A blue and white logo

Description automatically generated

**LEARN**

**CONNECT**

A group of people sitting in chairs

Description automatically generatedA person looking at a piece of paper

Description automatically generated

**NETWORK**

**GET INSPIRED**

A group of people standing around a table

Description automatically generatedA person giving a presentation to a group of people

Description automatically generated

**Foreword from the ASQ Audit Division Member Leaders & Conference Team**

*We welcome you to our 30th ASQ Audit Division Conference being held Oct. 9 – 10, 2024 at the Peppermill Resort in Reno, Nevada!*

*The purpose of the conference is to provide a premiere opportunity for learning, networking, knowledge-sharing, professional development and career growth. In addition, our conference always offers entertaining activities for all to take part in, such as Audit Jeopardy where there are opportunities to test your auditing knowledge and win prizes, Sponsor Bingo, and the Oct. 9th evening Gala which is a fun networking opportunity with great food and live music.*

*We are thrilled to be collaborating with the ASQ Food, Drug & Cosmetics Division! They will have one full track of five sessions (Track E) on Day 1 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. We want to express our gratitude to the members of the Conference Team, Keynote Speakers, Pre-Conference Tutorial Instructors, Session Speakers, Sponsors, ASQ Headquarters and the Staff of the Peppermill Resort.*

**Sponsor Bingo! What Is It? How Does It Work?**

*In your conference bag, you have a Sponsor Bingo card. Please go to the registration desk if you need a replacement.*

*Just like normal Bingo, Sponsor Bingo will have a free space in the center. The rest of the boxes will be assigned to our generous Sponsors. You will need to visit their respective booths to get their bingo boxes checked off on your bingo card. When you have all the boxes filled, turn in your card at the registration desk and cross your fingers that you’re a prize winner!*

**Audit Jeopardy! Test Your Auditing Knowledge!**

*At lunch on Day 2 of the conference, our energetic and amazing Susan Gorveatte will be hosting an Auditing version of Jeopardy! Your team will be the people that are sitting at the table with you.*

*It is an enjoyable way to meet new people, work as a team to answer the questions and hopefully win some prizes!*

**Pre-Conference Tutorials**

**A person with short white hair

Description automatically generatedCORRECTIVE ACTION PROCESS: FUNDAMENTALS AND INNOVATIONS FOR OUR TIME**

**2-Day Course: Monday Oct. 7 –Tuesday Oct. 8**

**Instructor: Denise Robitaille**

**ASQ Member Pricing: $800**

**Non-ASQ Member Pricing: $950**

**Course Description:**

The past decade has brought us a global pandemic that forever altered how we work. Additionally, there have been changes in technology, increased focus on climate change and social governance. The ever-present element of risk and the need to understand its consequences continues to inform our decisions. In the past, the role of AI, remote working and digitized processes were rarely part of root cause analysis or corrective action planning.

Corrective action continues to be a vital component of any quality management system. Things happen. The ability to respond to a problem in a manner that mitigates recurrence and incorporates improvement is a hallmark of effective organizations.

This two-day workshop will provide training on the corrective action process. It will incorporate consideration of factors that weren’t yet conceived when many organizations first established their CA programs. The workshop is applicable to individuals who are new to the process as well as those who will benefit from a refresher that focuses the lens on issues like risk, new technologies, remote processes, and global considerations.

Included in the workshop will be:

·      Obstacles to the corrective action process

·     Deciding how and when to initiate corrective action

·     Role of risk throughout the process

·     Ensuring the right people are participating in the process

·       Root cause analysis

·     Corrective action planning

·     Implementation

·     Verifying both implementation and effectiveness

·     Supplier SCARs

·     Responding to customers

**Instructor Bio:**

Denise Robitaille has authored over a dozen books on a variety of quality topics including ***The Corrective Action Handbook***. She has participated internationally in standards development for over 20 years and has served in several leadership roles, including her current position as chair of TC176/SC1 the committee responsible for ISO 9000, the guidance on quality fundamentals and terminology which is the foundation for ISO 9001.

She also chairs PC302 the committee responsible for revising the ISO 19011 guidance standard on auditing quality management systems. She has facilitated the implementation of ISO 9001 for multiple organizations for over 25 years. She is a Fellow of the American Society for Quality and a certified lead assessor.

A person in a suit and tie

Description automatically generated**WRITING EFFECTIVE AUDIT REPORTS**

**2-Day Course: Monday Oct. 7 –Tuesday Oct. 8**

**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.

A person in a suit and tie

Description automatically generated**RISK MANAGEMENT WORKSHOP BASED ON ISO 14971:2019**

**1-Day Course: Tuesday Oct. 8**

**Instructor: Angelo Scangas**

**ASQ Member Pricing: $400**

**Non-ASQ Member Pricing: $550**

**Course Description:**

This course is designed for engineers, technicians, and professionals focusing on product and process risk, this course teaches you the common risk-management methods used in product design and manufacturing processes. Using case studies and interaction, you will practice identifying and analyzing potential product and process hazards using the FMEA risk analysis template.

Application of risk management to medical devices and other industries defines a standard process for identifying risks at all stages in a product’s life cycle, from product design to production and post-production use. The goal of this workshop is to develop a risk management plan that can assess, evaluate, identify controls, and monitor the risks associated with each life-cycle stage.

Learning Objectives  
Through training, participants will be able to:

·       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

·      Identify and Quantify Risks for their Organization

·      Apply Risk Management Tools and how they align with the Product Life Cycle and requirements in ISO 13485:2016

**Workshop Outline**

·       Applicable standards and normative references

·     Terms and definitions

·     General requirements for risk management system: process, responsibilities, competence of personnel, risk management plan and file

·     Risk analysis

·       Risk evaluation

·      Risk control

·      Evaluation of overall residual risk

·       Risk management review and risk management file

·      Production and post-production activities

·       Impact of the risk analysis on the QM-system

**Instructor Bio:**

**Angelo Scangas** is President of Quality Support Group, Inc., an International Consulting and Training organization. Angelo has a B.S. in Chemical Engineering, M.S. in Manufacturing Engineering and 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.

**DATA ANALYTICS AND INFORMATION SECURITY – What Every Auditor Should Know**

A person in a suit and tie

Description automatically generated**(includes selected questions based on ISO 27001)”**

**1-Day Course: Tuesday Oct. 8**

**Instructor: Rai Chowdhary**

**ASQ Member Pricing: $400**

**Non-ASQ Member Pricing: $550**

**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, include or contain references to the use of data for one or more reasons. Furthermore, it is a data driven world we live in; not only there is increasing reliance on the use of data and analytics, but the pace of data generation is astounding. According to one source\*, the amount of data created, captured, copied, and consumed worldwide from 2010 to 2025 is estimated to increase by 90X. This naturally comes with enormous information security risks as well.

\* <https://www.statista.com/statistics/871513/worldwide-data-created/>

However, the sad part is that a vast majority of the auditors (various disciplines) lack the knowhow and skills to understand enough about data, analytics, and formulating the right questions to ask during an audit – even though the standards and regulations (indicated above) specifically require use of appropriate data analysis.

Join us for a unique, timely, and engaging event as Rai shares his know-how on what every auditor should look for when examining data, its analysis, and information security.  Here are the key takeaways:

1.       The chain from events 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.       Hands on practice with numerous audit case studies and develop / create the right questions to ask in each case. You can subsequently use these while conducting audits.

3.       In class practice on (using Excel on your laptop) data set 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 ISO 27001 that are applicable to data, analytics information security, and - .

5.       Learn over 20 things you can do to boost immunity against data errors at your organization.

**Instructor Bio:**

**Rai Chowdhary** brings over 40 years of diverse experience across automotive, aerospace, life sciences, food products, and service industries. His undergraduate studies included Mechanical, Production Engineering. Graduate study was 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 1995 covering a broad range of industries and regulations; he serves on standards development committees (ISO TC 176, among others).

Rai was recognized as “Expert on WG 28 for the development of ISO/TS 10020:2022” (Organizational Change Management).

A person in a suit

Description automatically generated**THE 7 HABITS OF HIGHLY EFFECTIVE QUALITY PROFESSIONALS**

**1/2-Day Course: Tuesday Oct. 8, 1:00 pm – 5:00 pm**

**Instructor: Lance Coleman**

**ASQ Member Pricing: $200**

**Non-ASQ Member Pricing: $350**

**Course Description:**

The 7 Habits of Highly Effective People by Steven R. Covey has sold over 40 million copies worldwide and presents a principle centered approach for solving both personal and professional problems, by drawing wisdom from actual case studies and shared anecdotes around the 7 principles.

Attendees will learn during this session, Quality, auditing and Lean tools that will provide a practical means of successfully implementing each of the 7 principles on a consistent basis. Tools to be taught in support of each of the 7 principles are:

1.      Be proactive

a.       Risk management

b.       Preventive action

2.       Start with the end in mind

a.       Hoshin Kanri

b.       Improvement kata

3.       First things first

a.       LSW

b.       Quad analysis

4.       Seek win-win scenario

a.       NGT and Multi-voting

b.       Negotiation skills

5.       Seek first to understand and then to be understood

a.       Active listening

b.       Direct Observation

c.       Data analysis

6.       Synergize by combining different strengths and perspectives

a.       Successfully working in teams

7.       Sharpen the saw by continuously improving

a.       Maslow’s Hierarchy

b.       Inverse Ishikawa

c.       S.W.O.T. Analysis

**Instructor Bio:**

**Lance B. Coleman Sr**. 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.

**Keynote Speakers**

****

**Opening Keynote Speaker**

**Michael Mascaro, ESPN Producer**

**Wednesday, October 9, 2024 (8am-9am)**

Michael "Mike" Mascaro has spent his career working in sports broadcasting and producing. He has worked for ESPN for 30 years! He covers at least one game per week, keeping him traveling anywhere from 35 - 40 weeks per year. Mike will be sharing with the audience the common threads between our two professional worlds. In addition, he will be presenting the very first John F. Mascaro Scholarship Award which is named after his father. John, who sadly passed away last year, was a longtime member leader for the ASQ Audit Division, an ASQ Fellow, a leader, mentor and friend to many who led and worked on countless efforts related to quality and auditing for multiple Divisions and ASQ. John always told us how he thought that his son Mike would be an interesting Keynote for the Audit Division conference - to share how his experiences relate to quality and even auditing. We are honored to have Mike as our opening Keynote Speaker.

**A person in a suit and tie

Description automatically generated**

**Day 1 Afternoon Keynote Speaker**

**Rai Chowdhary, CEO – The KPI System**

**Wednesday, October 9, 2024 (12pm – 1pm)**

Title: The Future is Now – and – It Will Evolve!

Rai will share on a number of aspects of being an auditor such as helping auditees change for the better, winning the trust of business leaders so they will listen to you, what every auditor should know about data analytics and information security and harnessing the power of quality tools and auditing methods for financial Independence. We expect this to be an interesting keynote for all attendees!

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: 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 1995 covering a broad range of industries and regulations; he serves on standards development committees (ISO TC 176, among others). Rai was recognized as “Expert on WG 28 for the development of ISO/TS 10020:2022” (Organizational Change Management)..

**A person in a pink shirt

Description automatically generated**

**Day 2 Morning Keynote Speaker**

**Shauna Wilson, President – Amazon Consulting**

**Thursday, October 10, 2024 (12pm – 1pm)**

**Title: The Auditor's New Role: Continual Learner!**

A person that audits can find themselves stuck between a rock and hard place with continued changes in audit methods and the growing number of management standards. Choosing the right audit method can help a company meet performance and standard conformance goals.  But how does an auditor stay current on possible audit methods that ensure review of objective evidence and the growing number of different management standards? We will explore how best to consolidate multiple standard requirements like Quality and Cyber Security.

Shauna Wilson is president of Amazon Consulting, Inc. working in Quality over forty years, Shauna holds the Certus Master Auditor Certifications.  Shauna’s research in virtual team communication and development of virtual auditing methods and auditing experience has made her the leading expert in Remote Auditing. She earned an MS in Engineering focused on Organizational Performance Technologies and Instructional Design.  Shauna wrote InterneTeaming.com: Tools to Create High Performance Remote Teams and co-authored eAuditing Fundamentals: Virtual Communication and Remote Auditing.  Shauna has been featured in Quality Progress, The Auditor, and ASTD’s InfoLine.  Shauna served as the US Expert for PC/TAG302 ISO19011:2018 Auditing Management Systems Guideline. Shauna Wilson was the 2022 recipient of the ASQ Audit Division Paul Gauthier Award.

A person with her hands out

Description automatically generated**Day 2 Afternoon: Audit Jeopardy!**

**Host: Susan Gorveatte, President, Gorveatte Consulting**

**Thursday, October 10, 2024 (12pm – 1pm)**

**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, Wednesday, October 9, 9:30 – 10:20**

**Session Speaker Name: Maria Habib**

**Session Title: Internal Auditing in a Small Business: Best practices for remote audits and how MS Teams can help**

**Session Summary**:

Small businesses must meet the same requirements for ISO certification as mid-size and large businesses and resourcefulness amidst dynamic change is important to ensure successful outcomes. Did a major change create an opportunity for you to perform remote audits in your small business? This presentation will share best practices about how small businesses can ensure remote audits are run effectively, efficiently and fun. The presentation will highlight how MS Teams can be used to organize the audit’s pre and post activities, as well as other useful tips to help organize the audit process.

**Speaker Bio**:

Maria Habib has been working at IntegrityM since 2007. Currently, she is the Quality Lead of IntegrityM’s Quality Department. Before becoming the Quality Lead, she worked with Executive Leadership supporting the company’s day-to-day quality, compliance, and contracts administration operations. Maria has a Bachelor of Science in Economics and a Master’s in Public Policy from George Mason University. She is a Certified Quality Auditor and certified CMMI Associate. In October 2023, she was appointed as the Process Improvement Chair of her local ASQ section. Maria is a lifelong learner, a champion of excellence, and enjoys being a part of the ASQ community.

**Session: B1, Wednesday, October 9, 9:30 – 10:20**

**Session Speaker Name: James Pan**

**Session Title: Digital Transformation in Auditing: Tools and Techniques**

**Session Summary**:

Discover the future of auditing in our session on "Digital Transformation in Auditing: Tools and Techniques." This session explores the readily available digital tools and methodologies reshaping the auditing landscape. Attendees will learn how to utilize in-house developed digital tools to enhance audit efficiency, accuracy, and scope. We will delve into the use of data analytics to uncover insights and patterns; Discuss how to implement automated systems to streamline audit processes. Practical implementation strategies, real-world case studies, and best practices will be shared to help you integrate these technologies effectively. Stay ahead in the evolving world of digital auditing and enhance your audit capabilities with innovative, in-house solutions.

**Speaker Bio**:

James Pan has over 40 years of experience in process automation, engineering, customer training, customer services, software development, project management, quality assurance, and technology education. Since joining Emerson in 2013, he has served as the Quality Manager at the Gulf Coast Engineering Center, implementing, and managing the Quality Management System (QMS) to ensure ISO 9001 compliance. James is an ASQ certified quality auditor and an Emerson certified Safety Instrumented System (SIS) auditor.

**Session: C1, Wednesday, October 9, 9:30 – 10:20**

**Session Speaker Name: Jeff Rosaine**

**Session Title: Quality Control at the Hula Bowl**

**Session Summary**:

In January, this Quality Manager stepped outside of his norm to attend a major college All-Star Football Game, tasked with scouting and evaluating players vying to turn professional. Although a sincere novice at player evaluation, the Quality Manager found himself working alongside NFL and CFL scouts at the top of their profession. To adapt, the entire process was handled similarly to a quality audit, but one in a hyper-dynamic environment, with a constantly changing scope. Armed only with Quality Tools and the skillset from years of auditing, the Quality Manager attempted to produce accurate evaluations and valuable outputs. The whole process created an interesting Case Study, following the Plan-Do-Check-Act Cycle. This presentation will describe how the Quality Tools worked, how scouting parallels an audit, lessons learned, and finally, will use the results of the recent NFL Draft to gauge how successful the evaluations were.

**Speaker Bio**:

Jeff Rosaine is the Corporate Quality Manager for CES Energy Solutions, based out of Calgary Alberta. Jeff has been involved in Quality Auditing and Management since 1996. Since then he has earned ASQ Certified Quality Manager and Certified Quality Auditor designations and has conducted over 500 internal audits. On the football side, Jeff has participated as a player, coach, hardcore fan, and recently as an Intern with All-22 Global Scouting. Jeff loves to share experiences with other Quality professionals. In turn, he is continuously looking to gain more knowledge and learn new ideas from this same group.



**Session: D1, Wednesday, October 9, 9:30 – 10:20**

**Session Speaker Name: Rob De La Espriella**

**Session Title: Part 1 of 2: Modernizing Oversight Programs in Regulated Industries: A New Approach for Evolving Risk Landscapes**

**Session Summary**:

Today’s modern sociotechnical work environment has created the need for more dynamic, innovative approaches to oversight. Deming Prize winning team member and pioneering Nuclear Quality Assurance expert Rob De La Espriella draws from four decades of experience to offer insights into how Quality Assurance (QA) oversight teams can break from the traditional audit framework and evolve to a modern model that is far more efficient and effective. In this session, Rob will present a set of practical skills and strategies that will enhance the effectiveness of internal and external Oversight Programs in closing performance gaps and strengthening defenses, while improving safety and reliability. Take-aways from this session include access to a virtual white board that replaces audit checklists, and training on critical thinking, systems theory, risk management and advanced techniques for conducting interviews.

**Speaker Bio**:

Rob De La Espriella is a former US Naval officer and is the CEO of DLE Technical Services, LLC. Rob has over 36 years of Nuclear Quality Assurance oversight experience: he was on the Florida Power & Light team that won the Deming Prize from Japan; he was a decorated Resident Inspector with the US Nuclear Regulatory Commission; he spent 6-years as the Site Quality Manager at a nuclear plant; and, he has developed QA programs for companies such as Schneider Electric and Burns & MacDonald. Rob received recognition from the DOE for leading a QA cultural transformation at their Yucca Mountain Project.

A person with curly hair wearing glasses

Description automatically generated**Session: E1, Wednesday, October 9, 9:30 – 10:20**

**Session Speaker Names: Cathleen Howick**

**Session Title: How to Audit for Food Safety Culture**

**Session Summary**:

TBD.

**Speaker Bios**:

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

**Session: A2, Wednesday, October 9, 10:30 – 11:30**

**Session Speaker Name: Laura Halleck**

**Session Title: Strengthening Quality Culture through Internal Audits**

**Session Summary**:

Join us for a compelling presentation on the pivotal role of internal auditing in cultivating a culture of quality within organizations. Discover what defines a quality culture and explore the key drivers that bolster it, such as leadership focus on quality, ensuring credibility of the quality message, promoting peer involvement, and enhancing employee ownership and empowerment. Learn practical steps to implement these drivers effectively. Delve into how internal auditors, with their objective and independent perspective, can assess processes, controls, and compliance to identify inefficiencies and areas for improvement. Real-world examples will highlight the focus areas for internal auditors and offer actionable recommendations to foster a culture of quality and continuous improvement, resulting in enhanced organizational performance and excellence.

**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. She has an M.B.A. from University of Massachusetts Lowell, an M.S. in Industrial & Systems Engineering from Georgia Institute of Technology and a B.S. in Industrial & Management Engineering from Rensselaer Polytechnic Institute. Laura has over 20 years of experience in manufacturing, quality 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: B2, Wednesday, October 9, 10:30 – 11:30**

**Session Speaker Name: Milton Krivokuca**

**Session Title: Elements of Quality 4.0 Supporting a Digital Transformation**

**Session Summary**:

Digital transformation is not an abstract or theoretical journey. Objectives cannot be effectively developed without analyzing data to establish a baseline. Data science, various types of analytics, and the emerging of unstructured data can be confusing and intimidating for leaders faced with the challenge of “Where do we begin?” This presentation examines the proposed Quality 4.0 focused components of data analysis. The distilling of information as it flows is a process. Developing a data analysis process, along with basic quality concepts are the critical Quality 4.0 components supporting digital transformation. This presentation addresses key issues of: How data analysis performed with basic quality concepts supports the accomplishment of digital maturity? The presenter continues to research the integration of Quality 4.0 as it applies to a Digital Transformation in Industry 4.0.

**Speaker Bio**:

Dr. Milton Krivokuca, is the Interim Program Coordinator for the Master of Science Quality Assurance program at California State University Dominguez Hills, Carson, CA. He is a recognized Quality 4.0 thought leader. He has instructed master’s classes in critical thinking and quality theories at several universities. Dr. Krivokuca frequently presents results of his quality related research through papers and presentations. He is past chair of ASQ Quality Management Division, an ASQ Fellow, ASQ 2024 Grant Award, ASQ Section 700 Simon Collier Award, and Quality Magazine’s 2024 Quality Professional of the Year. Dr. Krivokuca’s degrees include an MA, MBA, and a DBA. He has earned 10 ASQ professional certifications.

A person with curly hair wearing glasses and a denim jacket

Description automatically generated

**Session: C2, Wednesday, October 9, 10:30 – 11:30**

**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!

**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: D2, Wednesday, October 9, 10:30 – 11:30**

**Session Speaker Name: Rob De La Espriella**

**Session Title: Part 2 of 2: Modernizing Oversight Programs in Regulated Industries: A New Approach for Evolving Risk Landscapes**

**Session Summary**:

Today’s modern sociotechnical work environment has created the need for more dynamic, innovative approaches to oversight. Deming Prize winning team member and pioneering Nuclear Quality Assurance expert Rob De La Espriella draws from four decades of experience to offer insights into how Quality Assurance (QA) oversight teams can break from the traditional audit framework and evolve to a modern model that is far more efficient and effective. In this session, Rob will present a set of practical skills and strategies that will enhance the effectiveness of internal and external Oversight Programs in closing performance gaps and strengthening defenses, while improving safety and reliability. Take-aways from this session include access to a virtual white board that replaces audit checklists, and training on critical thinking, systems theory, risk management and advanced techniques for conducting interviews.

**Speaker Bio**:

Rob De La Espriella is a former US Naval officer and is the CEO of DLE Technical Services, LLC. Rob has over 36 years of Nuclear Quality Assurance oversight experience: he was on the Florida Power & Light team that won the Deming Prize from Japan; he was a decorated Resident Inspector with the US Nuclear Regulatory Commission; he spent 6-years as the Site Quality Manager at a nuclear plant; and, he has developed QA programs for companies such as Schneider Electric and Burns & MacDonald. Rob received recognition from the DOE for leading a QA cultural transformation at their Yucca Mountain Project.

**Session: E2, Wednesday, October 9, 10:30 – 11:30**

**Session Speaker Name: Food Drug & Cosmetics Division Member-Leaders**

**Session Title: The Power of FSMA Law - Training to Build a Culture of Food Safety While Advancing the Audit Careers of the NextGen’s**

**Session Summary**:

TBD

**Speaker Bio**:

TBD

**Session: A3, Wednesday, October 9, 1:30 – 2:20**

**Session Speaker Name: Andy Nichols**

**Session Title: Internal Audits – You Might Be Doing Them Wrong!**

**Session Summary**:

A significant sector of currently available auditor training is based on a frame work which was established years before ISO 9001 publication in 1987, and therefore, before 3rd party (CAB) certification was available. The very first "Lead Auditor" training was developed within a number of the UK's (then) government-owned procurement entities, such as British Gas, the CEGB, the Ministry of Defence and others. A professional standard of quality assessment was needed by them to ensure government funds were spent with suppliers who were capable of meeting the procurement quality requirements - or the Prime Minister was asked difficult questions about a lack of business awards in a constituency, by the Member of Parliament representing those suppliers!

With the arrival of ISO 9001 Certification, the first CABs were looking for similar auditor qualifications, so Lead Auditor became the required training for 3rd Party auditors too - mainly since there was nothing else available. Some CABs even started running their own training (against the accreditation rules?) Indeed, I have delivered BSI's and UL's Lead Auditor courses - both rebranded versions of the Excel Partnership courses, which were some of the earliest available (based on the British Gas organization's SQA training). Further more, it became almost de rigueur to attend a Lead Auditor course, partly to learn what a CAB auditor would do during certification audits - to be prepared!

To satisfy the need, because ISO 9001 required Internal Audits, auditor training courses simply became a stripped-back version of 2 days length, not the Lead Auditor's 4 or 5 days. Same basic framework, methods, terminology etc. What could go wrong?

35 years later, nothing substantial has changed. We're still using a model for auditing based on external audits. The result is that organizations get little/no benefit from their internal audits. The planning is minimal. There's little engagement with anyone affected by the audits. As a result, internal auditors get little/no recognition and, experience shows, often become disenfranchised. In addition, 3rd Party Certification auditors see results of the organization's internal audits which are similar to theirs – after all, imitation is the sincerest form of flattery!

 Time to change!

 More emphasis should be placed on engaging the leadership and in consideration of the performance of the organization’s business processes, particularly in the ability to meet customers’ needs as well as effectively and efficiently. Less effort should be expended on arbitrary aspects such as a regular calendar of audits or auditing ISO clauses.

**Speaker Bio**:

Andy has more than 40 years’ Quality Management experience in multiple roles. He has been involved in the implementation and 3rd Party certification of Quality Management Systems including ISO 9001, AS 9100, and IATF 16949, as well as ISO/IEC 17025.

Andy is an active member of the ISO TC 176, which writes the ISO 9000 standards. He is a Fellow of the UK’s Chartered Quality Institute, an “IRCA” Principal Auditor, holds certification as Exemplar Global “Certified Lead Trainer” and is a member of the ASQ. Andy has authored 3 books on Quality Management Systems and Auditing.

**Session: B3, Wednesday, October 9, 1:30 – 2:20**

**Session Speaker Name: Mike Fank**

**Session Title: Auditing Tools in a Quality 4.0 World**

**Session Summary**:

In the presentation titled "Auditing in a Quality 4.0 World," attendees will explore how the auditing process can be enhanced in the era of Quality 4.0. The session will delve into the utilization of innovative tools that streamline administrative tasks, enabling auditors to concentrate on crucial human-centric activities such as interviews and risk evaluations. The presentation will highlight the integration of cutting-edge technologies like Large Language Models (LLMs), AI meeting summaries, and project management software, and explain their impact on expediting planning, enhancing interview accuracy, report writing, result tracking, and efficient closure of action items. By leveraging these new tools, organizations can optimize auditing procedures, boost efficiency, and ensure continual improvement in their quality management systems.

**Speaker Bio**:

Mike Fank is a Six Sigma Black Belt, CMQ/OE, and ASQ Senior member with over 13 years of experience as a Quality Professional. He has a proven track record of emphasizing business improvements through the use of quality standards and tools. Mike has contributed to corporate-wide audit standards in several companies, using the standards to raise the performance of all divisions. When not working, you’ll find Mike hiking with his family through the National Parks.

**Session: C3, Wednesday, October 9, 1:30 – 2:20**

**Session Speaker Name: Benjamin Trujillo**

**Session Title: Into Action: Commuting Audit Findings into Corrective Actions**

**Session Summary**:

The audit is over, findings have been documented, and the business of causal analysis and development of corrective actions is underway. Whether developed by an individual or a group, corrective actions need to be readily understood by the individuals who will be asked to implement them, the individuals that will be asked to verify their completion, and the individuals who will audit the program at a later date to confirm program compliance and efficiency. How we write corrective actions matters. If the parameters of the corrective action are not well defined, then personnel may not understand what constitutes successful implementation. If the corrective action did not stipulate how to document implementation, then the records necessary to verify implementation or audit the process may be absent. This session will examine the life cycle of a corrective action, helping participants understand the various audiences they are writing for when developing a corrective action. In support of this understanding, this session will present several writing rules for participant consideration. The purpose of these rules is to promote clarity of corrective action statements, resulting in a corrective action that can be readily implemented, verified, and understood. During the session, example findings will be presented to the group for discussion and to practice application of the writing rules discussed. Practice will consist of participants writing corrective actions against example findings and subsequent group discussion of the effectiveness of the presented writing rules.

**Speaker Bio**:

Mr. Trujillo has more than twenty years’ experience designing and managing business requirements and quality systems for organizations engaged in design, fabrication, and construction projects for commercial, nuclear, and government clients. He engages with calibration agencies, design firms, fabricators, testing laboratories, special inspection agencies, and construction management firms. He has designed and implemented business management programs addressing the requirements of multiple regulations and quality standards: notably AASHTO R18 and associated ASTMs, ASME NQA-1, DOE O 414.1D, NAP 401.1A, and the ISO 9001 and ISO/IEC 17025 standards. He currently operates as a business and quality systems consultant, auditor, and trainer.

****

**Session: D3, Wednesday, October 9, 1:30 – 2:20**

**Session Speaker Name: Angelo Scangas**

**Session Title: Risk Management Jeopardy**

**Session Summary**:

Join for a live educational experience to put your risk management knowledge to the ultimate test!

Risk is inherent in all aspects of a quality management system. There are risks in all systems, processes and functions. Risk-based thinking ensures these risks are identified, considered and controlled throughout the design and use of the quality management system.

By considering risk throughout the system and all processes, the likelihood of achieving stated objectives is improved, output is more consistent, and customers can be confident that they will receive the expected product or service. Successful companies intuitively incorporate risk into their daily decision-making process.

The game will consist of 4 players testing their risk management knowledge utilizing the Jeopardy format.  The “host (Angelo Scangas)” has added content throughout the game that is focused on best practices and based on his “real-world” experience.

**Speaker Bio**:

Angelo Scangas is President of Quality Support Group, Inc., an International Consulting and Training organization.

Angelo has a B.S. in Chemical Engineering, M.S. in Manufacturing Engineering and an MBA. Angelo 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: E3, Wednesday, October 9, 1:30 – 2:20**

**Session Speaker Name: Lisa El-Shall**

**Session Title: OTCs: Cosmetic Audits – What is the Standard?**

**Session Summary**:

TBD

**Speaker Bio**:

TBD

****

**Session: A4, Wednesday, October 9, 2:30 – 3:30**

**Session Speaker Name: Paul Russell**

**Session Title: Writing Nonconformances with Confidence**

**Session Summary**:

This session is designed for beginners or those who may want a refresher on the importance of writing good nonconformities. this session will cover both good and bad examples, and how to assemble the basic nonconformity statement.

**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, Wednesday, October 9, 2:30 – 3:30**

**Session Speaker Name: Alison Baduel**

**Session Title: Part 1 of 2, Transforming the Auditing Process: Leveraging Technical & Leadership Tools**

**Session Summary**:

This session is designed to help lead auditors identify new tools to help bolster the efficiency and effectiveness of the audits they conduct. The tools covered will address both technical and human elements of the auditing process (i.e., technological tools and organizational leadership tools). The topics covered will be pertinent to all types of audits (i.e., internal, 2nd, 3rd party).

Although this session will cover a variety of tools it is important to note that the purpose of a tool is to enable/support a process. Tools should be leveraged to support what is to be achieved through the auditing process but should not be confused a short cut solution to auditing. While more technologically advanced tools can aid in achieving the desired results in a more efficient manner they should never be substituted for human involvement in the process or the critical thinking skills that experienced auditors bring to the auditing process.

**Examples to be covered include:**

* The use of statistical tools/statistics programs
* Leveraging ChatGPT, internal versions of ChatGPT, and other Artificial Intelligence (AI) tools to help with high-level data mining exercises.
* Use of external competent authority databases prior to starting an audit to gauge areas of risk (i.e., for medical devices the use of FDA’s Total Product Lifecycle database).

Lead auditors also need to be well-equipped to engage with the human elements of the audit process which includes the audit team, clients, and auditees. Several tools available within the realm of organizational leadership theories and concepts that can enable lead auditors to achieve our audit goals in a more efficient and effective manner. A brief overview of each of the concepts listed below and application examples will be provided during the seminar.

**Examples to be covered include:**

* Adaptive leadership theory
* Situational leadership theory
* Ethical leadership theory
* Recognizing the power bases that are being used (negative, positive)
* The art of inquiry (i.e., humble inquiry approach)

**Speaker Bio**:

Alison Baduel is an experienced lead auditor who has spent most of their career in the medical device industry. They have served as a supporting auditor, lead auditor, and internal audit program manager for multiple medical device companies over the past two decades. Their roles in the auditing realm have spanned across 1st party, 2nd party, and 3rd party audits. The speaker currently holds a ISO 13485:2016 Lead Auditor certification and an ASQ Certified Medical Device Auditor certification along with several graduate degrees in health law, systems engineering, regulatory science, and management.

A person in a black jacket

Description automatically generated

**Session: C4, Wednesday, October 9, 2:30 – 3:30**

**Session Speaker Name: Christy Furlan**

**Session Title: LAARPG (Live Action Audit Role-Playing Game)**

**Session Summary**:

Have you ever dealt with a nervous auditee? How about a distracted one? Or maybe an angry one?

These situations can be tough to deal with, even for the most experienced auditors. This session will focus on tips and tricks to handle difficult auditees like these. It will also offer a chance for participants to test out these skills in real time by role-playing specific audit scenarios in this safe space. If you want to hone your skills for handling tough auditees – and/or if you like acting, improv, or RPGs like Dungeons & Dragons – come join in!

**Speaker Bio**:

Information here

**Session: D4, Wednesday, October 9, 2:30 – 3:30**

**Session Speaker Name: Tom Taormina & Steven Garner**

**Session Title: The New Future of Auditing – Identifying and Removing Foreseeable Risk**

**Session Summary**:

Traditional management systems auditing is wholly inadequate for the future of robust organizations. 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.

Last year, we presented the concept of Forensic Investigations at the Audit Division Conference in Reno, NV. It was received with great enthusiasm and positive reviews. That debut has focused our efforts on whole-enterprise Business Management Systems where quality is more than just an overhead function but instead becomes a profit center, and audits have a return on investment and take a deep dive into foreseeable risk.

**Speaker Bios**:

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.

Steven Garner has more than 25 years as a senior quality professional in the chip manufacturing and Defense contracting industries, following his career as a Major in the Army Corps of Engineers. Steven has trained dozens of Quality Engineers, Managers and Directors in developing cross-functional/department Key Process Indicators that allow senior management to readily see how they are doing in real time, and what adjustments are needed to maintain process excellence and profitability.

**Session: E4, Wednesday, October 9, 2:30 – 3:30**

**Session Speaker Name: Chris Bennett**

**Session Title: OTCs: Most Common Findings in Audits**

**Session Summary**:

TBD

**Speaker Bio**:

TBD

****

**Session: A5, Wednesday, October 9, 3:40 – 4:30**

**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.

**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 Lead and Technical 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.

**Session: B5, Wednesday, October 9, 3:40 – 4:30**

**Session Speaker Name: Alison Baduel**

**Session Title: Part 2 of 2, Transforming the Auditing Process: Leveraging Technical & Leadership Tools**

**Session Summary**:

This session is designed to help lead auditors identify new tools to help bolster the efficiency and effectiveness of the audits they conduct. The tools covered will address both technical and human elements of the auditing process (i.e., technological tools and organizational leadership tools). The topics covered will be pertinent to all types of audits (i.e., internal, 2nd, 3rd party).

Although this session will cover a variety of tools it is important to note that the purpose of a tool is to enable/support a process. Tools should be leveraged to support what is to be achieved through the auditing process but should not be confused a short cut solution to auditing. While more technologically advanced tools can aid in achieving the desired results in a more efficient manner they should never be substituted for human involvement in the process or the critical thinking skills that experienced auditors bring to the auditing process.

**Examples to be covered include:**

* The use of statistical tools/statistics programs
* Leveraging ChatGPT, internal versions of ChatGPT, and other Artificial Intelligence (AI) tools to help with high-level data mining exercises.
* Use of external competent authority databases prior to starting an audit to gauge areas of risk (i.e., for medical devices the use of FDA’s Total Product Lifecycle database).

Lead auditors also need to be well-equipped to engage with the human elements of the audit process which includes the audit team, clients, and auditees. Several tools available within the realm of organizational leadership theories and concepts that can enable lead auditors to achieve our audit goals in a more efficient and effective manner. A brief overview of each of the concepts listed below and application examples will be provided during the seminar.

**Examples to be covered include:**

* Adaptive leadership theory
* Situational leadership theory
* Ethical leadership theory
* Recognizing the power bases that are being used (negative, positive)
* The art of inquiry (i.e., humble inquiry approach)

**Speaker Bio**:

Alison Baduel is an experienced lead auditor who has spent most of their career in the medical device industry. They have served as a supporting auditor, lead auditor, and internal audit program manager for multiple medical device companies over the past two decades. Their roles in the auditing realm have spanned across 1st party, 2nd party, and 3rd party audits. The speaker currently holds a ISO 13485:2016 Lead Auditor certification and an ASQ Certified Medical Device Auditor certification along with several graduate degrees in health law, systems engineering, regulatory science, and management.

**Session: C5, Wednesday, October 9, 3:40 – 4:30**

**Session Speaker Name: Bradley Rush**

**Session Title: What is the DNA of a Great Auditor?**

**Session Summary**:

What key factors are required to become the “Auditor of the Year” and can anyone obtain the knowledge to elevate their performance as an auditor. This session will cover the skills required to conduct a highly effective audit, auditor should maintain a positive attitude, and exceed the customer expectations. As part of the audit, the auditor is to bring different people together and understand their personalities to obtain the desired information.

**Speaker Bio**:

Brad Rush stands as a gold standard in auditing within audit programs, embodying a rare blend of specialized knowledge, unwavering dedication, and passion for fostering industry-wide advancement. His career is marked by consistently high performance and commitment to ongoing training and mentorship, Brad’s impact on the field of food safety auditing is profound and far-reaching. Beyond remarkable auditing skills, Brad excels at mentorship. His desire to cultivate the talents of emerging auditors is evident in his patient guidance and unwavering support. For Brad, each audit represents not only a professional responsibility but also an opportunity for personal enrichment.

****

**Session: D5, Wednesday, October 9, 3:40 – 4:30**

**Session Speaker Name: Shauna Wilson**

**Session Title: Remote Auditing Fundamentals – How to Mitigate Audit Risks**

**Session Summary**:

In 2000, virtual teams started when “work from home” was used to cut overhead costs; employees experienced limited communication and working remotely training. Remote workers went to email to communicate, resulting in 100’s of daily email. How inefficient was that! The pandemic caused a similar response; companies banned external interested parties from their factories; forced remote auditing on reluctant registration bodies. More history repeating itself! As we know, auditing is a process, and changes to that process can impact the audit result. Without defined remote auditing processes and proper training in mobile technology checks, device handling, interviewing, and touring the remote site, the validity of some remote audits is unknown. In this session, participants will learn fundamental processes and tools to use to ensure audit objective evidence is adequately collected from the remote location.

**Speaker Bio**:

Working in Quality for over forty years, Shauna holds the Certus Master Auditor certification. Shauna’s experience in virtual team communication and development of virtual auditing methods has made her the leading expert in Remote Auditing. She earned an MS in Engineering focused on Organizational Performance Technologies and Instructional Design. Shauna wrote InterneTeaming.com: Tools to Create High Performance Remote Teams and co-authored eAuditing Fundamentals: Virtual Communication and Remote Auditing. She has been featured in Quality Progress, The Auditor, and ASTD’s InfoLine. Shauna served as the US Expert for PC/TAG302 ISO19011:2018 Auditing Management Systems Guideline. Shauna Wilson is the 2022 recipient of the ASQ Audit Division Paul Gauthier Award.

A person with curly hair wearing glasses

Description automatically generatedA person wearing glasses and a suit

Description automatically generated

**Session: E5, Wednesday, October 9, 3:40 – 4:30**

**Session Speaker Name: Tatiana Miranda & Cathleen Howick**

**Session Title: Auditing a Food Safety Plan for a Dietary Supplement using a FSP Model**

**Session Summary**:

In 2017, FDA promulgated 21 CFR 117, requiring all food companies to implement a risk-based Food Safety Plan (FSP). Dietary Supplements were exempt from certain portions of the regulations, including the requirement for a full FSP. In 2018, the Food Safety Preventive Controls Alliance (FSPCA) created a standardized curriculum for the regulations. Training included a limited set of example Food Safety Plan models; however, no model plans had been developed for dietary supplements. Using the model templates provided by the Alliance as well as the draft guidance documents for reference, the FSP created in this project is one specific to the dietary supplement industry that FSPCA could include in its training material and can be used as “what to look for” when auditing this type of operations.

**Speaker Bio**:

Tatiana Miranda is a QA Manager-GMP Audits at Unilever. She manages US GMP compliance with CFR111 as well as conducts GMP audits to ensure the suppliers’ cGMP 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’ Certified Food Safety & Quality Auditor, PCQI Lead Instructor, HACCP Trainer by the IHA, and adjunct faculty member at Chapman University.

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



**Session: F1, Thursday, October 10, 9:30 – 10:20**

**Session Speaker Name: Paul Russell**

**Session Title: Internal Audit Handbook**

**Session Summary**:

Information here

**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: G1, Thursday, October 10, 9:30 – 10:20**

**Session Speaker Name: Tatiana Miranda**

**Session Title: TBD**

**Session Summary**:

Information here

**Speaker Bio**:

Tatiana Miranda is a QA Manager-GMP Audits at Unilever. She manages US GMP compliance with CFR111 as well as conducts GMP audits to ensure the suppliers’ cGMP 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’ Certified Food Safety & Quality Auditor, PCQI Lead Instructor, HACCP Trainer by the IHA, and adjunct faculty member at Chapman University.



**Session: H1, Thursday, October 10, 9:30 – 10:20**

**Session Speaker Name: Angelo Scangas**

**Session Title: Case Studies on the importance of: Is it Nonconformity? Are you sure?**

**Session Summary**:

Nonconformity in terms of ISO 9001 and other Management System Standards is defined as the failure to meet one or more requirements that are outlined throughout the mandatory clauses. Nonconformity can also refer to the requirements of a regulatory body, the organization itself, or even the customers.

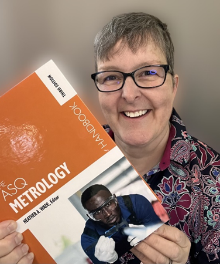
1. Include the requirement. To demonstrate that there is a problem, you need to ensure that the person who will address the nonconformity understands what the requirement is.
2. Include what was wrong. What exactly is the Non-Conformance
3. Include audit evidence.

So, how do you ensure that your nonconformity statement is good? It is important to remember why we are writing a nonconformity statement in the first place. The reason you are writing the statement in the audit report is to allow the auditee to take action to correct the nonconformity and to eliminate the cause.

**Speaker Bio**:

Angelo Scangas is President of Quality Support Group, Inc., an International Consulting and Training organization.

Angelo has a B.S. in Chemical Engineering, M.S. in Manufacturing Engineering and an MBA. Angelo 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: I1, Thursday, October 10, 9:30 – 10:20**

**Session Speaker Name: Heather Wade**

**Session Title: Beyond the Sticker & the Cert (Ensuring Better Measurements and Reducing Risk)**

**Session Summary**:

Do you evaluate suppliers and/or review external calibration certificates? Do you just make sure you have the “sticker and the cert”? Do you often wonder what you should review on a calibration certificate to make sure you are getting what you need? Do you know what the differences are between accredited and non-accredited calibration certificates? What is supposed to be on an accredited calibration certificate? Do you now how to use the information on a calibration certificate? If you answer yes to any of these questions, then this session is for you. You’ll leave the session empowered with the knowledge and a handy checklist to review and evaluate your next calibration certificates. Help you company ensure better measurements and reduce risk.

**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 Lead and Technical 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.



**Session: F2, Thursday, October 10, 10:30 – 11:30**

**Session Speaker Name: Rai Chowdhary**

**Session Title: Auditing Behind the Curtain of Statistical Methods (with case studies)**

**Session Summary**:

While audits are aimed at verifying if requirements are being met, and various standards / regulations point to the use of “appropriate” statistical methods, there is much ground to be covered when it comes to examining the use of statistical methods by the auditee. This is important because organizations increasingly rely on data driven decisions, and auditors examine the evidence to determine if there is a non-conformance or not in this area. Therefore, a certain amount of deftness is required on the part of the auditor when it comes to data, its presentation, and analysis.

How This Session Adds Value: This session will demonstrate (via case studies) the consequences that follow from cursorily accepting whatever evidence is presented regarding the use of statistical methods and the results therefrom. It will then proceed to identify a set of questions auditors can ask rather than giving a check mark that statistical methods have been used.

**Speaker Bio**:

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: 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 1995 covering a broad range of industries and regulations; he serves on standards development committees (ISO TC 176, among others). Rai was recognized as “Expert on WG 28 for the development of ISO/TS 10020:2022” (Organizational Change Management)..

**Session: G2, Thursday, October 10, 10:30 – 11:30**

**Session Speaker Name: TBD**

**Session Title: TBD**

**Session Summary**:

Information here.

**Speaker Bio**:

Information here

**Session: H2, Thursday, October 10, 10:30 – 11:30**

**Session Speaker Name: Colleen McGuigan**

**Session Title: How I Learned to Stop Worrying and Love the Checklist**

**Session Summary**:

Discover a fresh perspective on audit checklists at this year's ASQ Audit Division Conference! While the potential shortcomings of checklists are well-known, my recent conversion to their use has shown me their untapped potential. Join me as I reveal how audit checklists can revolutionize your audit processes, offering not only efficiency and consistency but also a gateway for new or volunteer auditors to master the art of checklistless auditing. Learn how to sidestep common pitfalls and harness the power of audit checklists to elevate your audits to new heights. Don't miss out on this insightful exploration of best practices for developing and implementing audit checklists—it's a game-changer you won't want to miss!

**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. Colleen also has volunteered both with the Wisconsin state Baldrige-based program and the national Baldrige program.

****

**Session: I2, Thursday, October 10, 10:30 – 11:30**

**Session Speaker Name: Joyjit Mukhopadhyay**

**Session Title: The Risks of Not Understanding the Risks**

**Session Summary**:

In a standardized or regulated quality management systems environment, failing to understand the risks associated with processes and operations can lead to significant negative consequences. Without a comprehensive grasp of potential hazards, organizations may overlook critical areas that require preventive measures, leading to product defects, compliance issues, and customer dissatisfaction. Additionally, this lack of awareness can result in inefficient resource allocation, as efforts may be misdirected toward less pertinent concerns. Ultimately, not understanding risks undermines the integrity of the QMS, jeopardizing continuous improvement efforts, increasing the likelihood of operational disruptions, and potentially incurring financial and reputational damage. Ensuring a thorough understanding of risks is thus essential for maintaining the robustness and effectiveness of a successful and conforming QMS.

**Speaker Bio**:

Joyjit Mukhopadhyay is an experienced Quality Management professional with extensive experience in high-tech, highly regulated Medical Device QMS and process improvement. He holds an M.Sc. in Applied Physics and ASQ certified CMQ/OE, CMDA, CSQP, CQA, CQIA, and Exemplar Global certified Lead Auditor for ISO 13485:2016 & ISO 9001:2015. Joyjit excels in risk-based auditing, regulatory compliance, and continuous improvement. Currently serving as Quality Assurance & Quality Systems Manager at Excelitas Technologies, he has a robust background in developing and implementing quality systems, managing audits, developing suppliers and ensuring product compliance.