Chair of the ASQ Quality Management Division and is a recognized expert in the application of the ISO 9001, IATF 16949 and ISO 14001 Standards. 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.

Keynote Speakers

Nov. 2, Morning, Conference-Opening Keynote: Lance Coleman

Lance B. Coleman Sr. has over 25 years of leadership experience in the areas of quality engineering, Lean implementation, quality and risk management in the Medical Device, Aerospace, and other regulated industries. He has a degree in Electrical Engineering Technology from the Southern Polytechnical University in Marietta, GA and is an American Society for Quality Senior Member as well as, Certified Quality Engineer, Quality Auditor, Supplier Quality Professional, and Six Sigma Green Belt. He is also an Exemplar Global certified ISO 9001:2015 & ISO 13485:2016 Lead QMS Auditor. Lance is the author of three books – "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 "The Customer Driven Organization: Employing the Kano Model (Productivity Press 2014)" and as well as, many articles on quality, Lean implementation and risk management. He is the Editor for the 5th Edition of the Quality Auditing Handbook to be released in2020. Lance was 2018 ASQ Lean Enterprise Division Chair and 2016-2018 Chair of ISO TAG 302 –Auditing Management Systems. He also is presently or has been an instructor for the ASQ FMEA, Certified Supplier Quality Professional and Certified Quality Auditor exam preparatory courses. He has presented, trained, and consulted throughout the United States and abroad.

Nov. 2, Afternoon Keynote: Heather Wade



Heather is an internationally recognized metrology subject matter expert & a popular presenter. She is ASQ-MQD Immediate Past Chair and an A2LA ISO/IEC 17025 Assessor for testing and calibration labs. She is an active member of several international metrology organizations and is editor and co-author of ASQ's Metrology Handbook, 3rd Edition. A graduate of University of Michigan with a B.S. in Biology, Heather has worked as a microbiologist, physical test engineer, and chemist before moving full-time into metrology. With her nearly 30 years professional experience, she provides "Pain Relief for Measurement Headaches" for her consulting clients.

Nov. 3, Morning Keynote: Erin Urban

Recognized as a "Top 15" Coach in Houston TX by Influence Digest, Erin Urban is a sought-after certified professional success and neuro-leadership coach. Her **mission** is to leverage brain science to help leaders and teams break through barriers to unlock potential. Her **passion** is to help you create success on your terms.

Erin partners with you to leverage your Zone of Genius so you can experience more impact with less stress.

Erin's impact is felt as a frequent keynote speaker and in delivering 1:1 coaching, corporate consulting, and group learning events. She is the host of the Career Coffee Chat live show and the author of the bestselling book, "*Elevate Your Career: More Impact + More Income*".

Erin is a Forbes Coaches Council Member, neuroscience nerd, ICF-Certified Coach, and certified in Leadership Psychology. She has a proven career in both the corporate and the private sector leading multi-generational transformational change.

Coaching: Professionals that partner with Erin enjoy success in a variety of industries, private & publicly held entities, from mid-sized companies to Fortune 500 organizations. Erin is known for her straightforward brain-based coaching that empowers clients to achieve more purpose, passion, and performance.

Speaking: Audiences from across the globe have enjoyed Erin's realistic, yet humorous, take on what it really takes to thrive in the "never normal" and achieve more impact with less stress. Erin's high-energy speaking career includes over 376+ appearances in a variety of industry conferences, workshops, and keynotes - both virtually and in-person.

Affiliations & Certifications: Certified Coach with the International Coaches Federation (ICF), Certified Leadership Coach (Rice University, Doerr Institute), Mentor - Women's Energy Network (WEN) Mentor Program, Certified Lean Six Sigma Black Belt culture change expert, Certified Leadership & Professional Development Coach (NOV CoachLAB), Leadership Psychology Certified (Cornell), Emotional Intelligence (EQ-i) and eDISC Certified Consultant in Work Style assessments.

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		Twitter: twitter.com/CoachEurban

Nov. 3, Afternoon: Audit Jeopardy Hosted by Susan Gorveatte!

Auditors love asking questions! So, join us for lunch and let your audit knowledge shine while you play the game that reverses your question-and-answer skills.

Do you have what it takes to be an Audit Jeopardy champion? Join your Jeopardy host, Susan Gorveatte, while having some fun and maybe even win some great prizes!

Conference Sessions/Technical Program

Session: A1, Thursday, November 2, 9:30 – 11:00

Session Speaker Name: Mark Durivage

Session Title: GHTF Nonconformity Grading for Audit Findings

Session Summary:

This presentation provides an alternative to the traditional qualitative nonconformity grading system subjectively rating findings as minor and major and offers an alternative risk-based approach using a quantitative system of grading audit nonconformities using a rating scale from 1-5 using a risk-based approach. This session will demonstrate how to apply quantitative audit scoring process to comply with internal audit requirements of standards and regulations.

Audit findings have been traditionally graded qualitatively using the generally accepted and widely used terms minor and major provided in ISO 17021-1 Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements. The latest edition of ISO 19011 Guidelines for auditing management systems suggests that "Nonconformities can be graded depending on the context of the organization and its risks. This grading can be quantitative (e.g., 1 to 5) and qualitative (e.g., minor, major). Minor and major audit nonconformity terminology, although widely used, their definitions are not standardized from industry to industry or organization to organization and can be somewhat subjective which frequently leads to confusion, misunderstanding, misinterpretation, and unsuitable corrective actions.

The Global Harmonization Task Force (GHTF) Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange authored by Study Group 3 provides a quantitative model based upon a numerical scoring system of rating audit nonconformities from 1 to 5 which considers product impact and other pre-established criteria. This quantitative audit scoring model can be easily adapted to satisfy the requirements of multiple standards and regulations including ISO 9001, ISO 14001, ISO 17025, ISO 45001, 21 CFR 820, 21 CFR 211, and 21 CFR 1271.

Speaker Bio:

Mark Allen Durivage has worked as a practitioner, educator, and consultant. He is Managing Principal Consultant at Quality Systems Compliance LLC, ASQ Fellow and SRE Fellow Durivage has written several books available through ASQ Quality Press, published articles in Quality Progress, and is a frequent contributor to Life Science Connect.

Quality Systems Compliance LLC supports quality management system implementation, integration, updates, training, internal and external audit support as well as FDA 483 and Warning Letter response and remediation services. Quality Systems Compliance LLC primarily works with companies in the FDA regulated industries (medical devices, human tissue, animal tissue, and pharmaceuticals) focusing on quality management system implementation, integration, updates, and training. Additionally, Quality Systems Compliance LLC assists companies by providing internal and external audit support as well as FDA 483 and Warning Letter response and remediation services.

Session: B1, Thursday, November 2, 9:30 – 11:00

Session Speaker Name: Susan Gorveatte

Session Title: Building Your AUDIT CHARACTER-istics – An Interactive Teambuilding Workshop

Session Summary:

It takes more than a roll of the dice to build a character that can be a successful auditor and it takes more than a game board to build an audit team that can tackle any audit challenge (20-sided dice anyone?). Designed for the young auditors and the seasoned young-at-heart auditors, participants in this interactive workshop will network with each other, conduct a self-assessment of their audit behaviors, get to share their own audit strengths, learn from each other and understand how to build effective audit teams to meet any challenge that any may be thrown at them.

Beware: there is fun, sharing, and learning to be had ahead!

Introduction

- Auditors are regular people - network
- Meet each other
- Commonalities – group work – SMARTIES PACKs for SMARTIEST Team, and NEW CARs for the most obscure/unique
- Share responses
- Welcome

Good audits begin with great introductions

- Introducing game Nancy Noonan SMARTIES PACKs for SMARTIEST Team, and NEW CARs for the most obscure/unique
- Share responses

Team building

- Auditors need to be great listeners and good report writers:
- Claydoh 2 min 2 min 2 min and show SMARTIES PACKs for SMARTIEST Team, and NEW CARs for the most obscure/unique
- Share responses

Traits of a Successful Auditor

- Star Wars Groups – Group Participation Activity
- Harry Potter Groups – Group Participation Activity
- Star Trek Groups- Group Participation Activity
- Self-assessment
- D&D Team group work – Select your Team
- D&D Find Your Team with each other
- Share stories and mentor/coach
- D&D Monsters – how would you approach the monster?
- Share responses

Speaker Bio:

Susan Gorveatte, President of Gorveatte Consulting Inc. is a Quality Auditor, Trainer and Coach working with businesses to demystify the ISO 9001 Standard. Susan has worked more than twenty-five years in Quality Management blending the right amount of art and science needed to create a formula to success for organizations to consistently meet customer expectations through positive engagement of their workforce.

Susan trains Internal and Lead Auditors across North America and currently resides in Nova Scotia, Canada.
She has Lead Auditor Training ISO 9001, AS9110B, AS9100C, ISO 14001 and Certified Safety Officer.
Susan currently travels throughout Canada and the US working with clients facilitating quality management programs in an effort to improve and grow their business processes so they may achieve their quality goals through international recognition.

Session: C1, Thursday, November 2, 9:30 – 11:00

Session Speaker Name: Brian Wish

Session Title: Communication: The Key to a Successful Audit

Session Summary:

Successful audits have one thing in common: good communication. This session will provide a brief theoretical foundation of the communication loop, then apply the theory to actual auditing practice. Moving to a tactical level, the session will cover specifics communication touchpoints relevant to all audits. Examples will demonstrate how clear and constant communication with the audit client and auditee can lead to success, while lack of communication can end in disaster.

The communication loop illustrates how communication is more than just talking. A sender must compose/encode the message and pick an appropriate channel. Then, the receiver must receive and decode the message. In best practice, communication is a closed loop where the receiver transmits their own message back to the sender as feedback. In audit terms, communication is employed with the audit client and the auditee with nested and continuing loops. Choosing the right channel, properly encoding the message, and demanding acknowledgement and feedback ensure that message are heard, understood, and actioned.

Auditors can incorporate communication touchpoints with the auditee into their standard work during three phases: Planning, Fieldwork, and Post-Audit. During planning, touchpoints include initial scheduling conversations, formal notification, information requests, pre-audit meetings, and schedule development. During the audit, ongoing communication during the audit day, end of day wrap-ups, and clarification meetings complement the opening and closing meetings, ensuring "No Surprises." After the audit, if there are corrective actions required, communication well before due dates can facilitate acceptable action plans, as well as discussions relating to action plan verification/validation.

Standardized communication touchpoints with the audit client can also facilitate customer satisfaction. Depending on the type of audit, during the Pre-Audit phase the client is kept appraised of scheduling and progress. Some situations require updates to the client daily as the audit occurs. After the audit, audit reports and other feedback to the client provides information needed for decision-making. Minimizing communication may make the audit client wonder what they are paying for.

Speaker Bio:

Dr. Brian E. Wish leads standing teams for both supplier (second-party) QMS and internal (first-party) Environmental, Safety, and Health (ESH) auditing at Lockheed Martin Aeronautics, and is recognized as an Associate LM Fellow. He has previously led the internal QMS audit team. He is certified for third-party audits by Exemplar Global (QMS Lead Auditor) and Probitas (IAQG Aerospace Experienced Auditor), and is also an IAQG Other Party Assessor. He holds a PhD from the University of Texas at Arlington, teaches graduate classes at Tarleton State University, and is a Colonel in the US Air Force Reserve.

Session: D1, Thursday, November 2, 9:30 – 11:00

Session Speaker Name: Rai Chowdhary

Session Title: Essential Tips and Skills for Auditing Suppliers in Asia (Focus Country – India)

Session Summary:

Why learn Tips and Skills for working with / auditing suppliers in India?

Like it or not - the global business center of gravity is shifting more towards Asia, and India is (and will be increasingly) a large player on the world stage. This is true in services, but now India is set to become a manufacturing hub. There can be a significant quality / performance gap – if you are not careful, and auditing properly can help.

This session will cover Five Tips and Skills that will be of immense value in Auditing suppliers.

Starting with a little bit of historical perspective on the march of India / Indian civilization through the ages we will come to the current state of affairs. We take a look at the Indian diaspora, and how it is emerging on the global stage as a manufacturing AND services hub. Then we will identify the types of folks you are likely to encounter as an auditor, and their responses to the various questions you might ask them as part of the audit.

Supported by firsthand / experiential learning (based on actual audits we have conducted in the past) – the attendees will see / experience what it would be like to audit a supplier from India – covering three different kinds of scenarios / companies.

Speaker Bio:

Rai Chowdhary, CEO – The KPI System

Rai 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. Graduate study was in Materials Science. He holds several ASQ Certifications: Six Sigma Black Belt, CQE, and CMQ/OE. Rai is also a Lead Auditor for ISO 9001, 13485, and 27001. He serves on standards development committees (ISO TC 176, among others) and was recognized as US Expert in Organizational Change Management (ISO 10020).

Session: A2, Thursday, November 2, 11:15 – 12:05

Session Speaker Name: Tatiana Miranda

Session Title: FSMA and Dietary Supplements: How to Audit

Session Summary:

Dietary Supplements audits in the US are currently under CFR 111 standards, however after the Food Safety Modernization Act was launched, requirements that were issued under CFR 117 are applicable to dietary supplements, with certain modifications. Due to the pandemic, the FDA slowed down inspections and requesting for these requirements, but now has ramped up and will keep going this route in the future. This session will go over the modifications from CFR 117 that are applicable to CFR 111 and the dietary supplement industry, and tools and resources will be shared to be better prepared when auditing under these modifications.

In this session, we will present in an organized manner the modifications of FSMA (CFR 117) that are applicable to dietary supplements industry (CFR 111). Starting with clarification on FSVP requirements (CFR 1.5) for receiving facilities or dietary supplement manufacturers that distribute to both Foods and Dietary Supplements companies.

We will also demonstrate the FDA's Food Defense Plan Builder® that can be used in the Dietary Supplement industry and what to look for during an audit of this plan as per CFR 121 regulation. We guide through the FDA interpretations of 'intentional adulteration' in the dietary supplement industry under FSMA as well as how to evaluate the regulation applicability to dietary supplement manufacturers and dietary ingredient suppliers.

And to close this session, we will discuss the modified requirements for Food Safety Plans and Hazard Analysis for the Dietary Supplement Industry. While is clear that dietary supplement manufacturers may be exempt from CFR 117, dietary ingredients manufacturers are not. During this presentation, we will highlight the key requirements of CFR 117 subpart C required for dietary ingredients suppliers and receiving facilities that will make a dietary supplement. Auditors will learn what documentation should be in place and what the dietary ingredient manufacturers need to do to be compliant with this part of the regulation.

Speaker Bio:

Tatiana Miranda is a QA Manager-GMP Audits at Unilever. She manages US GMP compliance and partner with dietary supplement businesses as well as conducts GMP audits to ensure the suppliers' GMP compliance. She has experience in supporting and implementing FSMA, FSVP, ISO, BRC and NSF standards. Before Unilever, Tatiana was a Quality Engineer for Nutrilite/Amway, FSQA Manager with Sabra Dipping Co. and Quality Engineer for SAB-Miller Breweries. Tatiana has a B.S. in Food Engineering and a MS in Food Science. She is an ASQ' CFSQA, PCQI Lead Instructor, HACCP Trainer by the IHA, and adjunct faculty member at Chapman University.

Session: B2, Thursday, November 2, 11:15 – 12:05

Session Speaker Name: Denis Devos

Session Title: I Hate Turtle Diagrams (So I'm Going to Teach You How to Do Them Properly)

Session Summary:

Many organizations use a Turtle Diagram as their model for defining processes. The presenter has seen far too many examples of incorrect Turtle Diagrams. If you have to use a Turtle diagram, at least use it correctly! This presentation will also show participants how flowcharts are an easier and more effective model for defining processes.

ISO 9001 requires that organizations define their key business processes, along with inputs, outputs, and measurables. Many organizations fulfil this requirement using a Turtle Diagram process model. This presentation will highlight the weaknesses in Turtle Diagrams, and then go on to teach participants how to properly complete each box of the Diagram.

The most common deficiencies with Turtle Diagrams are the (mis)use of the Inputs and Outputs boxes, along with a lack of specificity around "how" work with performed, and "who" participates. This presentation will explain the meaning of those boxes, along with how to avoid the most common pitfalls in completing them.

Finally, once a firm understanding of the Turtle Diagram is accomplished, the presenter will show a flowcharting alternative to the Turtle Diagram which is simpler to understand and use and is a more accurate representation of a process.

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 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 recently-published ASQ Certified Quality Auditor Handbook, Fifth Edition.

Session: C2, Thursday, November 2, 11:15 – 12:05

Session Speaker Name: Ernie Booth

Session Title: Unleashing the Power of Automation: Elevating Audit Program Management

Session Summary:

Discover how you can transform your audit program management from mundane spreadsheets to dynamic automation tools. Join us as we explore the benefits, opportunities, and advancements available in the realm of technology. From streamlining manual activities using SharePoint list applications with automated workflows, to leveraging the immense potential of database solutions linked by Application Program Interfaces (APIs). Don't miss this insightful session where we'll unlock the secrets to optimizing process performance and maximizing efficiency in audit program management.

Speaker Bio:

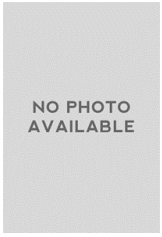
Professional Experience: Ernie Booth is the Director of Supplier Quality Auditing for Business Excellence Professional Consulting (BEPC, Inc.) and has been with BEPC since 2020. He leads a group of quality system auditing professionals based in North America, Europe, and the Asia Pacific region. Prior to BEPC, Ernie has over 20 years' experience with Johnson & Johnson medical device quality and compliance including 6 years' experience implementing requirements for combination products (medical devices combined with drugs).

Education & Certifications:

• BS degree in Chemistry from Angelo State University
• American Society for Quality (ASQ) certifications as a Quality Engineer (CQE), Quality Auditor (CQA) and Manager of Quality/ Organizational Excellence (CQM/OE)

Fun Facts/What you did not know: Ernie served 27 years (6 years active, 21 years reserve) with the US Navy including service as nuclear power trained submarine officer and finished his service with the US Navy's Space and Naval Warfare Systems Command as chief of staff for naval reserve program personnel. He retired from the US Navy as a Captain (O-6).

Session: D2, Thursday, November 2, 11:15 – 12:05



Session Speaker Name: Colleen McGuigan

Session Title: Malcolm Baldridge Examining as Advanced Auditor Training

Session Summary:

While there are many courses out there to teach people to become auditors, there are very few that seek to improve the skills of already good, experienced auditors. Using the Malcolm Baldrige criteria and examination methods is the best way I have found to take people's auditing to the next level.

Using the Wisconsin state Baldrige-based award program as an example, I will explain how Examiner training, Independent and Consensus Reviews, and Site Visits work to improve the way an auditor will return to audit to ISO 9001 or other standards.

1. Introduction
2. Explanation of Baldrige Criteria
3. Training – how it improves auditors
4. Independent Review – how it improves auditors
5. Consensus Review – how it improves auditors
6. Site Visit – how it improves auditors
7. Overall benefits and how to volunteer
8. Questions

This presentation would be unique in that many who volunteer to be Baldrige Criteria Examiners pointedly comment that what they do is Examining, not Auditing. However, there are many ways that, especially ISO 9001 auditing, has become more and more like Baldrige Criteria Examining since the 2015 version of ISO 9001 was released.

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. Colleen's expertise expands beyond quality systems. She has also made contributions to business excellence through her work with the Baldrige program and the Wisconsin state Baldrige-based award program.

Session: A3, Thursday, November 2, 2:00 – 3:30

Session Speaker Name: Angelo Scangas

Session Title: Advanced Product Quality Planning (APQP) – Best Practices and Auditing Techniques

Session Summary:

The APQP process defines a methodology for ensuring that the product development processes deployed throughout the organization are fully integrated phased processes that extend from concept and design through manufacturing process planning and execution, and on into product use, service, and customer feedback. The PPAP (Production Part Approval Process) is an output of APQP confirming that the production process has demonstrated the potential to produce products that consistently fulfill all requirements at the customer demand rate.

This presentation provides a brief overview of Advanced Product Quality Planning (APQP) and its relationship to PPAP along with an overview of the core tools used in PPAP (FMEA, Control Plan, MSA, and Process Capability). We will also discuss the tools/techniques for auditing this process.

An ever-growing number of companies must comply with Advanced Product Quality Planning (APQP) requirements. Even those that are not subject to a compliance mandate recognize the APQP process as a product development best practice that improves performance for new product introduction. To implement APQP effectively, companies must account for a series of key considerations that will determine the success of the initiative and ultimately the performance of future product launches.

This presentation provides valuable information and examples for the successful implementation of the APQP process at companies of all sizes and across industries. In addition, this presentation will provide effective techniques for conducting effective audits.

Learning Objectives

- Discuss the key phases of APQP
- Integrate compliance requirements with auditing techniques
- Demonstrate knowledge of APQP and how it relates to the Quality System
- Describe the importance of APQP to successfully implement the launch of a new product

Speaker Bio:

Angelo 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 a 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.

Session: B3, Thursday, November 2, 2:00 – 3:30

Session Speakers' Names: Lance Coleman and Kristen Wagner

Session Title: The Importance of Scope in Successful Supplier Audits

Session Summary:

Increased emphasis on supplier control in federal regulations along with various industry specific quality management system standards such as ISO 9001, ISO 13485, AS 9100, IATF 19649, and API-Q1 has made conducting effective supplier audits more important than ever. A critical attribute of the successful supplier audit is proper scoping. Session attendees will be taken through key aspects of the four phases of auditing – planning, executing, reporting, and closure – all from the perspective of supplier auditing, with an emphasis on application of proper scope.

In our current global economy, more than 50% of value creation is achieved outside of an organization's walls, or through their suppliers. In the United States, recent studies show that 100% of manufacturers include at least one element of their finished product that is obtained from outside of their organization. With this being the case, along with the increased emphasis on control in federal regulations along with various industry specific quality management system standards such as ISO 9001, ISO 13485, AS 9100, IATF 19649, and API-Q1 has made conducting effective supplier audits more important than ever. A critical attribute of the successful supplier audit is proper scoping.

Conducting a successful supplier audit can be used to identify, assess, and mitigate organizational risk. Audits can be combined with Lean and Six Sigma methodologies to help drive supplier improvement. They can help foster communication and build relationships (unfortunately, the opposite can also be true). Session attendees will be taken through key aspects of the four phases of auditing – planning, executing, reporting, and closure – all from the perspective of supplier auditing, with an emphasis on application of proper scope.

Speakers' Bios:

Lance B. Coleman Sr. has over 25 years of leadership experience in the areas of quality engineering, Lean implementation, quality and risk management in the Medical Device, Aerospace and other regulated industries. He has a degree in Electrical Engineering Technology from the Southern Polytechnical University in Marietta, GA and is an American Society for Quality Fellow as well as, Certified Quality Engineer, Quality Auditor, Supplier Quality Professional, and Six Sigma Green Belt,. He is also an Exemplar Global certified ISO 9001:2015 & ISO 13485:2016 Lead QMS Auditor. Lance is the author of three books – "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 "The Customer Driven Organization: Employing the Kano Model (Productivity Press 2014)" and as well as, many articles on quality, Lean implementation and risk management. He is also the Editor for the 5th Edition of the ASQ Certified Quality Auditor Handbook (Quality Press 2020). Lance was 2018 ASQ Lean Enterprise Division Chair and 2016-2018 Chair of ISO TAG 302 –Auditing Management Systems. He also is presently an instructor for the ASQ Certified Supplier Quality Professional and Certified Quality Auditor exam preparatory courses as well as, the ASQ Lean Foundations and Auditing for Improvement courses. He has presented, trained and consulted throughout the United States and abroad. Lance is currently a Director of Quality Assurance and Regulatory Affairs for IDEX Health and Science, LLC in Oak Harbor, Washington.

Kristen Wagner has over 10 years of experience in the areas of quality engineering, supplier quality, and supplier auditing in the Medical Device industry. Her supplier portfolio includes component and sourced finished device suppliers covering Contract Manufacturers (CM), Original Equipment Manufacturers (OEM) and Non-Medical (NM) suppliers. In addition, Kristen Wagner has experience as Supplier Quality lead within the acquisition space. Kristen has a Bachelor of Science in Materials Science and Engineering from the University of Minnesota – Twin Cities. She currently sits as the Vice Chair – Social Media for the ASQ Audit Division. Kristen is a Senior Supplier Quality Engineer – Sourced Finished Medical Devices (Peripheral Interventions) at Boston Scientific in Maple Grove, MN supporting new acquisitions and sustaining projects. Outside of work and ASQ, Kristen is an Event Coordinator and Foster for Kitty Revolution, a volunteer-based no-kill rescue for cats in the Twin Cities, and a HoA Director. She is an avid rock climber and 'Peloton-er' who loves to cook, read, and spend time with her cats – Euridice and Apollo.

Session: C3, Thursday, November 2, 2:00 – 3:30

Session Speaker Name: Erin Urban

Session Title: More Impact, Less Stress – Wire Your Brain for Leadership Success

Session Summary:

You may have noticed that there isn't a 'new normal' yet. In fact, most leaders are finding the ever-evolving workplace challenging and sometimes chaotic. The workplace paradigm is shifting. We aren't quite sure what the future of work looks like, yet we know that doing what we've always done isn't working. Join certified neuro-leadership coach, Erin Urban, in a lively discussion about how to effectively manage the NOW and elevate your leadership style for what's NEXT.

Discover essential skills that future-proof your leadership and ensure greater influence with less stress. Create authentic alignment across your personal and professional activities to unlock your zone of genius for long-term impact and fulfillment. Reveal key steps to reduce friction in your work life by connecting what you do with who you are. Take away strategies that uplift your professional path and elevate your leadership presence far beyond this session.

We will focus on the following areas to uplift your leadership in the evolving workplace:

1. Connect key skills that empower you to increase your leadership influence.
2. Learn how to shift your leadership mindset to tackle tough challenges and thrive.
3. Discover key actions that elevate your executive presence and ensure your impact.

Speaker Bio:

Recognized as a "Top 15" Coach in Houston TX by Influence Digest, Erin Urban is a sought-after certified professional success and neuro-leadership coach. Her **mission** is to leverage brain science to help leaders and teams break through barriers to unlock potential. Her **passion** is to help you create success on your terms.

Erin partners with you to leverage your Zone of Genius so you can experience more impact with less stress.

Erin's impact is felt as a frequent keynote speaker and in delivering 1:1 coaching, corporate consulting, and group learning events. She is the host of the Career Coffee Chat live show and the author of the bestselling book, "*Elevate Your Career: More Impact + More Income"*.

Erin is a Forbes Coaches Council Member, neuroscience nerd, ICF-Certified Coach, and certified in Leadership Psychology. She has a proven career in both the corporate and the private sector leading multi-generational transformational change.

Coaching: Professionals that partner with Erin enjoy success in a variety of industries, private & publicly held entities, from mid-sized companies to Fortune 500 organizations. Erin is known for her straightforward brain-based coaching that empowers clients to achieve more purpose, passion, and performance.

Speaking: Audiences from across the globe have enjoyed Erin's realistic, yet humorous, take on what it really takes to thrive in the "never normal" and achieve more impact with less stress. Erin's high-energy speaking career includes over 376+ appearances in a variety of industry conferences, workshops, and keynotes - both virtually and in-person.

Affiliations & Certifications: Certified Coach with the International Coaches Federation (ICF), Certified Leadership Coach (Rice University, Doerr Institute), Mentor - Women's Energy Network (WEN) Mentor Program, Certified Lean Six Sigma Black Belt culture change expert, Certified Leadership & Professional Development Coach (NOV CoachLAB), Leadership Psychology Certified (Cornell), Emotional Intelligence (EQ-i) and eDISC Certified Consultant in Work Style assessments.

Session: D3, Thursday, November 2, 2:00 – 3:30

Session Speaker Name: Tom Taormina

Session Title: Forensic Investigations – The New Standard of Auditing

Session Summary:

Traditional management systems auditing is wholly inadequate for the future of business success. Since the current system of QMS auditing was devised, it has evolved into a passive system of conformance verification with little proactivity in determining process effectiveness.

Forensic Investigations were developed when QMS audit techniques were applied to expert witness investigations in products liability and organizational negligence litigation. They were expanded to prove whether a company exhibited an appropriate or inappropriate standard of care in introducing products and services to the stream of commerce. The outcome is identifying the root cause of nonconformances, not the symptoms.

Forensic Investigations not only look for compliance with standards but examine processes for their effectiveness and ability to identify and remove risk. They are also used to determine the competence of the process operators.

Forensic Investigations are a non-traditional approach for evaluating process effectiveness and determining risk within an organization. It is an amalgamation of experiences derived from the author's 50+ years as a quality control engineer, consultant, and trainer having worked with more than 700 companies. And is the product of nearly two decades as a consulting and testifying expert witness in products liability and organizational negligence.

Used as a business process excellence tool, application of forensic investigations within an organization can:

• Create processes that are virtually risk free

• Put metrics in place to track potential risks

• Achieve the goal of zero outgoing critical defects

• Continually evaluate process operators' competence

As a risk avoidance tool, forensic investigations:

• Determine potential risks

• Assess all foreseeable risk factors

• Inculcate the tools of risk avoidance in all business processes

As a tool for determining appropriate or negligent standard of care, Forensic Investigations:

• Establish the appropriate and required duty of care

• Compare actions of an incident to the duty of care

• Build a legally compelling case for appropriate or negligent standard of care

Speaker Bio:

Tom Taormina was one of the first Quality Control Engineers at NASA's Mission Control Center. He supported all 17 Apollo Moon Missions. He went on to run three manufacturing companies successfully replacing QC with self-inspection. Over the last 50 years, he has worked with more than 700 companies as a consultant, auditor, and trainer. He has trained scores of QMS auditors and conducted hundreds of audits. For 20 years, he has provided expert witness testimony in more than forty lawsuits. Tom is the former Chair of ASQ QMD Quality Management Systems Committee. He has published 12 books on quality management.

Session: A4, Thursday, November 2, 3:45 – 4:35

Session Speaker Name: Paul Russell

Session Title: You Already Do This and You Might Not Be Aware: Describing Several Requirements of the ISO9001:2015 for those New to the Standard

Session Summary:

Context? Quality Policy? Risk-Based Thinking? Organizational Knowledge? The ISO 9001:2015 is not as alien as those new to the standard might initially think. For many companies, to exist and thrive, they most likely already have several ISO 9001 requirements under their belt. This 50-minute class will allow attendees to start looking in the right direction for discovering and organizing that existing data into satisfying the requirements of the standard.

Speaker Bio:

Paul Russell is Managing Director for QualityWBT Center for Education and the JP Russell Learning Center. For 20 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: B4, Thursday, November 2, 3:45 – 4:35

Session Speaker Name: Stephanie Gonzalez

Session Title: Back to Basics: Risk Centered Internal Audits

Session Summary:

Risk seems to be such a catch phrase these days. But how do we truly implement it into the foundation of our audits? This session will take you from audit planning to closeout, as well as follow-up of an audit. We will look at the different risk categories; risk to the audit, and risk to the organization. Reviewing these risks ensures we are getting the most out of an audit program's time and budget. We will be getting back to the basics of auditing with an emphasis on risk-based thinking.

Starting at audit planning, using data and analytics to determine the audits that need to be completed. We will review why opening and closing meetings are so important in reducing the risk of audit miscommunication and preventing lack of buy in. Look at how to make opening meetings impactful and interactive. Together we will review an audit, utilizing a case study. The case study will concentrate on a review of a partially completed audit. With time constraints, where would you have the auditor concentrate their time? We will work in teams to determine the best course of action to complete the audit. Then move into audit close out. How to use tact to get buy-in and set-up the team for success with a detailed problem statement. We will finish the session with the importance of follow-up evaluations. Risks do not vanish just because they are identified. Everything must be completed with intention and planning.

Speaker Bio:

Stephanie Gonzalez has over 20 years of Quality experience in both the Commercial and Aerospace and Defense industry. She is a Six Sigma Black Belt, Quality Engineer, and Lead Auditor with ASQ certification, as well as Lead Auditor certification for the AS9100 and ISO13485 standards.

Session: C4, Thursday, November 2, 3:45 – 4:35

Session Speaker Name: Alicia Davis

Session Title: Sensory Digital Tools and Transformations for Auditors and Industry

Session Summary:

Advances in the development for evaluating seafood quality attributes have led to the development of new digital tools to transform the seafood industry. Methods for fish freshness assessment are based on the measurement of attributes related to fish appearance, color, texture, odor, and taste. In this presentation, we will explore the roles of a qualified sensory analyst and some new digital tools and techniques used in industry.

Analytical methods for seafood assessments are based on the measurement of chemical and physical attributes related to fish appearance, color, texture, odor, and taste. As fresh seafood is highly perishable and subject to a rapid decay process. Reliable methods and techniques are required to evaluate the fish quality and spoilage.

During this presentation, two methods of evaluating seafood quality attributes will be explored. A qualified sensory analyst has the ability to perform a sensory evaluation as a subject matter expert. While a few of the new digital tools currently used in industry can perform an expert scientific sensory evaluation as well. Advances in the development of digital tools and techniques for evaluating seafood quality attributes have led to some novel instrumental techniques, such as the e-tongue, the optical nose, the electronic nose and the fish freshness meter currently used in industry. We will explore each method of evaluation and the advantages and disadvantages. We will explore how each method of sensory evaluation works and why. In either technique, we can agree that it will require some form of a highly skilled operator.

Case studies will reference the ongoing oppositions and trends with either method of seafood sensory evaluation. Resources relevant to the digital tools and abilities of the qualified sensory analyst will be on hand. Strategies and tools will allow attendees to come to their own conclusions as how to move forward in the digital age. The presentation will provide hands on activities and ongoing discussions with pre and post evaluations to define the measurable outcomes of what was implementation and learned during the presentation.

Speaker Bio:

Alicia Davis is currently a Consumer Safety Officer for The Department of Commerce. As a Certified HACCP Auditor, she conducts audits, writes reports and collects surveillance samples. She is assigned to perform sanitary inspections and lot inspections in Northern California with duties including inspecting seafood products for domestic and export while ensuring food is safe and sanitary to enter market trade. Alicia's greatest accomplishment moving from military to government employment has been the ability to still honors and support her fellow soldiers by providing seafood inspections for airlifts to our troops like herself!Alicia is a decorated Gulf War veteran and she was only one of a handful of female non commissioned officers who participated in advanced operations. She has served in CONUS and OCONUS including the Generals Dining Facility at 101st Airborne for over 7 years. Alicia was selected to assist the National Sensory Training Team for the Seafood Inspection Program. This team actively trains selected seafood inspection staff to harmonize during petroleum taint disaster emergencies. She has been an advocate for veterans and the disabled for many years. She participates in local, national, and international public awareness programs that meet the needs of the disabled and our veterans. Currently she serves as the secretary for The Veterans Employee Resource Group @ NOAA.

Session: D4, Thursday, November 2, 3:45 – 4:35

Session Speaker Name: Kellan Ilse

Session Title: Audit Nightmares: Five Real-World Supplier Stories with Lessons for Us All

Session Summary:

Supplier audits are an essential element of a robust quality management system. But what happens when things go awry? In this engaging session, we'll take you on a rollercoaster ride through five supplier auditing stories that will both entertain and educate. Each situation offers more than just shock value; we extract actionable lessons that can help you rethink your supplier audit strategy. From jaw-dropping compliance blunders to outrageous oversights, these stories illustrate the pitfalls that even seasoned auditors can fall into. By delving into these real-world cautionary tales, you'll come away with valuable insights to improve your supplier auditing program, making it a strategic asset rather than a box-checking exercise. Prepare for an eye-opening session that will redefine how you approach supplier audits.

Speaker Bio:

Kellan Ilse is a Partner at Quality Auditing LLC, a leading provider of internal & supplier auditing services across North America. He has performed hundreds of audits across a variety of quality standards in 15 countries and is a voting member of TAG 176, an Exemplar Global Certified Lead QMS Auditor for ISO 9001, 13485, and ISO/IEC 17025. Ilse is also a devoted member of ASQ where he holds a CQA, CMDA, CQE, CPGP, and CSQP certifications. Ilse received a bachelor's degree in Engineering from Bucknell University, a Masters in from USC Viterbi School of Engineering, and an MBA from NYU Stern School of Business.

Session: E1, Friday, November 3, 9:30 – 11:00

Session Speaker Name: Bill Hackett

Session Title: CAPA – Developing and Auditing the Organizational Knowledge Requirement of ISO 9001

Session Summary:

The fact that "knowledge" is the key word in clause 7.1.6 of ISO 9001:2015 and AS9100D, attests to the implication that learning must have something to do with that knowledge. Learning is gathering facts and knowledge is the application of those facts. There are various learning theories and methodologies, some which become the "flavor of the month", but all have the goal of helping to pass along significant knowledge to new generations.

Understanding what organizational knowledge will be presented considering (1) current and anticipated technologies, (2) the knowledge that allows the organization to exist, (3) within the organization, who has to know what and how much should each individual be aware of, and (4) any additional venues that will assist in continually improving the quality management system.

How an organization provides evidence of fulfilling the requirements of 7.1.6 will be discussed with practical applications. The attendee will come away with several approaches to ensuring the proper audit evidence is obtained in support of the organizational knowledge requirement of the standards. Examples of excellent approaches to organizational knowledge including the armed forces, professional sports, and basic life skills.

Since organizational knowledge is also part of the quality management system, risks to the quality management system will be presented with emphasis on U-theory and the Dunning-Kruger effect as well as the intension action gap. The prime risk will be the elimination of "tribal knowledge" and how it differs from organizational knowledge.

Attending training, conferences, and seminars can only add to both increasing new knowledge and eliminating what was the traditional "tribal" knowledge which may not be effective anymore. At times, old knowledge does get in the way of improvements. One of the risks in collecting new knowledge and making it organizational knowledge involves what is known as a "U-theory". As stated earlier, one cannot just get updated training but also has to be able to apply the gained knowledge.

Organizational knowledge is also linked to training and competency, awareness, people, and the controls in production and service provision. Those linkages provide evidence that all learning has become effective knowledge in the quality management system ending with what amounts to a simpler way for an organization to fulfill requirements.

Speaker Bio:

Bill Hackett, principal at QBD Strategies LLC in Massachusetts, has over 30 years' experience in QMS development and implementation for ISO 9001 and ISO 13485 programs. He was quality manager for Saint-Gobain R&D, served Lockheed Martin as quality consultant to the FAA, and has experience as a quality manager for electronic manufacturers and healthcare providers. Bill's capabilities include training internal auditors and conducting audits to ISO 13485 and ISO 9001 schemes. He is an Exemplar Global certified Lead Auditor and instructor for ISO 9001:2015 and ISO 13485:2016, as an associate and lead auditor for NQA-USA and Dekra.

Session: F1, Friday, November 3, 9:30 – 11:00

Session Speaker Name: Heather Wade

Session Title: Help! I Need a Competent Calibration Vendor!

Session Summary:

Valid metrological traceability of measurement resources is a key requirement of both ISO 9001 and ISO/IEC 17025. Ensuring this unbroken chain of calibrations is both a risk-reduction practice and a fundamental basis of quality measurements. A common audit and assessment deficiency is not using appropriate & competent calibration vendors and not having calibrations that are traceable to international standards. This is often because folks do not know how to find and evaluate calibration vendors and then how to request calibrations to get what they need. This session will provide easy-to-follow steps for searching and evaluating competent calibration vendors as well as a take-away tool for requesting calibration services.

Both ISO 9001 and ISO/IEC 17025 require that critical measurement equipment be calibrated with their metrological traceability to international standards. Ensuring this unbroken chain of calibrations is both a risk-reduction practice and a fundamental basis of quality measurements. A common audit and assessment deficiency is *not* using appropriate & competent calibration vendors and ***not*** having calibrations that are traceable to international standards. This is often because folks do not know how to find and evaluate calibration vendors and then how to request calibrations to get what they need. This presentation will include the official definitions of calibration and metrological traceability. Attendees will learn how to search and evaluate calibration vendors. The attendees will then learn the details to include in calibration requests so the appropriate calibration is performed.

Learning Objectives:

At the end of this session, participants will be able to:

1. Search for competent calibration vendors;
2. Evaluate differences between calibration vendors;
3. Request calibrations using a standardized format.

4.

Speaker Bio:

Heather is an internationally recognized metrology subject matter expert & a popular presenter. She is ASQ-Measurement Quality Division's Immediate Past Chair and an A2LA ISO/IEC 17025 Assessor. She is an active member of several international metrology organizations and is editor and co-author of ASQ's Metrology Handbook, 3rd Edition.

A graduate of University of Michigan with a B.S. in Biology, Heather has worked as a microbiologist, physical test engineer, and chemist before moving full-time into metrology. With her nearly 30 years professional experience, she provides "Pain Relief for Measurement Headaches" for her consulting clients.

Session: G1, Friday, November 3, 9:30 – 11:00

Session Speaker Name: Anthony DeMarinis

Session Title: Auditing for Value and Continuous Improvement; Taking Full Advantage of Management's Power Tool

Session Summary:

Most auditees believe an audit is "Good" if the auditor finds nothing, so they have no extra paperwork or workload for their existing scarce resources. However, if issues remain hidden, these audits add no value & may even increase risks. On the other hand, "Bad" audits, especially if conducted by inexperienced auditors, can misdirect scarce resources to trivial busywork and add needless complexity to processes. Unfortunately, most audits fall into the 2nd category where a list of non-conformances results in fixing symptoms. This leads to similar issues found in subsequent audits. Sound familiar?

There has been a dramatic change in audit philosophy since 1988. Today, compliance is (or should be) the norm for most organizations…If not, WHY not? Management doesn't just want compliance, they want cost effective compliance, waste reduction and higher profits. In addition to looking for compliance, auditors should also target waste and non-value-added (NVA) activities, and report actionable findings directed at the root cause(s) of any non-compliance. The primary purpose of an audit is to benefit the Auditee…to help them do whatever they do better. In value added auditing, the auditors also examine the metrics used by the Process Owners to evaluate their own performance and the need for improvement. If the metrics are customer and compliance focused, then activities and goals will align with improved customer service, procedural compliance, safety, etc.

This session examines the differences between compliance-only auditing and value-added auditing. If the Audit Program goals are not aligned & linked to the strategic Organization Goals, the audit program is not designed to add value. If the only goal of the audit program is to comply with the requirements in a standard and get audits done per the schedule, then the real benefit of this management power tool is wasted (similar to using a circular saw only to make noise…which it does very well). In the hands of a master, there is no limit to the value a tool can create.

Speaker Bio:

Tony has BS degrees in Biology & Microbiology and a MS in Quality Management. He is currently an independent Consultant for the medical device and pharmaceutical industries. He is ASQ Certified Quality Auditor, Certified BioMedical Auditor, Certified Manager of Quality and Organizational Excellence, Certified 6Sigma Black Belt and Certified Pharmaceutical GMP Professional. He is also an ASQ Fellow and teaches courses for Root Cause Analysis, Quality Improvement, CQA & CMQOE certification programs for the local ASQ sections.

Tony has over 30 years of experience using enhanced Quality Management Systems, Value-Added Auditing, Failure Investigation and Root Cause Analysis for process improvement.

Session: H1, Friday, November 3, 9:30 – 11:00

Session Speaker Name: Angelo Scangas

Session Title: Auditing Risk Management - Best Practices based on the ISO 14971:2019 Standard

Session Summary:

Application of risk management to medical devices" defines a standard process for identifying risks associated with medical devices at all stages in a device's life cycle, from product design to production and postproduction use. The goal of ISO 14971 training is to develop a risk management plan that is capable of assessing, evaluating, identifying controls, and monitoring the risks associated with each life-cycle stage.
This presentation will cover the following.

- Describe the Risk Management Process as defined in ISO 14971:2019
- Identify how ISO 14971:2019 relates to ISO 13485:2016 Risk Management Requirements
- Leverage the relationship of ISO TIR 24971:2020 to ISO 14971:2019
- Effective auditing techniques

To help understand ISO 14971:2019, this presentation will use ISO 24971:2020 "Medical devices— Guidance on the application of ISO 14971" which is a companion document. Tools and techniques described in ISO 24971:2020 will be used to demonstrate how risks can be assessed and evaluated.
In addition, this presentation will review ISO 13485:2016, "Medical devices — Quality management systems —Requirements for regulatory purposes" where the concepts from ISO 14971:2019 and ISO 24971:2020 can be applied.

Speaker Bio:

Angelo 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 a 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.

Session: E2, Friday, November 3, 11:15 – 12:05

Session Speaker Name: Day Boswell

Session Title: TBD

Session Summary:

TBD

Speaker Bio:

Day Boswell has been active with the ISO standards since the first version of 9001. Her boss bought a copy, tossed it on her desk and told her to figure it out. Since then, she's been auditing, coaching, and consulting on ISO implementation for previous employers, and for client organizations. A certified CQA, Day Boswell holds lead auditor certifications in 8 different standards, and a Masters degree in communications from the University of Connecticut. Now principal for Better Days LLC, in Overland Park, KS, she helps organizations simplify so they can certify or satisfy their customers.

Session: F2, Friday, November 3, 11:15 – 12:05

Session Speaker Name: Denis Devos

Session Title: Writing Effective Opportunities for Improvement Workshop

Session Summary:

Every auditor has been trained how to write effective nonconformance statements. However, it is far less common that auditors are trained to write effective Opportunities for Improvement statements. During this hands-on workshop, participants will learn a simple and effective format for OFIs and have an opportunity to contrast their content and tone with similar nonconformance statements.

Every auditor has been trained how to write effective nonconformance statements. However, it is far less common that auditors are trained to write effective Opportunities for Improvement statements. During this hands-on workshop, participants will learn a simple and effective format for OFIs and have an opportunity to contrast their content and tone with similar nonconformance statements.

The format for Opportunities for improvements is written in three parts:

- What was observed
- Why is it a problem
- What should be done about it (if the auditor knows a better way)

The purpose of this Workshop is to introduce a format for writing Observations and reinforce the difference in writing style between Nonconformance Statements and Observations. This presentation is 45 minutes long. After 15 minutes of introducing the approach, participants have 30 minutes to try the approach by using a set of audit scenarios. Each scenario is a non-conformance, and participants will write the issue as both a nonconformance and as an opportunity for improvement. Writing issues both ways emphasizes the difference in tone between the two ways of presenting findings. Nonconformances are mandatory for correction, but OFIs are not. As a result, OFIs have to more persuasive as the auditor points out an area of risk or weakness that should be improved. As a result of attending this presentation, attendees will have learned the following: 1. Understanding the role of Opportunities for Improvement in an audit, 2. Understanding of the difference between Nonconformances and Opportunities for Improvement, and 3. Have a real technique and tool for writing Opportunities for Improvement.

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 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 recently-published ASQ Certified Quality Auditor Handbook, Fifth Edition.

Session: G2, Friday, November 2, 11:15 – 12:05

Session Speaker Name: Ray Santos

Session Title: Performing Onsite Audit Protocol

Session Summary:

Are you responsible for performing onsite audits at your facilities or suppliers' facilities? Do you ever wonder what areas in the facilities to focus on and what processes to review when you perform an onsite audit given the limited of time you have onsite? This session will walk you through being efficient in performing onsite audits and maximize your efforts.

Performing onsite audits that adds value to the organization can be challenging due to many obstacles that an organization faces such as limited resources available to help with the audits. This presentation will walk you through in what areas and processes to focus on to ensure a comprehensive onsite audit whenever you perform audits at any manufacturing facilities. The takeaway from this presentation is to share "Best Practices" and be efficient in future onsite facilities audits to objectively evaluate the overall health of the company's Quality Management Systems and ensure compliance to the ISO Quality standards such as ISO 9001.

Speaker Bio:

Ray Santos has over 25 years of experience in the Quality arena. He has experience in Quality Engineering, Quality Management Systems, Six Sigma, Calibration, and Supplier Quality. Ray brings tremendous experience working from the top technology companies in the world such as Apple, Emerson Electric, and Samsung. Ray has performed over 150+ 3rd Party Audits and has compiled some of his “Best Practices” into this presentation.

Session: H2, Friday, November 2, 11:15 – 12:05

Session Speaker Name: TBD

Session Title: TBD

Session Summary: