



# 2019 ASQ Audit Division Conference

at the Double Tree by Hilton at the Entrance to Universal Studios



# Conference Program



The full version of the document can be accessed at: <https://asq.org/conferences/audit-division>

The ASQ Audit Division would like to thank the Double Tree by Hilton, our Sponsors, Exhibitors, Keynote and Session Speakers, Tutorial Instructors, the staff at ASQ Headquarters and the many volunteers that make our conference a success!

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### Keynote Speakers

Grace Duffy

Jay Arthur

### Session Speakers

Jay Arthur

Erin Wright

Marty Cronin

Colleen McGuigan

Mark Rohlfig

Janet Bautista Smith

Tracy Barnhart

Narendra S. Patel

Dennis Welch

Stan Cherkasky

Robert Deysher

Barrett Craner

Mark Durivage

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### Tutorial Instructors

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Denise Robitaille

Barrett Craner

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Larry Whittington

Tracy Omdahl

Kurt Robinson

Darby Israel

Van Le

Daniel Castle

# Conference Overview

## Wednesday, October 16, 2019

1:00PM – 5:00PM	Conference Registration and Conference Bookstore Open
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## Thursday, October 17, 2019

7:00AM – 8:00AM	Breakfast: Convention Lobby and Seminole Ballroom C
8:00AM – 8:30AM	Welcome, Announcements, Keynote Introduction: Seminole Ballroom C
8:30AM – 9:30AM	Keynote Speaker - Grace Duffy: Seminole Ballroom C
9:45AM – 10:30AM	Sessions in Progress
10:30AM – 10:45AM	Mid-morning Break: Snacks, Beverages, Networking, Sponsors and Exhibitors
10:45AM – 11:30AM	Sessions in Progress
12:00PM – 1:30PM	Lunch, Entertainment (Barnes & Miner) and Announcements: Seminole Ballroom C
1:45PM – 3:30PM	Sessions in Progress
3:30PM – 3:45PM	Afternoon Break: Snacks, Beverages, Networking, Sponsors and Exhibitors
3:45PM – 4:30PM	Session in Progress
5:00PM – 6:00PM	Audit Division Business Meeting: Seminole D
6:30PM – 7:00PM	Gala Reception begins: Seminole Ballroom C Heavy hours d'oeuvres, carving station, beer and wine bar
7:00PM – 7:30PM	Raffle Drawings, Sponsor Raffle Prizes
7:30PM – 10:00PM	Music by the "Bay City Band": Dancing and Refreshments

## Friday, October 18, 2019

7:00AM – 8:00AM	Breakfast: Convention Lobby and Seminole Ballroom C
8:00AM – 8:30AM	Welcome, Announcements, Keynote Introduction: Seminole Ballroom C
8:30AM – 9:30AM	Keynote Speaker – Jay Arthur: Seminole Ballroom C
9:45AM – 10:30AM	Sessions in Progress
10:30AM – 10:45AM	Mid-morning Break: Snacks, Beverages, Networking, Sponsors and Exhibitors
10:45AM – 11:30AM	Sessions in Progress
12:00PM – 1:30PM	Lunch and Announcements: Seminole Ballroom C
1:45PM – 3:30PM	Sessions in Progress
3:30PM – 3:45PM	Afternoon Break: Snacks, Beverages, Networking, Sponsors and Exhibitors

# Conference/Hotel Layout



**DOUBLETREE**

BY HILTON™

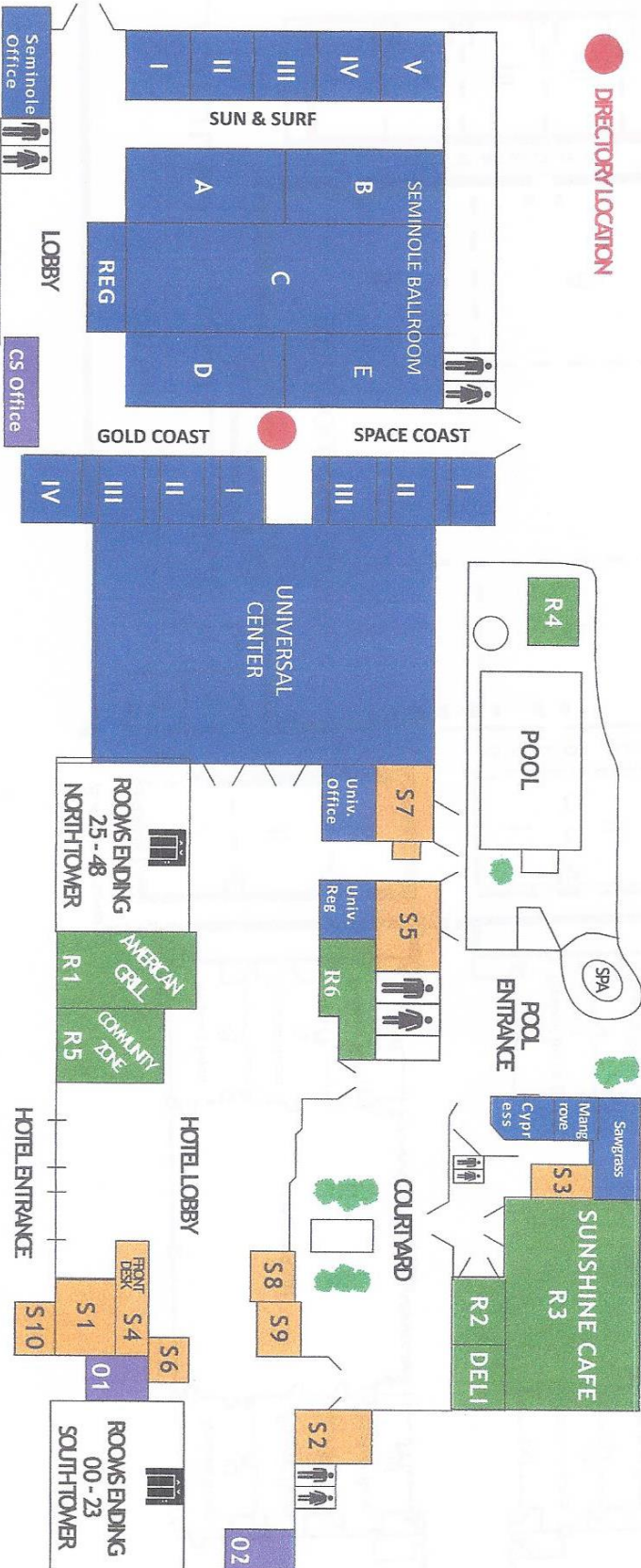
AT THE ENTRANCE TO  
UNIVERSAL ORLANDO



- SERVICES**
- S1 Bell Desk
  - S2 UPS Store
  - S3 Fitness Center
  - S4 Front Desk
  - S5 Game Room
  - S6 Gift Shop
  - S7 Guest Laundry
  - S8 Universal Desk
  - S9 Rent a Car Desk
  - S10 Valet Desk

- RESTAURANTS / BARS**
- R1 American Grill
  - R2 Starbucks / Angelo's
  - R3 Sunshine Cafe
  - R4 Pool Bar
  - R5 Community Zone
  - R6 Leond's Gelato

- OFFICES**
- 01 Executive Offices
  - 02 Sales Office



# Pre-Conference Tutorials

## Pre-Conference 3-day Course

### **Certified Quality Auditor Certification Preparation**

Monday Oct. 14 – Wednesday, Oct. 16

Instructor: Kevin Posey

Location: Space Coast I



The Certified Quality Auditor Refresher training, developed and delivered by the ASQ Audit Division, is a three-day course designed and taught to help experienced auditors become better prepared for the CQA exam. It is not for beginners. The course is based on ASQ's CQA Body of Knowledge. Students will receive a course manual and a copy of the ASQ Auditing Handbook, Fourth Edition.

## Pre-Conference 2-day Courses

### **ISO 19011:2018 – New Key Concepts and Best Practices**

Tuesday Oct. 15 – Wednesday, Oct. 16

Instructor: Denise Robitaille

Location: Space Coast II



The workshop will contain several exercises designed to spur conversation and provide tips to help individuals determine how best to implement their organization's internal audit program from planning through execution to audit report and follow-up.

### **Risk Management – Tools and Auditing for All Trades**

Monday Oct. 15 – Wednesday, Oct. 16

Instructor: Barry Craner

Location: Space Coast III



This two-day tutorial will identify state of the art risk management processes, including Hazard Identification, Hazard Analysis (product and process), Fault Tree Analysis (product and process), Failure Modes and Effects Analysis (product, process, use, cyber), mitigation analysis, auditing your risk management program, a review of and use of templates for most of these analyses and other risk management documentation practices in workshops for you to solidify your knowledge of and use of solid risk management practices.

#### **Daily Tutorial Schedule**

7:00am – 8:00am	Continental Breakfast provided to all Tutorial Attendees
8:00am – 10:00am	Tutorials in Session
10:00am – 10:15am	Break – Refreshments and Networking
10:15am – 12:00pm	Tutorials in Session
12:00pm – 1:00pm	Lunch provided to all Tutorial Attendees
1:00pm – 3:00pm	Tutorials in Session
3:00pm – 3:15pm	Break – Refreshments and Networking
3:15pm – 5:00pm	Tutorials in Session

# Keynote Speakers



Keynote Speaker: Grace Duffy

Date: October 17, 2019

Presentation: Modular Kaizen

## Biography

Grace has over 40 years' experience in successful business and process management in corporate, government, education, and healthcare. Grace uses her experience as President, CEO and senior manager to help organizations improve. She has authored 13 texts, additional book chapters, and many articles on quality, leadership and organizational performance. Grace is a frequent speaker and trainer. Grace holds an MBA from Georgia State University. She is an ASQ CMQ/OE, CQIA, SSGB, and CQA. Grace holds an LSS Master Black Belt, ASQ Fellow and Distinguished Service Medalist. Grace is the 2014 Quality Magazine Quality Person of the year and the 2016 recipient of the Asia-Pacific Quality Organization Miflora M. Gatchalian International Woman in Quality Medal.



Keynote Speaker: Jay Arthur

Date: October 18, 2019

Presentation: Lean Six Sigma Demystified

## Biography

Jay Arthur teaches people how to Turn Data Into Dollars® using Microsoft Excel and the Magnificent Seven Tools of Lean Six Sigma. Jay helped one healthcare system reduce denied claims by \$5 million per year and rejected claims by \$24 million. Jay is the author of Lean Six Sigma Demystified (2nd), Lean Six Sigma for Hospitals, and the QI Macros SPC Software for Excel—a software package that automates all of the charts, graphs, and documents required for quality improvement. Jay holds a BS in Systems Engineering from the University of Arizona.



**Session #:** A1

**Date:** Thursday, October 17, 2019

**Time:** 9:45 – 10:30

**Speaker Name:** Jay Arthur

**Session Title:** The Language of Motivation

**Session Summary:** Ever have trouble with leadership, project teams, family, friends or people in general? You know they're speaking English, but you can't understand what they're saying? There are three types of team members and each has their own way of talking. Learn how to influence your team's dreamers, realists and critics by using *their* language. Using the language of influence, you'll learn a handful of questions to discover each person's style and motivating/influencing language for each one

**Speaker Bio:** Jay Arthur teaches people how to Turn Data Into Dollars® using Microsoft Excel and the Magnificent Seven Tools of Lean Six Sigma. Jay helped one healthcare system reduce denied claims by \$5 million per year and rejected claims by \$24 million.

Jay is the author of *Lean Six Sigma Demystified (2<sup>nd</sup>)*, *Lean Six Sigma for Hospitals*, and the QI Macros SPC Software for Excel—a software package that automates all of the charts, graphs, and documents required for quality improvement.

Jay holds a BS in Systems Engineering from the University of Arizona.



**Session #:** A2

**Date:** Thursday, October 17, 2019

**Time:** 10:45 – 11:30

**Speaker Name:** Erin Wright

**Session Title:** Audit Readiness – Take the Pain out of Audits

**Session Summary:** Are you being audited frequently by clients, notified bodies, or regulatory agencies? Want to learn a few tricks of the trade to make those audits as painless as possible? This session will focus on delivering practical tips and tricks throughout all stages of the audit, including audit preparation, audit hosting (facilitation), and audit remediation.

**Session Abstract:** Do you deal with frequent audits by clients, notified bodies, or regulatory agencies? Would you like to learn a few hints on how to make those audits as painless as possible? Undergoing an audit can be a nerve-wracking experience, but it doesn't have to be. In this session, expert Erin Wright will share practical tips and tricks for all stages of the audit process, including audit preparation, audit hosting (facilitation), and audit remediation. You will learn pointers on how to get your organization into an audit-ready state, and you will be given actionable tools that you can take back to your company and start implementing immediately. This session will provide attendees with universal principles that can be applied to any industry and to any audit. The presenter will go beyond the audit itself to teach guidelines on how best to interact with the auditor before, during, and after the audit. Discover how to create an environment for the auditor that builds a constructive relationship while also protecting your company. The tips and tricks from this session will teach you how to take the sting out of the auditing process, so you can focus on creating a positive outcome for everyone involved.

**Speaker Bio:** Erin Wright, MasterControl's validation product manager, has supported regulatory audits for customers throughout her career and is an expert in quality and validation as they apply to regulated industries. She has hosted and participated in hundreds of audits for regulated software, including high-risk trial software for patient randomization and drug-dispensation to low-risk automated test software.

She joined MasterControl in 2013 as a professional services consultant and worked closely with hundreds of regulated companies, including the FDA's Center for Drug Evaluation and Research (CDER), Ancestry.com, Abbott Point of Care, Institute for Transfusion Medicine (ITxM), and

the University of Utah, in conducting custom validation implementations. Her extensive experience in quality, validation, and regulatory compliance includes working for an automated-testing software company and several clinical-trial software providers.

Wright graduated summa cum laude from West Chester University with a degree in psychology.

**Session #: A3**

**Date: Thursday, October 17, 2019**

**Time: 1:45 – 2:30**

**Speaker Name: Marty Cronin**

**Session Title: Auditing Around the Edges**

**Session Summary:** How to audit around the edges is about auditors having their eyes open to the things that aren't found via questions – the posters on the wall, the subtle signs that there are gaps in the firm's ability to rely on their process instructions.

**Session Abstract:** Almost always, when auditing, I run into "signs" that tell me there are challenges with following work instructions or process maps. These are often in the form of special "reminders" or instructions "above and beyond" that are posted on the walls, the bulletin boards, etc. in a workplace. If something is happening often enough to warrant such special attention, it surely is something that should be noted and followed. Special notes, either handwritten in work instructions or in an employee's special "documentation", there are often clues that should be investigated right there in plain sight.

**Speaker Bio:** Marty Cronin, who has been working in the standards world since the UCC project to define the attributes of the UPC code for the retail industry, has taught EDI 101 to thousands of participants in user group conferences. She teaches ISO 9001, IATF 16949, ISO 14001, ISO 45001 and Internal Auditing to hundreds of new and experienced managers every year. She conducts approximately 25 pre-assessment or gap analysis audits yearly.

**Session #: A4**

**Date: Thursday, October 17, 2019**

**Time: 2:45 – 3:30**

**Speaker Name: Colleen McGuigan**

**Session Title: Baldrige-inspired Audits: A Case Study and Lessons Learned**

**Session Summary:** Asked to conduct a Baldrige-inspired assessment of one of the company's Business Units, the presenter was excited to bring comprehensive assessments to her company but found herself pushing against current state inertia once the report was published. This case study examines the excitement and pitfalls of initiating a sudden switch to Baldrige-style assessment in an environment used to ISO 9001-based audits.

**Session Abstract:** Asked by senior leadership to do a deep-dive audit into one business unit as the result of multiple quality issues, I chose to use a modified Baldrige methodology going beyond ISO 9001:2008's requirements and moving toward identifying root cause issues. I was incredibly excited to finally use my Baldrige experience at my place of employment. We called it a deep-dive audit rather than using the word Baldrige because it was easier for people to understand and didn't carry the same baggage. This deep-dive started with marketing, continued through design and manufacturing, and finished with sales and remanufacturing. To accomplish my assigned task, I chose a small group of experienced internal auditors who had an inclination to go farther than an ISO 9001:2008 audit would allow. We focused on the key business indicators of that business unit, evaluated on the effectiveness and efficiency of the processes we reviewed, and looked at hand-offs between functional groups. To evaluate what we saw, we looked at the process as it was defined, the deployment of that process, improvements made to the process, and the results of the process. We worked hard to ensure our report reflected what we saw and learned and were excited to present it to management. It was then that I realized there was more to this assessment than just presenting the report—I should have spent more time preparing the business unit and its leadership for the differences between an ISO 9001 audit and a Baldrige-type assessment. Now that I have moved through this experience, I can look back and see a better path. That is what I will share with you.



**Speaker Bio:** Colleen McGuigan has been working at Rockwell Automation for 16 years and during that time her ISO 9001 responsibility has increased from a single facility to encompass the entire company. She was a Baldrige Examiner, Senior Examiner, and Alumni Examiner for 10 years, during which time she also volunteered with the Wisconsin Forward Award.



**Session #: A5**

**Date: Thursday, October 17, 2019**

**Time: 3:45 – 4:30**

**Speaker Name: Mark Rohlfing**

**Session Title: Auditing for Business Excellence: Lessons from the Operations Side**

**Session Summary:** Audits are a valuable management tool, used to assess operations against expected business performance and quality standards. Audits that are effectively planned and executed can provide great value to an organization and help drive business excellence. Conversely, if done poorly, audits add waste, thereby weakening an organization’s ability to compete.

In this talk, a seasoned quality manager who is now responsible for overall site operations for his company will provide his unique insight into the business benefits and risks of quality auditing.

Learning Objectives:

- Create a better audit strategy by considering key needs and motivations of the executive and operations teams
- Recognize positive and negative aspects of audits in order to optimize continuous improvement and business excellence initiatives
- Improve career development as an auditor by being a better team member and problem solver

**Session Abstract:** Audits are a valuable management tool, used to assess operations against expected business performance and quality standards. Consequently, an audit is not an activity onto itself, but a key strategic investment. Audits that are effectively planned and executed can provide great value to an organization and help drive business excellence. Conversely, if done poorly, audits add waste, thereby weakening an organization’s ability to compete.

This talk will provide unique insight into the benefits and risks in quality auditing taken primarily from the operations side of the business. While working in quality management for over 20 years, Mark Rohlfing performed and hosted hundreds of quality audits. In his current role as the head of operations at a leading clinical trial supplies manufacturer, he continues to work with quality and operational managers to optimize the business benefits of his company’s customer and internal audit programs.

By the end of this session, attendees will be able to:

- Create a better audit strategy by considering key needs and motivations of the executive and operations teams
- Recognize both positive and negative aspects of audits and how they can accelerate or dampen meaningful continuous improvement and business excellence initiatives
- Develop a list of suggestions on how being a successful auditor can help advance career opportunities in both quality and operations

**Speaker Bio:** Mark Rohlfing is Vice President of Operations at Almac in Souderton, PA, leading site operations in clinical supply chain management, manufacturing, packaging, and global logistics. Mark was previously Director of Quality at Almac and has 25 years of experience within GMP/GCP Operations, QA/QC, and Regulatory Compliance including positions at Cell Pathways Inc. and Teva Pharmaceuticals USA.

Mark holds a BS degree in Biology from Millersville University and a MS degree in Biology from Villanova University. He is an ASQ Certified Manager of Quality/Organizational Excellence, ASQ Certified Quality Auditor, and ASQ Certified Six Sigma Green Belt.

**Session #: B1**

**Date: Thursday, October 17, 2019**

**Time: 9:45 – 10:30**

**Speaker Name: Janet Bautista Smith**

**Session Title: Starfish and Turtles – Auditing Tools**

**Session Summary:** Process Grid Walk is a lean quality tool with features including methodology for self-check, quality sustainability at minimum operating cost. The “Starfish and Turtle” were designated icons to reflect compliance or non-conformance to trigger action plans as needed. The purpose of the tool includes providing a platform to identify incremental and measurable improvement visible to the system as well as empowerment of the workforce as VOP (voice of the process).

**Session Abstract:** This session will focus on the step-by-step techniques that can be easily deployed in creating and deploying the Process Grid Walk program in actual implementation at the speaker’s company (ProTrans). Group visit

Case studies from real events (masked identity for confidentiality) will be given during the session (discussion and hand-out) to share lessons learned from these events. Examples of completed Process Grid Walks (masked information for confidentiality) will also be provided as templates for use.

The highlights of this tool was published in QP, Back to Basics – March 2019.

**Speaker Bio:** Presenter: Janet Bautista Smith – Director of Quality and Continuous Improvement at ProTrans, 3PL company in Indianapolis, IN.

- 25 plus years of QA management in creating, implementing and sustaining effectiveness of quality programs for medical device, automotive and military controlled manufacturing and logistics environments.
- ASQ certified Six Sigma Black Belt, Auditor, Quality Engineer and Quality Manager
- BS Chemical Engineering degree from University of Santo Tomas, Philippines (US accredited university).
- Author of:

--Auditing Beyond Compliance, ASQ

--The Art of Integrating Strategic Planning, Process Metrics, Risk Mitigation and Auditing, ASQ

--Nielda Is Different, Amazon

- Have been a speaker in ASQ conferences such as:

--20<sup>th</sup> Audit Conference 2011 – Reno, NV

--21<sup>st</sup> Annual Audit Conference 2012– Augusta, GA

--2012 National Quality Education Conference, Louisville, KY

--25<sup>th</sup> Annual ASQ Audit Division Conference, Memphis, TN

Have exhibited paintings in various venues using watercolor and alcohol ink media.



**Session #: B2**

**Date: Thursday, October 17, 2019**

**Time: 10:45 – 11:30**

**Speaker Name: Tracy Barnhart      Session Title: Audit – The Focus on Improvement**

**Session Summary:** The importance and benefits of conducting effective audits will be explored, including the focus on continual improvement. Learn the skills needed to be an effective and successful auditor. See how AASHTO re:source handles its own internal audits, as well as the second and third party audits that AASHTO re:source personnel conduct. The session will include a review of recent audit findings from each type of audit.

**Session Abstract:** AASHTO re:source is a unique organization in that it conducts first, second, and third party audits as well as having its own accreditation program for laboratories that test construction materials. This session will focus on the importance and benefits of conducting different types of audits effectively while continually improving the audit process and the organizations that are being audited. Other important aspects of auditing will be explored, including (1) support from management, (2) selecting the right auditors and auditor attributes, (3) effective planning, (4) sampling, (5) interviewing techniques, and (6) collecting objective evidence. We'll discuss the importance of objectivity in the auditing process, and the concept of "If you *think* it's a nonconformity, it's not!" Each audit process step will be discussed in detail, including the three-dimensional aspect of an effective audit and determining if audit criteria are of equal importance. This session will also include real examples of recent findings from first, second, and third party audits conducted by AASHTO re:source. The quality management system of AASHTO re:source has been certified for ISO 9001 since 2006, and recent findings from AASHTO re:source's registrar for its ISO 9001 certification will be shared with attendees. The session will also include a discussion of the different terminology that can be used to classify findings on audit reports as well as the importance of conducting effective opening and closing meetings.

**Speaker Bio:** Tracy Barnhart has been with AASHTO re:source (formerly AMRL) for 29 years, serving as Quality Manager since 2006. She has also been a Laboratory Assessor, Quality Analyst, and LAP Assistant Program Supervisor. Tracy has conducted hundreds of third party audits in her career as well as over forty internal audits. She is responsible for ensuring that AASHTO re:source's quality management system is maintained in accordance with the requirements of ISO 9001 and ISO/IEC 17043. Tracy also manages the ISO/IEC 17025 assessment and accreditation programs at re:source. She is a graduate of the University of Pittsburgh and holds a B.S. degree in Geology.

Session #: B3

Date: Thursday, October 17, 2019

Time: 1:45 – 2:30

Speaker Name: Narendra S. Patel

**Session Title: Dr. Shewhart and Deming Data Collection and Analysis Tools Improve the Medical Device CAPA System**

**Session Summary:** This session will provide examples of Dr. Shewhart's statistical data collection and analysis techniques and Dr. Deming's management principals in improving Corrective and Preventive Action (CAPA) System for medical devices. Deficiency in the CAPA system is one of the major findings of the FDA Quality Audits and as a result corporation have received a warning letter. This presentation will assist an auditee organization in utilizing statistical tools to enhance their Quality Management System, reduce their customer complaint rate, improve & monitor quality, delight customers and pass the Quality Audit with flying colors.

**Session Abstract:** Tools and techniques are identified to assist in the prevention of problem/ quality deficiency therefore avoiding an audit finding. This presentation is based on case studies and personal experience. The presentation will provide auditee organizations necessary statistical tools/ techniques to measure, analyze, correct, improve and monitor their Corrective and Preventive Action (CAPA) system. Data, charts and graphs are utilized throughout in an effort to make the auditing process as engaging as possible for auditor & auditee organizations. The following is a brief description of my presentation:

- The presentation provides examples of my 25 years of external and internal auditing experience, knowledge in preparing organizations for FDA regulatory, ISO notified bodies, federal government and customer audits.
- I will be sharing my learning experience that I acquired from Walter Shewhart books "Statistical Method from the viewpoint of Quality Control" and "Economic control of quality of manufactured product". Additionally, I will be sharing the knowledge I gained from Dr. Deming & Dr. Juan's training in continuous quality systems improvement and management.
- FDA quality systems regulations for medical devices subpart 820.100 Corrective and Preventive Action, subpart 820.22 Quality Audit and ISO 13485 standard clause for Internal Audit & clause for complaint handling, analysis of improvement and data analysis will be discussed.
- Conference attendees will learn about process mapping & flow charting which will directly result in improving their CAPA system using various statistical methods during all phases of the CAPA process. Attendees will gain knowledge and learn how to apply best practices and tried and true techniques. This presentation will teach attendees how to perform root cause analysis and corrective action plans, reduce the customer complaints and improve the processes using six sigma tools. This will result in improved device quality, reliability/ safety and delight customers.
- This presentation will show how to use data & statistical tools to get senior management to engage in successfully carrying out the CAPA program which will result in improved employee morale and customer satisfaction. It will also enhance the auditing process significantly.

#### **Expected Takeaways**

1. Attendees will learn to use statistical tools/techniques to improve the CAPA system, reduce customer complaints which will result in passing Quality Management System (QMS) Audit with flying colors.
2. Attendees will walk away with improved skills and learn to engage senior management in solving quality problems which will break down the barriers between management and employees

#### **Speaker Bio:**

- ASQ Fellow, CQA, CQE, CRE
- ASQ volunteered leadership positions: Current: Advisory board member with ASQ, Baltimore. From 1980 to 2009 held leadership positions with various ASQ chapters. Taught refresher courses to prepare for CQA exams.
- Papers Presented: 34th ASQ World Conference, 1980, ASQ Audit Conference, 2012 and 2017, PMI Symposium, June - 2017, ASQ Biomedical Conference -2008. Various papers at ASQ NEQC conferences.
- Professional Training: Quality Management training from Dr. Deming and Dr. Juran. Workshop: Presenting Data & Information by Edward Tufte.
- Over 35 years of experience in all aspect of Quality Management including quality auditor.



**Session #: B4 and B5**

**Date: Thursday, October 17, 2019**

**Time: 2:45 – 3:30; 3:45 – 4:30**

**Speaker Name: Stan Cherkasky**

**Session Title: The Human Side of Auditing—Taking Audits to the Next Level of Organizational Excellence: Part 1 and Part 2**

**Session Summary:** This captivating interactive presentation focuses on the human-side of the audit. It provides unique insights, and a step-by-step approach to improve auditor interpersonal skills and audit effectiveness. Participants will know how to take the “best approach” from the very beginning, and how to be proactive throughout the entire audit. The result—a successful value-added audit—that drives business excellence.

A nationally recognized business consultant will share some practical tools and techniques to help you improve your business relationships and audit effectiveness. A dynamic and enthusiastic speaker, Cherkasky will deliver a powerful message that you will find helpful in your business world and with your family and friends as well. You’ll be surprised how much you will learn about yourself and others.

**Session Abstract:** Auditors that acquire and hone these ‘human behavior’ skills will be able to build rapport quickly, make an instant connection and be able to engage the auditee to contribute more. The ‘auditor-auditee relationship’ will significantly improve and counterproductive behavior (e.g. defensiveness, withholding of information, apprehension, anxiety, nervousness, etc.) will virtually be eliminated. The engaged auditee will quickly see the value-added audit impact.

Organization-wide improvement is accelerated and improved by focusing on the ‘people-side’ of auditing. This has been proven in my consulting practice over an eleven-year period working with nearly 300 auditors in forty-five organizations. Clients ranged from small to mid-cap organizations, including six multinationals—service organizations and manufacturers alike across America and in Europe. Audit results were compared before and after the “Human Side of Auditing” Auditor Training.

You will acquire renewed auditing insight and proven risk-prevention techniques to significantly improve organization-wide audit performance; continual improvement that can be measured and reported. There is a powerful advantage by combining auditing principles with proven human behavior science methods. In short you will be able to apply powerful, researched-based techniques that will go beyond compliance to the next level of organizational excellence.

**Speaker Bio:** Managing Director of Comprehensive Food Safety, Stan Cherkasky has more than four decades of diversified business and consulting experience. Stan specializes in building high-performance teams and working closely with senior leaders to achieve breakthrough financial, organizational, and operating improvement.

A dynamic performance coach, professional motivational speaker and past Malcolm Baldrige Examiner, Stan has personally guided more than 45 leading organizations to realize a competitive advantage. He has trained more than 20,000 auditors and managers in leadership and communication skills, best practice auditing techniques, organizational effectiveness, and change management. Stan’s academic credentials include a BS in Engineering and a Master’s in Management from the New Jersey Institute of Technology.



**Session #: C1**

**Date: Thursday, October 17, 2019**

**Time: 9:45 – 10:30**

**Speaker Name: Robert (Bob) Deysher**

**Session Title: How do you Audit “Thinking” in Risk Based Thinking**

**Session Summary:** ISO 9001:2015 specifies that the organization shall plan actions to address risks but there is no requirement for formal methods for risk management or a documented risk management process. Auditing those organizations that have not chosen to implement a structured approach to Risk Based Thinking requires an auditor to use their judgment to decide if the standard’s requirement has been met. This presentation will explore how to audit both scenarios, with and without a structured approach, and describe the challenges that auditors face.

**Session Abstract:** Risk Based Thinking has been one of the most successful addition to the ISO 9001:2015 International Standard. The standard requires that an organization understands its context as well needs and expectations of interested parties as an input to their quality management system planning. Additionally, as external and internal environmental changes occur, the organization needs to react to mitigate new risks or take advantage of new opportunities. While specifying actions to address risk and opportunities is required, there is no requirement for a detailed method of risk management or documented risk process. This allows organizations latitude in how this requirement is effectively implemented.

Organizations can decide to implement a quantitative or a qualitative approach to demonstrate risk-based thinking. The quantitative approach can use tools like FMEA’s, Risk Registers, or Risk Matrices. These tools provide a numerical value allowing risk and opportunity prioritization and subsequent action planning and effectiveness follow up. The qualitative approach is less formal. It can be a simple table capturing risks and opportunities, but it does lack the rigor of the quantitative approach. The qualitative approach requires “Due Professional Care, ISO 19011:2018, 4c” by the auditor who has to demonstrate the ability to make a reasoned judgment as to its effectiveness.

While quickly reviewing the ISO 9001:2015 requirements for dealing with risks and opportunities, this session will focus on what information an auditor should be looking for that can be used as evidence in making a conforming or non-conforming conclusion. Both qualitative and quantitative approaches will be examined and how they pose different challenges for an auditor. This presentation will focus on how an organization has used the information relating to their internal and external issues and interested parties to determine risks and opportunities. Also being discussed will be the decision-making process they have gone through to decide what actions they are going to take. In other words, what “Thinking Process” was conducted by the organization leading to the effectiveness of actions taken against risks and opportunities?

**Speaker Bio:** Bob is a Senior Consultant working with the Quality Support Group. He has over 40 years of manufacturing experience in the semiconductor industry. In that time, he has held senior management positions in industrial engineering, process engineering, package assembly, manufacturing, quality, and reliability. He has also worked as a senior staff member and consulting engineer in quality and reliability in between managerial assignments. His areas of training and consulting expertise include ISO 9001 & AS9100, Toyota Production System (TPS) and Lean, Corrective Action and Problem Solving (8D) and he is an ISO 9001:2015 Certified Lead Auditor and a Certified Lead Auditor Trainer.

Bob has a BS and MS in Metallurgy and Material Science from Lehigh University.

**Session #: C2**

**Date: Thursday, October 17, 2019**

**Time: 10:45 – 11:30**

**Speaker Name: Barrett Craner**

**Session Title: Are You Ready for an Audit of Your Risk Management System?**

**Session Summary:** All major Quality Systems standards call for risk-based decision making, and a Risk Management system, and as such, many auditors are coming up to speed on auditing aspects of risk management, including Hazard Identification, Hazard Analysis, Failure Modes and Effects Analysis (Product and Process), Risk Management File, Risk Management Reporting, Risk Management Planning, and even other less commonly used Risk Management tools like Fault Tree Analysis and Hazard Analysis and Critical Control Point. Are you ready for an audit of your Risk Management System and your analysis tools? One way to find out is to attend this informative session and check off the thoughts discussed, and during the Q&A, share your own additional thoughts. Attendees should include Management, Engineering, QA, Regulatory, Manufacturing, and Project Management, and attendees at all levels will benefit from this presentation and discussion.

**Session Abstract:** We Will be Audited!

(1) Risk Management is now a major regulatory player in industry: Regulations, standards and requirements now exist in design, development, manufacturing and field product experience, and when product problems occur, corporate risk management systems and decisions will come under increasing scrutiny.

(2) Risk is everywhere: Risk Management has become an increasingly mandatory expertise and requirement in almost all industries. The risk management history is especially evident in the two most critical and safety-related industries of Aerospace/Defense and Medical Devices/Pharmaceuticals. Anyone involved in those industries can tell you how much effort is expended in creating, implementing, and documenting the activities of company Risk Management Systems. The EN/ISO14971 was the first full risk management standard, launched in 2000, with many aerospace/defense equivalents, and even now, standards regulating hospital data systems involve risk-benefit decisions, some which may come under scrutiny from clients or auditors.

(3) There are many tools available to analyze risk: These will be reviewed and audited. Some are traditional and required, such as Risk Management Planning, Risk Management Reporting, the Risk Management File, Failure Modes and Effects Analyses (for Product, Process, and Use), Fault Tree Analysis (Product and Process), Risk Benefit Analyses, Hazard Analysis and Critical Control Point (for Process risk analysis), each with a good likelihood of review during an audit. There are also tools which have been created as equivalent risk analyses that have been accepted by clients, reviewers, and auditors, each sufficiently presenting risk analysis in efficient and clear ways. No matter, all have the potential for review and audit. This presentation will provide detail for many aspects of these tools to be prepared for review and audit.

(4) Risk Management requirements are expanding: The regulatory environment around Risk Management has expanded and deepened, with all major critical industries creating standards, many having undergone major revisions, significantly swelling Risk Management Systems requirements in these industries (Pharmaceuticals, Hospital, Medical Devices, Aerospace/ Defense, and even moving into and beyond foodstuffs, etc.).

(5) This presentation will summarize the wide focuses on risk management seen in regulatory documents: Selected standards, regulations and directives will be highlighted for their focuses on Risk Management, and for their expanding requirements as examples for us to see where the "Risk management" industry is going, and where we need to place our practical and required Risk Management efforts.

(6) Workshops have been prepared: Attendees may take back these simple workshops with clear problem statements to their companies to use as examples or actual discussion platforms to determine if your firm is Risk Management audit-ready. Six workshops have been prepared for various intensities of audits, and when product problems occur.

(7) All levels of management, process engineering, QA, and Regulatory professionals will benefit from this presentation: Be prepared, as you've also been involved in creating the Risk Management Program, and to some extent in the individual company Risk Management projects. Thus, review and audit questions may come your way.

**Speaker Bio:**

**FDA, Silver Springs, MD**, - Medical Device Risk Management (38 FDA attending, two seminar days): October 2017

**Teacher for ASQ Silicon Valley Section** (0613) courses since 2003, incl. Risk Management and others (>50 times).

**ASQ Learning Offerings, >25** 8 - hour Virtual and on-site (US/Canada) Courses, Risk Management, Regulated Industries, 2007, 2008, 2012 – 2019.

**WCQI** – multiple papers 1994, 1995, 2008, 2009, 2010, 2014 (many on Risk Mgt topics)

**ASQ Biomedical Conferences** – multiple papers on Risk Mgt 2014, 2016, and 2017

**ASQ Los Angeles:** 2-day Risk Mgt Seminar, 2016

**ASQ Biomedical Division** - Northern California Discussion Group: >20 presentations 2003-2019

**Honorary:**

**FDA Pacific Region - sole invited industry speaker** at FDA Centennial: *An Industry Perspective*, Oakland, 2006

Royal Pharmaceutical Society, London Reinvigorating Risk Mgt, Invited Conference Co-Chair on behalf of ASQ Biomed Division, 2008

Presented Stanley Marash Memorial Paper in Risk Management at Tel Aviv, Israel, Int'l Quality Control Congress, 2010

**Session #: C3**

**Date: Thursday, October 17, 2019**

**Time: 1:45 – 2:30**

**Speaker Name: Mark Durivage**

**Session Title: A Quantitative Risk-Based Approach to Internal Audit Nonconformity Grading**

**Session Summary:** Traditionally, audit findings have been graded qualitatively using the generally accepted and widely used terms major and minor. The latest edition of ISO 19011:2018 *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). This presentation will provide an alternative to the traditional qualitative nonconformity grading system of minor and major findings and offer an alternative risk-based approach using a quantitative system of rating audit nonconformities.

**Session Abstract:** Traditionally, audit findings have been graded qualitatively using the generally accepted and widely used terms minor and major. The latest edition of ISO 19011:2018 *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 company to company, sometimes leading to confusion, misunderstanding, misinterpretation, and sometimes unsuitable responses.

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 model can be easily adapted to satisfy the requirements of ISO 9001 and other similar business management systems.

This presentation will provide an alternative to the traditional qualitative nonconformity grading system of minor and major audit findings and offer an alternative risk-based approach using a quantitative system of grading audit nonconformities. The session will demonstrate how to apply the quantitative audit scoring process to comply with ISO 9001 internal audit obligations requiring the organization to “plan, establish, implement and maintain an audit program (s) including the frequency, methods, responsibilities, planning requirements and reporting, which



shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits.”

**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. He holds several certifications including; CRE, CQE, CQA, CSQP, CSSBB, RAC (Global), and CTBS. He has written several books available through ASQ Quality Press, published articles in Quality Progress, and is a frequent contributor to Life Science Connect.

Mark primarily works with companies in the FDA regulated industries focusing on quality management systems including internal and external audit support as well as FDA 483 and Warning Letter response and remediation services.



**Session #: C4**

**Date: Thursday, October 17, 2019**

**Time: 2:45 – 3:30**

**Speaker Name: Jim Leonard**

**Session Title: Corrective Actions Guided by Systematic Root Cause Analysis**

**Session Summary:** In this conference’s “Call for Speakers,” one stated objective was to encourage attendees “to go beyond compliance and help their organizations achieve business excellence.” This session presents a systematic approach to root cause analysis that will empower the auditor to help clients get to the root causes and assure effective corrective actions to address areas of non-conformance and other problems that may be identified during an audit. It will add a powerful tool to auditors’ and quality professionals’ skill sets.

**Session Abstract:** For decades, management consultants, academicians and practitioners have been searching for effective approaches to solving problems. The size of the problems may range from major non-conformance issues captured in an audit to small glitches in completing a capital project on schedule to massive, catastrophic failures of critical components or equipment. Regardless of the problems’ scope, American managers have nonetheless been searching for the Holy Grail – a foolproof approach to solving their problems.

Shewhart, Deming, Ishikawa, Wheeler, Chambers, Taguchi and others developed statistical approaches and methods for analyzing problems and testing solutions. Analytic statistical methods like statistical process control (SPC) and design of experiments (DOE) can yield a better understanding of problems and their causes in dynamic processes. Some people, however, question whether statistical methods can effectively harness people’s creativity and intuition when searching for solutions to challenging problems.

Kepner, Tregoe, Erickson and others developed and applied intuitive yet structured techniques for problem analysis. Brainstorming, cause-and-effect analysis, 5 Why and basic problem-solving methodologies have also been used with some success. Unfortunately, these approaches sometimes aren't successful in capturing systemic variation and problems that may be due to interactions between and among several factors or causes, as opposed to one, single, identifiable "root cause." So, the search continues.

This session presents a technique that combines a structured methodology for root cause analysis to a statistical understanding of the nature of work to yield better, faster and more effective solutions to work problems. Beyond applications in the wake of an audit, root cause analysis is a critical tool for everyone involved in process improvement projects. Such teams conduct stability studies and may find evidence of special cause variation. In the face of special cause variation, systematic root cause analysis is applied to identify the special cause and take action to remove and prevent the re-occurrence of that special cause, thereby achieving statistical control and a baseline for improving the process.

More specifically, this session will open with an operational definition of the term "problem" and examine common pitfalls in problem solving that must be avoided. Next, we will examine a procedure for clearly defining and analyzing problems, followed by techniques for generating and testing possible causes of those problems.

Too often, however, the missing ingredient in basic problem analysis is applied knowledge of the theory of variation. In the face of one type of variation, systematic root cause analysis works very well. In the face of a different type of variation, apply this technique at your peril! It is not enough to be skilled in problem investigations; we must connect our skill with *knowledge* – knowledge of theory of variation. Connecting our skill to knowledge of theory is what moves us out of reactive, basic root cause analysis and into *Advanced Problem Solving*.

**Speaker Bio:** Jim Leonard is a consultant who specializes in teaching the principles of W. Edwards Deming. He is a Senior Consultant for Quality Support Group and for 29 years taught courses for Corporate and Professional Education at the Worcester Polytechnic Institute, where he was also a Graduate Adjunct Professor. Jim serves clients in China as an instructor for the China Institute for Innovation in Shanghai. He is an alumnus of the U.S. Naval Academy, George Washington University, and Clark University.

Jim resides in Ave Maria, FL, with his wife Kate. They have six wonderful children and ten beautiful grandchildren.

**Session #: C5**

**Date: Thursday, October 17, 2019**

**Time: 3:45 – 4:30**

**Speaker Name: Sandra Storli**

**Session Title: Supplier Auditing Beyond the Standards**

**Session Summary:** Supplier management programs will use a supplier survey or an on-site audit to verify if a supplier is compliant with the requirements of a standard or regulation. However, for a supplier management program to be value-added to an organization, the supplier evaluation should look beyond the requirements of a standard or regulation. Supplier auditing should consider items such as supplier capability, capacity, contingency plans, effectiveness, and efficiency and outsourced processes.

**Session Abstract:** You need a supplier auditing program that helps you stay on top of all your outsourced operations. Outsourcing represents a critical and complex process involving many parties and covering many geographical areas. This process has become a global phenomenon. Dependency on suppliers and outsourcing is on the rise. Organizations are increasingly realizing the vulnerability of their brand reputation and risk of financial loss resulting from supplier incidents and nonconformities. The key question: do you know what hidden risks lie within your global supply chain.

This session will outline details of the outsourcing process beyond the standards in the FDA regulated industries with emphasis on the critical aspects of monitoring and preserving the integrity of the supply chain. The importance and use of risk management techniques will be presented.

- Why audit your supplier?
- Who will audit your supplier?
- When will you audit your supplier?
- What will you audit?
- How will you conduct the audit?

**Speaker Bio:** Sandra Storli brings more than 30 years of professional experience and leadership in quality, regulatory, clinical, operations, and product design for life sciences companies. Some regulations and standards include ISO 9001:2015, 13485:2016, ISO 17025:2017, FDA 21CFR 210, 211, 820 to name a few. She is currently operating his own organization, providing Quality and Regulatory consulting services by establishing quality systems, resolving compliance problems, representing firms in FDA inspections and Notified Body audits, developing quality systems, cleaning, and design and process validations.

Sandra is an ASQ Fellow, and currently the Regional Director for Region 12, and also member of the Food Drug and Cosmetic Division, Audit Division and Biomedical Division. She was the past Chair of the NEI North Eastern Illinois Section Group of the ASQ, a current member of ISPE and a frequent lecturer on quality auditing, relevant to the medical device industry.

**Session #: D1**

**Date: Thursday, October 17, 2019**

**Time: 9:45 – 10:30**

**Speaker Name: William Taraszewski**

**Session Title: First Impressions: The Myth of the Objective & Impartial Audit**

**Session Summary:** Studies have shown that you make judgements on the trustworthiness and competence (among other traits) of other people after looking at their faces for 100 milliseconds. How then does an auditor maintain objectivity and impartiality for the remainder of an audit? This session will examine the science behind first impressions; how they can be both advantageous and disadvantageous during an audit; what to do to attempt to overcome them; and perhaps most importantly, how to create better first impressions as auditors to enhance the overall effectiveness of audits.

**Session Abstract:** You've driven to your audit site, parked the car, entered the building, signed in, and met your host. Within those first minutes, you have already formed impressions about the company, its commitment to quality, and the competence, likability, aggressiveness, and trustworthiness of the people who work there. And the data suggests that these impressions may persist, in spite of available information that contradicts your first thoughts. How then do you conduct a fair, objective, and impartial audit?

In this presentation, we will discuss the science behind first impressions. Numerous examples will be presented, highlighting the types of things people decide within seconds – and there are many! The effects of similars and dissimilars, such as cultural influences, accents and speech, will be presented. Research on the relative importance of verbal and non-verbal cues is will also be shown.

Because there are differences in perceptions of video vs. in-person contacts, the particular risks of remote or virtual audits will be addressed.

Given the apparent persistence of first impressions, the need and ability to overcome a first impression, particularly with regard to audit performance, will be discussed in detail. Strategies such as finding areas in common, and how to proactively tackle assumptions, will be shown.

In addition, it is particularly important that auditors also present and portray desirable first impressions to the auditee, so as to set the stage for a productive audit. Discussion of several key, controllable ways to make a positive first impression as an auditor will conclude the presentation.

**Speaker Bio:** Dr. William Taraszewski is an independent consultant and quality systems auditor. He is a member of the Food, Drug, & Cosmetic, Audit, Biomedical, Quality Management, and Lean Enterprise Divisions, and is an ASQ Fellow. Bill has been on the Executive Team of the FDC

Division since 2015 and was Chair in 2018. He holds the CQA, CMQ/OE, and CPGP certifications from ASQ, and Certified QMS Auditor and Certified Management Systems Specialist certifications from Exemplar Global.



**Session #: D2**

**Date: Thursday, October 17, 2019**

**Time: 10:45 – 11:30**

**Speaker Name: Randall Pittman**

**Session Title: Understanding ISO 45001, a Safe and Healthy way to realize Profit and Productivity.**

**Session Summary:** Occupational Health and Safety programs directly impact an organizations' working environment, quality program and financial capabilities. Direct and indirect costs associated with even a single injury can cost millions in sales dollars, delaying allocation for planned improvements. Replacing experienced injured employees introduces new risks, which could lead to reduced quality or even more injuries. Maintaining a safety management system is a great way to take control of these risks and opportunities.

ISO 45001 is the latest occupational health and safety (OSH) management system standard designed to integrate seamlessly with ISO 9001. This session makes a business case for ISO 45001 and highlights the benefits and efficiencies of integration. This session is presented by a technical expert and 3<sup>rd</sup> party auditor who will share auditor resource documents that are essential to the proper assessment of ISO 45001 and explain the intent of certain requirements based upon the specific language used.

**Session Abstract:** It is assumed that most in attendance are already familiar with ISO 9001. A very general overview regarding the value of an implemented management system and how an implemented safety management system like ISO 45001 can also drive positive performance and operational excellence will be described. The session progresses by presenting a business case for adopting a safety management system by providing a couple of real-world scenarios regarding the costs, risks and opportunities to an organization when an injury occurs. This information is based upon the most recent data available. Then there is a brief interaction regarding the top injuries in the workplace which then includes the opportunity for selected attendees to describe how an injurious event impacted their company. ISO 45001 is then introduced with a brief explanation regarding its evolution and the eventual retirement of OHSAS 18001. The main areas of change will be highlighted to include the gaps between the two standards while sharing the high-level structure to illustrate the alignment to ISO 9001 for easy integration and discuss the benefits of integration. The last part of the session dives a little deeper into how to identify specific key words within the standard which unlock the process approach for auditing ISO 45001. This involves introducing resources beyond the standard that each and every auditor should be aware of and also know how to gain access to them. Throughout the presentation the importance of understanding entire ISO45001 document from introduction to bibliography and not just the auditable sections is emphasized.

It is expected that Attendees will walk away with an understanding of what ISO 45001 is intended to achieve, why the standard is structured the way that is, and how to achieve understanding of the intent for each requirement for maximum auditing effectiveness and performance.

**Speaker Bio:** Randy Pittman is the Business Unit manager for Environmental Health and Safety Standards with NQA. For over a decade, Randy has conducted and led teamed audits around the world for ISO 9001, ISO 14001, OHSAS 18001, & ISO 45001. He presents technical material to 3<sup>rd</sup> party auditors and participates as a technical expert to various industry groups.

Randy Acquired his skills while supervising commercial and residential construction projects within his family business. Attaining a degree in Geo-Physical Science he re-entered the workforce in the environmental industry. Certificate course within MSHA, OSHA, NEBOSH, ASP, RCRA, contribute to his professional portfolio.



**Session #:** D3

**Date:** Thursday, October 17, 2019

**Time:** 1:45 – 2:30

**Speaker Name:** Maribel Colon

**Session Title:** Bringing Excellence to the Cannabis Industry through the Auditing and Self-Inspection Path

**Session Summary:** Get on the pulse of the billion-dollar state-sanctioned but highly legislated cannabis consumer products and therapies industry. Discover the new policy landscape with FDA approvals and licenses to make cannabis-derived pharmaceuticals and learn the benefits of developing effective self-inspection programs and compliance auditing systems that mitigate risk while delivering better quality products and excellent services. While the approval and commercialization of cannabis offer a multitude of new opportunities, quality management systems deliver a competitive advantage, inspire trust in brands, and attract potential investors. Learn the necessary strategies to begin the audit path.

**Session Abstract:** Used for over 3,000 years for its health benefits, today cannabis is one of the most highly-legislated fields with massive growth potential. Amid conflicting state and federal laws is an increasing awareness and demand for quality and safe cannabis consumer products and therapies. The landmark FDA approvals of Marinol, Syndros and Epidiolex have helped securely establish cannabis in the US market. Along with licenses for authorized manufacturers of cannabis plant extracts and CBD that are approved to make cannabis-derived pharmaceuticals

Amid the exponential growth of CBD and cannabis industries is the increasing widespread issue of safety and quality risks. One solution is to create a robust cannabis quality management system and develop an effective self-inspection program and compliance auditing system from cultivation and manufacturing to retail.

Being a fairly new industry, cannabis brings challenges for both organizations and auditors. But the benefits of developing quality management systems offer excellent benefits. Along with mitigating risk, organizations can stay ahead of the competition by offering better customer services and quality.

The growing state-sanctioned U.S. cannabis industry needs effective self-inspection programs and compliance auditing systems to reach its full commercial potential in all verticals. Strategies to begin the audit path have tremendous payoffs for quality, risk management, innovative processes, and potential market share.

This session will provide the basic steps on how to develop, implement, and conduct a cannabis industry auditing and self-inspection program to deliver on the promise of safe and reliable cannabis while achieving full commercial potential. Discussed will be the primary reasons why to consider implementing an effective self-inspection and auditing program, including the primary risks, credibility, and sustainability of an organization. The unique factors to consider when developing and conducting an auditing program for the cannabis industry will also be examined.

Acquiring an effective auditing and self-inspection program is the foundation on how to create a culture of business excellence in organizations that are passionate about becoming a profitable, transparent, and trusted leading brand for quality cannabis. Effective programs are also highly desirable to create trust with potential investors.

**Speaker Bio:** An active member of the ASTM D37 Committee developing the first cannabis industry self-inspection and auditing standard, Maribel Colón is a bilingual results-driven engineer. Working with fortune 500 companies in quality management systems and remediations, auditing, cGMP, ISO and FDA readiness, risk management, new process development, process improvement, and lean manufacturing, Colón's

experience includes the heavily regulated industries of biotechnology, radiopharmaceutical, medical devices, APIs, the food industry and cosmetics/OTC in the U.S. and Latin America. A certified Lead Auditor, Colón holds a Chemical Engineering degree with a concentration in Industrial Biotechnology. She's also a Lean Six Sigma Black Belt.

**Session #: D4**

**Date: Thursday, October 17, 2019**

**Time: 2:45 – 3:30**

**Speaker Name: Jeremiah Genest**

**Session Title: Lessons on Change Management from a Consent Decree Site**

**Session Summary:** Drawing on the experiences of a company under a FDA consent decree, this session will consider change management and change control, and how they are improved upon by a grounding in knowledge management and risk management. The lessons learned and applied are relevant not only to the pharmaceutical industry, but to other FDA industries (medical devices, cosmetics, food, etc.), and to other heavily regulated industries (energy, mining, financial services and beyond). It is easy for a company in these situations to focus on change control and forget the wider scope of change management. During this session we will share improvements made in our processes as a result of being under the consent decree, as well as several templates, and tools to enable good change management, and change control activities.

**Session Abstract:** The Pharmaceutical Quality System described by the International Conference of Harmonization (ICH) is a holistic approach which facilitates the consistent development and production of high quality pharmaceutical products. It aims to support innovation and continual improvement of products, processes, and methodologies using knowledge management and quality risk management. Providing a lifecycle approach to pharmaceuticals, change management is a key element to this approach.

The Pharmaceutical Industry is one of the most regulated industries. In the US, the Food and Drug Administration (FDA) often uses the consent decree as the ultimate enforcement tool for those who break the rules. A company under consent decree needs to prove, via third party, that it has achieved and can sustain regulatory compliance. Companies under a consent decree must break down and build up their entire quality system.

After this session attendees will be able to:

- Evaluate lessons learned from a consent decree and building a robust pharmaceutical quality system for your use.
- Explain how the pharmaceutical experience can deepen your understanding of ISO 9001:2015, especially risk based thinking
- Identify how change management fits into a culture of quality
- Understand how the change management system increases compliance
- Use a few simple but effective tools for change management.

The ICH quality approach developed from ISO 9001:2008 but in many ways preceded the risk based thinking pivotal to ISO 9001:2015. Utilizing a matrix of similarities and differences between traditional GMPs, the ICHs and ISO 9001:2015, we will explore several lessons learned from consent decree activities, and demonstrate principles of change management.

This session will explore change management from the three lenses of science, regulation and risk, with a focus on knowledge management and risk management as enablers of successful change management. Several examples will be shared to demonstrate the fundamental connections between these systems.

The basis of this session will be change management as a fundamental part of a culture of quality. We will share best practices based on lessons learned from the consent decree around the impact of cumulative changes and large-scale versus incremental change.

Compliance for change management necessitates clear accountabilities, prioritization of changes, and the role of the quality unit – including the importance of a change champion or steward. This session will explore the relationship between change control, which often refers to the execution step of an individual change, and change management, which is a more systematic, holistic approach to the review and management of a portfolio of changes and the change process

**Speaker Bio:** Jeremiah Genest is an Associate Director of Quality Systems at Sanofi and has 20 years quality systems experience in the energy and pharmaceutical industry, with over a decade's experience implementing and running quality systems in the biotech field. He has experience implementing change management and data integrity at a consent decree site. He is a Certified Manager of Quality/Operation Excellence and Pharmaceutical GMP Professional.



**Session #: D5**

**Date: Thursday, October 17, 2019**

**Time: 3:45 – 4:30**

**Speaker Name: Denis Devos**

**Session Title: Writing Effective OFI Statements**

**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.

**Session Abstract:** 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.

The value of this presentation is teaching participants the role of Opportunities for Improvement in an audit, and to have an effective technique for writing these.

**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 and IATF 16949 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 ASQ conferences at the Audit Division, Management Division, and the World Conference on Quality and Improvement.

Session #: E1

Date: Thursday, October 17, 2019

Time: 9:45 – 10:30

Speakers Names: Daren K. Jensen (primary speaker) with Jeff Fluckiger and Jill Owens

**Session Title: First Impressions: Predicting the Future by Delivering the Goods – How the Idaho National Laboratory prepared for and Achieved American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA-1) Certification**

**Session Summary:** As the United States of America's lead nuclear laboratory, Idaho National Laboratory (INL) in operation for 70 years is committed to lead by example to ensure that products and services exceed customer requirements and demonstrate quality excellence. To achieve this result, INL established an American Society of Mechanical Engineers (ASME) nuclear quality assurance (NQA-1) based quality assurance program and achieved ASME NQA-1 Certification of this QA program. This presentation will discuss how INL planned, prepared for and achieved ASME NQA-1 Certification.

**Session Abstract:** As the United States of America's lead nuclear laboratory, Idaho National Laboratory (INL) in operation for 70 years is committed to lead by example to ensure that products and services exceed customer requirements and demonstrate quality excellence. To achieve this result, INL established an American Society of Mechanical Engineers (ASME) nuclear quality assurance (NQA-1) based quality assurance program that aligns with nuclear industry and NRC requirements, is easy to understand and follow, is transparent to workers and researchers and provides for grading of QA requirements based on end use. After planning and preparing for certification, in May of 2019 INL achieved ASME NQA-1 Certification of the INL's QA program. This presentation will discuss how INL planned, prepared for and achieved ASME NQA-1 Certification.

**Speaker Bio:** Mr. Daren Jensen is the Quality Assurance Program Manager at the Idaho National Laboratory. He is an Exemplar Global certified QMS Lead Auditor and Lean/Six Sigma Black Belt. Mr. Jensen is nearing completion of an Executive Leadership certificate from Cornell University and holds a M.S Degree from the University of Idaho and a B.S. Degree from Idaho State University.

Daren serves as the Chair for the American Society of Mechanical Engineers (ASME) NQA-1 Applications Subcommittee, is a member of the NQA-1 Main Committee and Executive Committee, is a member of the American Society for Quality (ASQ) Technical Advisory Group (TAG) to ISO/PC 302, Guidelines for Auditing Management Systems, a member of ASTM ISO/TC 85 Working Group, a member of the ASQ Energy and Environment Division and is the Chair of the ASQ Intermountain Section.

Daren has developed and implemented quality assurance and independent oversight programs, lead and/or participated in hundreds of audits for DOE laboratories and other customers, and has designed, developed and provided quality engineering, human performance, auditing and nuclear quality assurance training. He enjoys photography, hiking and spending time with family.





**Session #: F1**

**Date: Friday, October 18, 2019**

**Time: 9:45 – 10:30**

**Speaker Name: Elisabeth Thaller**

**Session Title: The Holistic Audit**

**Session Summary:** The Holistic Audit – A new comprehensive audit approach that will produce outcomes that really matter.

Since the creation of the first management system standard more than 30 years ago the context for their users globally has significantly changed. Through the continual revision process and the contribution of experts from the international community the requirements in management systems standards have somehow adapted to those changes and become more practical in their application. But what happened to auditing practices? Since the publication of the first international guidance on auditing management systems not much has changed. While ISO 19011 is a great guidance document it does not give you the tools that will make you successful as an auditor.

During this presentation we will discuss a new and comprehensive approach to auditing, with ready-to-use tools and focus on producing audit outcomes that really matter.

**Session Abstract:** While management systems standards have somehow adapted to changing contexts throughout the past three decades, guidance on how to audit these management systems and how auditors are being trained have mostly remained the same.

Trained auditors are familiar with the auditing principles, they understand the flow of an audit, and they know that the output will be an audit report with relevant findings and related evidence. Some might even have some insight into managing audit programs. This basic knowledge is typically taught at any auditor class while real auditing skills are being acquired in through real-life practice and by observing experienced auditors. But is that enough to make you a good auditor?

Auditors are expected to understand within a few hours or less how the organization functions and at the end come to a conclusion if the organization meets the requirements and the management system effective.

Typical challenges that new and experienced auditors face nowadays include that fact that most management system standards now include more requirements which at the same time are less prescriptive than in the past. Add the fact that the auditees have become smarter and will most likely argue any finding the auditor might encounter. Management system audits are not supposed to be done by element of the standard in a sequential order, as they used to, but rather through a process-approach. If you are not supposed to use an audit checklist to mark off conformity or nonconformity for each requirement, then what should you use? Focus should not be on documentation but on output.

During this presentation I will discuss these and other challenges auditors face and provide solutions that auditors might find practical for their work.

**Speaker Bio:** 25+ years of experience in conformity assessments of management systems, consulting, training, examinations and competence of persons.

- Represented ASQ in the international committee ISO PC 302 for the revision of ISO 19011:2018.
- Member of US TAG 176, US TAG 207, ISO CASCO, US VTAG (ISO High Level Structure), ISO STTF.
- As a Senior Evaluator for Exemplar Global (RABQSA), has performed 300+ assessments of training providers in the US, Europe, Latin America, Australia and Africa.
- Lead Assessor for accreditation programs (ISO 17021-1); Lead Auditor for management system certifications.
- Multi-lingual, with ample experience working in international and multicultural environments.



**Session #:** F2

**Date:** Friday, October 18, 2019

**Time:** 10:45 – 11:30

**Speaker Name:** Denis Devos

**Session Title:** QMS Audits as an Enabler for Organizational Change

**Session Summary:** Quality Management System Audits are not just for assessing compliance with customer requirements or a QMS Standard but can be used by Senior Management to gauge the performance of their organization. Examples will show how Quality Management System audits can be an important tool to assist with organizational turn-around. Although third-party audits can be used for this purpose, this paper will focus on the role of *internal* audits as the enabler for organizational change. QMS audits by registrars have their place, they are not by their nature the most suitable vehicle for supporting organizational change. The paper includes examples from three organizations where internal audits were used as enablers to accomplish leader-led organizational change.

**Session Abstract:** Much has been written on organizational design, and methods of optimizing performance for customer focus and profitability. This presentation will not be reiterating these concepts but will begin from the point of view that an organization has been set up with a suitable structure. Organizational structures can be considered as either newly implemented or mature. The approach to auditing the effectiveness of these two types of organizations will differ slightly in strategy and focus.

Whether a company's organization is a mature one, or is a state of upheaval and renewal, it is essential that the leadership set an appropriate culture of customer-focus and accountability. Clearly defined goals and objectives, and a clear strategy for deployment and measurement is absolutely essential. Once the infrastructure is in place, Senior Management can begin to use its internal auditing resources to assess the status of the organization, and the degree to which policies and directions are being followed effectively.

By working with a number of organizations suffering through a turn-around, we have learned about the vital role that on-going internal audits can play in that very challenging period. No matter what problems are being addressed, internal audits can be instrumental in supporting those improvement efforts. An internal audit can be used two ways. Firstly, the audit can be used as a gap analysis to assess current state; and secondly, the audit can be used to follow the deployment of an improvement initiative.

At the most basic level, an internal audit is the "checking" function of Plan-Do-Check-Act. As an organization creates its turn-around strategy, it is *planning* to accomplish a certain set of objectives. As the organization undertakes to *do* the tasks and complete the projects associated with the strategy, senior management will need to *check* on progress, and *act* to respond to challenges facing their objectives. Wise organizations will make deliberate and frequent use of their internal auditing resources to continuously monitor progress. These auditors will assess objective evidence and report back on the true performance of the organization, despite what "official" reports suggest.

Many organizations who opt to use QMS audits as a tool to support their change programs will select external auditors to perform their internal audits. There are many external auditors who can be retained by organizations to perform their audits on an ongoing basis. These auditors may be contract auditors employed by registrars or may be in private practice. The selection should be based on audit and industry experience, and a proven track record. Many auditors have particular expertise with such management standards as ISO 9001, ISO 13485, IATF 16949, etc. With a little bit of research, organizations should be able to find professional auditors with many years of auditing experience, and specialization in their own industry. It is often appropriate for companies to use professional auditors from outside of their organizations to assure an unbiased view and mitigate the risk that inexperienced internal auditors will draw inaccurate conclusions.

**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 and IATF 16949 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 ASQ conferences at the Audit Division, Management Division, and the World Conference on Quality and Improvement.



**Session #:** F3

**Date:** Friday, October 18, 2019

**Time:** 1:45 – 2:30

**Speaker Name:** Jeff Rosaine

**Session Title:** Engaging Management by Applying Dollars and Cents to Internal Audits

**Session Summary:** It is a constant challenge for Quality Professionals, and auditors in particular, to achieve buy-in and commitment from top Management. Management is focused primarily on dollars and cents, they want to know how all business activities effect the bottom line. When auditors can validate that their activities and the information they are reporting has a tangible effect on an organization's profitability, Management will certainly take notice. An effective way to do this is to assign cost and benefit, in actual dollars, to your audit Findings.

This session, through case studies and examples, will demonstrate how to assign a realistic cost to audit nonconformances, opportunities for improvement, and other findings. Case studies and examples will be used to exhibit an interactive process where the managers and auditors work together to determine the true cost of the issues found during internal quality audits.

**Session Abstract:** Top Management often believes Quality, and internal audits in particular, are a cost of doing business with limited positive effects on the bottom line. This presentation will focus on changing that way of thinking by incorporating into the audit what Managers know best, dollars and cents.

As an example, auditors are trained to look for and document nonconformances in their audit reports. But are some nonconformances more significant than others? Should corrective actions be prioritized when resources are limited? And if so, how do we communicate to Management which problems need the most attention?

Rather than simply classifying a nonconformance as major or minor, what if internal auditors could determine the actual dollar cost of a nonconforming activity? If Management sees how much nonconformances cost the organization, be it in loss of efficiencies, decreased customer satisfaction, regulatory concerns, etc. they will be much more receptive to allocating the necessary resources towards corrective action. And they will place more value on the audit process, as they see it can help the company save money and even generate revenue, as opposed to being a cost center.

The presentation will explain how to do this, even when the Quality Auditor has little access to financial information. They may not know the exact dollar figures associated with things like lost business, overtime and equipment depreciation, but they can certainly detect when these costs are unnecessarily occurring. The key is to turn these situations into an opportunity to engage and involve managers, accountants, legal and others that possess the necessary financial knowledge. The more involvement in the audit, especially at higher levels of management, the stronger the entire Quality Management System can be.

How the auditor engages Management is critical. There is nothing wrong with making estimates, as long as Management is asked for input. For example, an auditor could present a nonconformance they believe costs \$1000 a week and even have some math to back up their numbers. But preface it by saying "this is only an estimate. As the Manager of this project/division/company, you have a much better understanding of the costs associated and I need your help to be more accurate" Then allow the auditee to adjust the numbers as they see fit. This starts a discussion and will further engage those running the organization. If an auditor can help them determine where to prioritize efforts and discover ways to be more profitable, the audit's value increase substantially. And the more conversation, the more likely this resonates.

The presentation will use case studies and examples to illustrate how an auditor can craft their estimates, how to present to management, and what to expect when managers get involved with their input. The presentation will also be interactive, as the audience will be encouraged to ask questions and share their own ideas and experiences.

**Speaker Bio:** Jeff is the President of J Rosaine Quality and Consulting, whose recent clients include National Oilwell Varco, TransCanada Corporation and CES Energy Solutions, where he is currently serving as the Corporate Quality Manager. Jeff has been involved in Quality Auditing and Management since 1996 and in that time has conducted over 500 internal audits. Along the way, he has earned ASQ Certified Quality Manager and Certified Quality Auditor designations. Jeff is always happy to share his experiences with any and all Quality professionals. In turn, he is continuously looking to gain more knowledge and learn new ideas from this same group.



**Session #: F4**

**Date: Friday, October 18, 2019**

**Time: 2:45 – 3:30**

**Speaker Name: Susan Gorveatte**

**Session Title: Audit Like a Leader – Communication in Auditing**

**Session Summary:** *Perform successful audits with effective communication and leadership skills while remaining true to the purpose of the audit. Build your confidence in auditing, while learning skills you can apply immediately within your organization.*

Being a trained auditor doesn't always mean you will be a successful auditor. An auditor's technical knowledge skills should be supported with appropriate personal behavior and interpersonal skills. Success in auditing relies on effective communication and being a strong team leader. Learn to be a leader in auditing by adhering to the principles of auditing and building strong audit relationships with your audit client, auditees, and team members. Learn how to approach people, how to build rapport, how to listen, how to resolve conflict and how to apply the traits of a successful auditor. These are the skills and attributes that will help you be more credible, trusted, and more confident when auditing.

**Session Abstract:** Auditors should have a range of knowledge and skills to conduct and manage audits. Knowing the criteria against which you will be auditing is one of the steps to becoming an auditor; although success in auditing also relies on effective communication and being a strong team leader.

Session Takeaways:

In this interactive session, participants will:

- Identify the "softer" skills of auditing that align with the principles of auditing outlined in ISO 19011:2018
- Understand the qualities of a successful team leader within the context of conducting an audit
- Practice positive communication skills that can be used in an audit

- Appreciate the value of building a strong, positive rapport with auditees
- Learn conflict resolution techniques to assist with issues raised during the audit either with the audit client/auditee or within an audit team
- Work within a group to highlight strategies to deal with challenging auditees
- Find success by fulfilling their role as an auditor who acts within the audit principles

#### Understanding the Principles of Auditing:

The session begins with brief review of the seven basic principles of auditing that guide the performance of management system audits contained within ISO 19011:2018, this will set the theme for the rest of the presentation.

#### Managing Communication:

Effective communication can make the difference between achieving mediocrity and reaching the top of your profession. Communication is a skill – and it can be learned. To keep things positive, auditors have to set the tone for the audit through building a strong rapport with the auditee. Auditors need to be good at introducing themselves. Having a quick introduction is a great way to help auditees feel confident in your abilities. Participants will practice their introductions with positive body language. Auditors spend about 80% of their time listening. We will introduce listening skills and identify the major behaviours that differentiate between good and bad listeners. Participants be able use these communication strategies to build a foundation for audit success.

#### Being a Leader:

As a team leader, there are additional responsibilities and communication paths that are required when auditing. The audit team leader may need to periodically communicate the progress of the audit and any concerns to the auditee and audit client. The team leader must be willing to be the person that starts the conversation with the client, auditee, and fellow team members to resolve issues and ease any potential tension before it becomes a combustion point. A review of problem resolution techniques is discussed with participants to ensure a smooth audit both with the auditee and client and within their audit teams.

#### Demonstrating the Traits of a Successful Auditor:

Participants will summarize as a group what makes a “successful auditor” as they brainstorm creating a list of their top Personal Attributes. This is reviewed to compile a comprehensive list of traits to ensure their ongoing success in the auditing field. From this, the participant will be aware how to conduct themselves in their next audit by applying their new communication and leadership strategies.

**Speaker Bio:** SUSAN GORVEATTE, has worked throughout North America in the service and manufacturing sectors training quality management system auditors and facilitating management programs including several years coaching and auditing in the automotive manufacturing hub of Detroit. Susan has audited and trained hundreds of companies providing tangible results through effective group facilitation and coaching. She has completed Lead Auditor training in AS 9100, AS 9110, ISO 14001 and ISO 9001, and is an active member of American Society for Quality as Past Section Chair, Content Management Leader for Quality Management Division and Technical Program Committee for World Conference on Quality and Improvement.

**Session #: G1 and G2**

**Date: Friday, October 18, 2019**

**Time: 9:45 – 10:30; 10:45 – 11:30**

**Speaker Name: Diana Baldi**

**Session Title: Part 1 and Part 2(Interactive): Revitalize Your Audit Program Using Engaging Audit Reporting Practices**

**Session Summary:** Many audit closing meetings and management reviews are boring. ISO-speak has limited understanding across the workforce. It is no wonder management seems unengaged. This session will present visual and written summary options for reporting audit results that tell a story and engage leadership. Imagine how powerful looking across quality, environmental and health and safety management systems could be if the views were balanced. This session will also touch upon audit program management to acquire reliable data to support the visual report styles.

**Session Abstract:** The way audit results are reported impacts the overall perception of the management system and affects (+/-) the level of engagement across the workforce and within leadership. By attending this session, participants will learn helpful insights for communicating audit results in meaningful ways. The workshop will provide an overview of common problems, underlying challenges, tips for success, and case study examples that demonstrate a range of audit reporting styles. In the longer session, the participants will have an opportunity to test their skills to develop 1-2 slides to summarize a test case.

Using simple spreadsheet formats and pivot tables, extensive text can become informative charts that inform and motivate leadership. Visuals help focus attention on rewarding success and directing action to make improvements, as appropriate.

An underlying challenge for generating robust audit reports is understanding the reliability of the auditor evaluations. Communicating this feedback to leadership effectively can help ensure proper resources are allocated to the audit program. This session will include examples of criteria-based visuals that communicate the strengths and weaknesses of the internal audit program.

In reviewing hundreds of audit programs and thousands of audit reports, it became quite evident that the common text-based reporting of audit results disillusioned leadership. Turning that same information into criteria-based visuals can dramatically increase understanding and engagement of leadership. Once this step is taken, it then becomes evident that a similar visual and criteria-based evaluation process is needed to assess the competencies of the auditors. Taken together, these enhancements in visualizing can dramatically improve your internal audit program.

**Speaker Bio:** Diana Baldi works across 5 management system standards (ISO 9001, ISO 14001, ISO 45001, ISO 17025 and Responsible Care). She has completed audits of USEPA contractors, internal and supplier audits for global chemical companies, and provides consulting and training in management systems and auditing. She has performed audits for 5 registrars, 2 accrediting bodies, and many clients. Diana has also trained thousands of auditors and mentored many to enhance their auditing skills. One of her strengths is engaging leadership through candid feedback via robust yet simple reporting styles.

**Session #:** G3

**Date:** Friday, October 18, 2019

**Time:** 1:45 – 2:30

**Speaker Name:** Karen Bolen

**Session Title:** Standardizing Product Development Process for Innovative Products

**Session Summary:** Research suggests that standardizing process in product development that is aligned with ISO 9001 quality management standards often results in improvements in quality and production efficiencies. Organizations that manufacture products with low variability in high volumes reap substantial benefits from standardized processes based on best practices and quality standards. Standardizing process in organizations that produce highly variable or innovative products in low volumes is more difficult. Research and development (R&D) organizations who produce proof-of-concepts or prototypes often find the costs of standardizing processes for short-term projects with one-off quantities can outweigh the benefits. Defining repeatable steps for R&D projects that solve unique problems with vague requirements using inventive methods that are unproven in production is challenging.

This session will describe approaches used to define quality management processes that standardize product design and development for innovative products. Guidance for performing audits in innovation processes and procedures will also be provided.

**Session Abstract:** Research suggests that standardizing product development process that is aligned with ISO 9001 quality management standards often results in improvements in quality and production efficiencies. Organizations that manufacture products with low variability in high volumes reap substantial benefits from standardized processes that are based on best practices and quality standards. Standardizing process in organizations that produce highly variable or innovative products in low volumes is more difficult. In particular, research and development (R&D) organizations who produce proof-of-concepts or prototypes often find the costs of standardizing processes for short-term projects with one-off quantities of many different product offerings can outweigh the benefits. Defining repeatable steps for R&D projects that solve unique problems with vague requirements using inventive methods that are unproven in the production environment is challenging. Further, assessing the effectiveness of meeting requirements for pure research studies with hypothesized applications may take years to fully

comprehend. Critics of federally funded R&D studies that are deemed wasteful may fail to understand the potentially impactful innovation that could result from the scientific findings (see Golden Goose Awards <https://www.goldengooseaward.org/>). However, increased costs in resources and technology as well as greater focus on meeting government and industry client expectations more fully, motivate R & D providers to consider repeatable process for product development.

ISO 9001's customer-focused process approach to consistent product development is sometimes adopted by R & D organizations to facilitate operational improvements and product quality. Once process is established, R&D organizations may seek ISO 9001 quality management certifications to satisfy requirements by commercial and industrial customers for ISO 9001 certification and to qualify for major procurements.

This session will describe the objectives and strategies used in determining work product development processes that resulted in the successful ISO 9001 certification of the quality management system for an applied research and development organization. The discussion will describe the definition of a flexible yet repeatable process framework that focuses on maximizing work product quality in an applied research and development environment. As a result, the organization has been able to maintain almost perfect on-time deliveries of contractual work with a very low rate of unbillable expenses while overall project workloads have doubled in two years. Other benefits include an organizational culture focused on quality, an improved usability of project resources, and greater utilization of organizational knowledge.

Tips and lessons learned from internal audits of innovation processes and practices are discussed, including auditing in a non-manufacturing environment with few common forms and work instructions and little or no production scrap or rework. Practical guidance regarding non-conforming work product, as well as informal versus formal control of project artifacts and change management will also be addressed.

**Speaker Bio:** Karen Bolen is the Quality Assurance Manager for the Electronic Systems (ELSYS) Laboratory at Georgia Tech Research Institute. Karen has a Bachelor of Science in Business Administration from the University of Tulsa, a Master of Science (MS) in System Engineering from Southern Polytechnic State University, and a MS in Quality Assurance from Kennesaw State University. She has led the quality improvement program in ELSYS since 2014, including the initiative that resulted in the laboratory's first ISO 9001 certification of its quality management system (QMS) in 2016, and the transition to ISO 9001:2015 standard certification in 2018.

**Session #:** H1

**Date:** Friday, October 18, 2019

**Time:** 9:45 – 10:30

**Speaker Name:** Nancy Pasquan    **Session Title:** Objectives and Process Measures

**Session Summary:** Objectives and Measures are both required for quality management systems under ISO 9001:2015 and related standards. The two requirements are often treated as the same thing or confusion exists about the differences and relationship between the two. This presentation will define the terms and describe how, when used correctly, they can guide an organization to desired achievements while simplifying management decisions. Examples of good and less than good measures and their usage are provided. These lessons learned come from ISO certification audits and supplier assessments over the past 10 years.

**Session Abstract:** Objectives and Measures are both required for quality management systems under ISO 9001:2015 and related standards. The two requirements are often treated as the same thing or confusion exists about the differences and relationship between the two. This presentation will define the terms and describe how, when used correctly, they can guide an organization to desired achievements while simplifying management decisions. Examples of good and less than good measures and their usage are provided. These lessons learned come from ISO certification audits and supplier assessments over the past 10 years.

Objectives are sometimes thought of as what an organization wants to be 'when we grow up', are often overly financial (versus quality) or are focused on the negative. When objectives are achievable but challenging, time limited, and communicated, they can motivate an organization to really move forward.

Processes are established to help the organization achieved the established objectives. Measuring those processes allows management to focus on the important things, having confidence that the measure will let us know when there is trouble brewing. Measures are frequently confused with objectives when applied to processes but are also often the things we want to avoid or are temporary.

Process measures are admittedly trickier to identify than objectives or product measures. Sometimes there are too many metrics and the idea of a KEY performance indicator (KPI) is lost. How the process in question interacts with its fellow processes is sometimes ignored or poorly understood.

Understanding both objectives and measures will allow managers to focus on what matters both to their own processes and the organization overall.

Used correctly, the requirements from the ISO standards can be used to guide an organization to desired achievements and greatly simplify management decisions. The time to establish objectives (aka goals) is now. The time to evaluate performance toward those objectives is daily, weekly, monthly and or annually. The data for goal vs actual performance may come from the process measures (ergo the confusion) or may be tracked via traditional business data collection.

This presentation provides definitions for measures and objectives and through example and story demonstrates how they can provide focus and improvement across an organization.

**Speaker Bio:** Nancy has over 30 years' experience in software systems development, maintenance, and management on pharmaceutical, medical device, clinical, military and commercial projects. She is currently performing ISO 13485:2016 certification audits and supplier assessments for pharmaceutical and medical device companies. She holds a BS in Computer Science, is Secretary of the ASQ Software Division and serves on the board of the ASQ San Diego Section. Nancy travels whenever the opportunity arises and can otherwise be found wandering around in the San Diego sunshine.

**Session #:** H2

**Date:** Friday, October 18, 2019

**Time:** 10:45 – 11:30

**Speaker Name:** Benjamin Trujillo

**Session Title:** After the Audit: Effective Deployment of the Corrective Action Process

**Session Summary:** Post-audit activities center on the deployment of an effective corrective action process aimed at both correcting immediate deficiencies and implementing solutions that will prevent future recurrence. How post-audit activities are performed is key to having an efficient and meaningful process, not just a reaction to contain the results of a mistake or process failure. This session will walk attendees through the corrective action process, including such steps as: identifying and describing the issue; “grading” the level of response required; finding the cause of the issue (root cause analysis); and implementing and verifying corrective actions. The necessary culture for successful audit response will also be discussed, especially as it pertains to deriving information from employees who may fear or resent the process.

**Session Abstract:** The following is the proposed outline for the presentation:

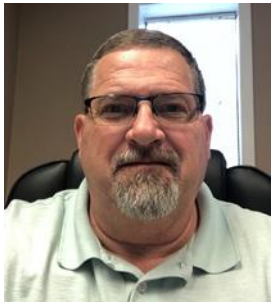
1. Introduction
2. Focus on the process
3. Identifying and describing the issue
  - a. Using interviews and records
  - b. Summarizing what happened
  - c. Tying what happened to a requirement
  - d. Performing remedial actions (i.e., containing the nonconformance)
4. “Grading” the level of response required
  - a. Evaluating for risk, repetitiveness, client impact, etc.
  - b. Establishing the parameters of analysis and response
5. Finding the cause of the issue
  - a. Why-Why method
  - b. Fishbone (Ishikawa) method
6. Implementing corrective actions
  - a. Identifying actions
  - b. Implementing actions
  - c. Verifying actions



The purpose of the session is to walk attendees through the post-audit response process, providing a step-by-step framework they can readily implement. Additionally, attention is paid to how information is collected from personnel during the interview process so that non-binary, open ended questions are used and a sense of trust is reinforced. Such interview skills can also be employed by auditors. The issue of grading the response will also be addressed, so that attendees can gain some understanding of how to determine what resources may need to be leveraged to properly address a finding.

This session has been presented twice at the AASHTO re:source Technical Exchange (2018 and 2019) and has been well received. At those events it has been run for 90 minutes with group work included where attendees form teams, pick an issue from a prepared list, practice defining their methods of collecting information, grading the issue, performing root cause analysis, and developing one or more corrective actions.

**Speaker Bio:** Mr. Trujillo has more than twenty years' experience managing business and quality requirement systems for multiple organizations. He has worked with calibration agencies, construction management firms, design agencies, production agencies, special inspection firms, and testing laboratories. He has designed and audited quality programs and implementation plans to address the requirements of many quality standards; notably AASHTO R18, ASME NQA-1, DOE O 414.1D, ISO 17020, ISO 17025, ISO 9001, and IAS AC291. He currently operates as a business and quality systems consultant and trainer and serves as the Immediate Past Chair for the ASQ Design & Construction Division.



**Session #: H3**

**Date: Friday, October 18, 2019**

**Time: 1:45 – 2:30**

**Speaker Name: Larry Litke**

**Session Title: RISK: What is it, Prove it, Show me**

**Session Summary:**

- What is Risk
- What is Risk Management?
- What do we look for?
- Who has the Responsibility?
- Who are the Concerned Parties?
- What makes a good audit, auditee and auditor?

How do we conduct an internal audit to see risk assessments and risk managements in a company? What are a few of the key items to look for during the audit? We will discuss what, when and how to see risk assessments at work

**Session Abstract:** We will look at the responsible parties and the objective evidence that we need to see to answer the requirements of ISO 9001:2015 and IATF 16949:2016. As an auditor what questions do we ask and of whom do we ask for the objective evidence to show risk assessment is an active process within a company. What can management do to show risk assessment? What information is available from management and how is it presented? How is risk management permeated throughout the organization? What are some key items to look for to see risk management? We will discuss this as well as show some examples of methods to be able to show risk management in action.

**Speaker Bio:** I have 40 years in the quality management field. I have worked in the steel forging, machining of aluminum and brass, rubber product manufacturing and fiberglass product manufacturing including resin injection molding fields during my career. I have extensive knowledge of TS 16949, ISO 14001, and ISO 9001:2015. I have been an internal and external auditor including 3<sup>rd</sup> party auditing for ISO 9001. I enjoy the education of and assisting companies to improve and succeed in the quality management programs in their organizations.

**Session #:** H4

**Date:** Friday, October 18, 2019

**Time:** 2:45 – 3:30

**Speaker Name:** Jeremiah Genest

**Session Title:** Auditing the Quality System for Data Integrity

**Session Summary:** Data integrity, involving both paper and electronic data, has been one of the hot topics of regulatory agency inspections in the pharmaceutical and medical device worlds, and is of interest across industries. Utilizing a risk-based approach based on the principles of ALCOA this session will cover the importance of a situational awareness to each company's data integrity issues and provide tools to:

- Analyze the technical and cultural hurdles
- Create data maps
- Apply mitigations

This session will be valuable for both those looking to improve and audit their quality systems for data integrity

**Session Abstract:** Data integrity is one of the hot topics of regulatory agency inspections of pharmaceutical and medical device manufacturers and is relevant to many industries. Many companies struggle with the concepts of data integrity as it involves both paper and electronic data, dealing with legacy computer systems and the organization culture. This session will provide a brief regulatory overview and then lay out the core principles of data integrity:

- Organizational culture should drive ALCOA
- Data governance is part of the management review process
- Data Risk Assessments with appropriate mitigations (full risk management approach)

The Quality Management System needs to have key processes and tools for the prevention, detection, analysis, reporting, tracking and remediation of noncompliance to these data integrity principles built in that:

- Prevent data integrity issues through governance, training, organizational controls, processes, systems underlying and supporting data integrity.
- Detect data integrity issues through leveraging existing Quality Systems, tools and personnel.
- Remediate data integrity issues through leveraging existing Quality Systems that identify and track implementation of corrective/preventive action(s).

Based on these principles this session will provide tools to:

- Apply a situational awareness to an organization
- Analyze the technical and cultural hurdles focusing on the core areas of governance, training, organizational controls, process and systems

- Create and utilize data maps to drive detection and remediation
- Apply mitigations to the common cultural hurdles

**Speaker Bio:** Jeremiah Genest is an Associate Director of Quality Systems at Sanofi and has 20 years quality systems experience in the energy and pharmaceutical industry, with over a decade's experience implementing and running quality systems in the biotech field. He has experience implementing change management and data integrity at a consent decree site. He is a Certified Manager of Quality/Operation Excellence and Pharmaceutical GMP Professional.

**Session #: I1**

**Date: Friday, October 18, 2019**

**Time: 9:45 – 10:30**

**Speaker Name: Mark Durivage**

**Session Title: Understanding the Medical Device Single Audit Program (MDSAP) Audit Nonconformity Grading Methodology**

**Session Summary:** Traditionally, audit findings have been graded qualitatively using the generally accepted and widely used qualitative terms minor and major. With the launch of the Medical Device Single Audit Program (MDSAP), there has been a shift in the traditional qualitative audit finding methodology to a new system developed by the Global Harmonization Task Force (GHTF) which quantitatively grades audit findings with a numerical score based upon product impact and other pre-established criteria. This presentation will provide an overview of the quantitative nonconformity grading system used by MDSAP.

**Session Abstract:** The International Medical Device Regulators Forum (IMDRF) which succeeded the Global Harmonization Task Force on Medical Devices (GHTF) acknowledged that to improve medical device safety and oversight that a harmonized global system was necessary for auditing, inspecting, and monitoring medical device manufacturing facilities. To address those objectives, the Medical Device Single Audit Program (MDSAP) was launched. MDSAP currently has five participating health authorities including; Australia's Therapeutic Goods Administration (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada/Santé Canada, Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), and The United States of America's Food and Drug Administration (FDA).

MDSAP utilizes 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. The grading systems breaks with the traditional qualitative model of minor and major audit findings and grades audit findings with a quantitative numerical score based upon product impact and other pre-established criteria.

The GHTF scoring system separates the ISO 13485 standard into two discrete components, clauses having an indirect and direct quality management system (QMS) impact. Clauses 4.1 through 6.3 are the foundation of the QMS which indirectly influence medical device safety and performance. Clauses 6.4 through 8.5 are considered to directly impact medical device safety and performance.

This presentation will explain how the MDSAP audit grading system functions and will provide examples demonstrating how to quantitatively grade audit nonconformities. The session will also demonstrate how to use the MDSAP audit grading process to comply with ISO 13485 internal audit obligations requiring the organization when planning the audit program take "into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits."

**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. He holds several certifications including; CRE, CQE, CQA, CSQP, CSSBB, RAC (Global), and CTBS. He has written several books available through ASQ Quality Press, published articles in Quality Progress, and is a frequent contributor to Life Science Connect.

Mark primarily works with companies in the FDA regulated industries focusing on quality management systems including internal and external audit support as well as FDA 483 and Warning Letter response and remediation services.

**Session #: I2**

**Date: Friday, October 18, 2019**

**Time: 10:45 – 11:30**

**Speaker Name: Cathelene Compton**

**Session Title: After the Audit: Auditing Current Trends in Cleaning Validation**

**Session Summary:** Fifteen percent of all US FDA 483 observations are related to Cleaning Validation. The current trends in US FDA 483 issuance has been related to lack of appropriate Cleaning Validation programs including but not limited to lack of proper acceptance criteria, lifecycle, campaign studies, and lack of swab data. This presentation will guide an auditor on how to effectively audit a cleaning validation program when there is limited time. This presentation will steer the auditor to specific areas to tackle when looking at Cleaning Validation documentation including how to cite the observations when found to CFR references.

**Session Abstract:** The presentation is focused on key areas to audit for Cleaning Validation. The current trend in FDA 483s has been Cleaning Validation. Mylan received a 32 page 483 in April of 2018 and 50% of the observations were targeted at Cleaning Validation. With the restructuring of FDA's Office of Regulatory Affairs, more FDA investigators are focused on Validation and the implementation of the Agency's guidance. Numerous trends have emerged with new Agency Guidance on how to calculate acceptance limits for Cleaning Validation. This presentation will guide an auditor through the trials and tribulations of finding and determining if a company has an acceptable Cleaning Validation program. Sustainable Validation programs are key to compliance success for any audit. The presentation is tailored towards areas of concern when an auditor has limited time. These areas of concern include periodic review, continued process verification, and surveillance programs. The presentation is concentrated on where to get started when auditing Validation programs during a general inspection audit or a 'for cause' audit, when there is limited time.

This presentation will help the attendee or auditor prepare for an audit when there is limited time. The presentation will also guide the auditor on how to write up the observations to specific CFR references to demonstrate to the site or facility that this observation could result in a FDA 483. Additional guidance and perspective will be provided in this presentation will include expectations detailed from guidance documents and observations from US FDA, EU, Health Canada, TGA, ANVISA, and more.

**Speaker Bio:** Cathelene Compton is a dedicated consultant to the Pharmaceutical, Nutraceutical, Medical Device and Food Industries with specialized experience in Consent Decree, Warning Letter Remediation and Third-Party verification, specifically Quality System and Validation program development. She has worked in the FDA and EU regulated industries for over twenty years specializing in Validation, Quality and Compliance. She holds multiple certifications including HACCP, Certified BRC GFSI Third Party Auditor, and ASQ CQM/OE. She is also the recipient of the ASQ FDC Shirli Furger Leadership and Meritorious Awards.



**Session #: I3**

**Date: Friday, October 18, 2019**

**Time: 1:45 – 2:30**

**Speaker Name: Dr. Ahmed Mubarak**

**Session Title: RISK: HSE Audits**

**Session Summary:** The scope, objective, philosophy and dynamics of conducting HSE audits at the Oil and Gas industrial operations, both onshore and offshore, as well as the chemical industry as a whole, is here presented and discussed. Auditors qualifications, pre-audit information, critical audit areas. and statistical analysis of audit findings based on real time audits are analyzed and audit durations are determined.

**Session Abstract:** HSE auditors often mix between Asset Integrity resource elements (comprising mainly trade assets; mechanical, electrical, civil and instruments) with straight up HSE management system elements (including pollution, waste management, ergonomics, BBS, etc.,). While asset integrity Management System (AIMS) audits would address, to a large extent, equipment behavior and catering practices, traditional HSE audits would concentrate more on human behavior based elements. Meanwhile, Management Indicators (i.e., management commitment, training, communication, monitoring, auditing, etc.) are fairly common to both audits.

In this presentation, HSE audit metrics are reported and discussed.

**Speaker Bio:** Dr. Mubarak is an IRCA and PECB certified lead auditor for QMS, EMS and SMS ISO management systems. He also has extensive auditing experience in conducting HSE as well as Asset Integrity type audits at oil, gas, chemical and energy installations, in general, including nuclear and wind turbine operations. Dr. Mubarak worked in manufacturing / operational industries for over 25 years; holds six sigma black belt and the rank of a full professor.

**Session #: 14**

**Date: Friday, October 18, 2019**

**Time: 2:45 – 3:30**

**Speaker Name: Dennis Welch**

**Session Title: ISO 26000, Guidance on Social Responsibility – A Business Perspective of How to Do the Right Things**

**Session Summary:** ISO 26000 Guidance on Social Responsibility has been around as an international standard for nine years. It seems to have gained traction over the last few years as OEM's integrate it into their systems and then push it down to their supply base. Also, if you are considering implementing ISO 26000, keep in mind it is a guidance standard. You cannot be registered to it, because it has no requirements, no "shall's."

ISO 26000 revolves around six topics called core subjects. In addition, each core value is broken out into its basic components. You will probably find that you have many of these integrated into your system already, e.g. specific clauses from your employee handbook for instance. The rest of the core subjects will fit easily into your business model. They are:

**A. Rights**

- Due diligence
- Human rights risk situations
- Avoidance of complicity
- Resolving grievances
- Discrimination and vulnerable groups
- Civil and political rights
- Economic, social and cultural rights
- Fundamental principles and rights to work

**B. Labor Practices**

- Employment and employment relationships
- Conditions of work and social protection
- Social dialogue
- Health and safety at work
- Human development and training in the workplace

**C. The Environment**

- Prevention of pollution
- Sustainable resource use
- Climate change mitigation and adaptation
- Protection of the environment, biodiversity, and restoration of natural habitats

**D. Fair Operating Practices**

- Anti-corruption

- Responsible political involvement
- Fair competition
- Promoting social responsibility in the value chain
- Respect for property rights

**E. Consumer Issues**

- Fair marketing, factual and unbiased information and fair contractual practices
- Protecting consumers' health and safety
- Sustainable consumption
- Consumer service, support, and complaint and dispute resolution
- Consumer data protection and privacy
- Access to essential services
- Education and awareness

**F. Community Involvement and Development**

- Community involvement
- Education and culture
- Employment creation and skills development
- Technology development and access
- Wealth and income creation
- Health
- Social investment

Of course, the guideline drills deeper into each core subject above and Clause 4 elaborates on the principles of social responsibility. There are two annexes and a bibliography. Purchase a copy of ISO 26000 Guideline on Social Responsibility from [www.iso.org](http://www.iso.org) if you don't already have it.

What I have found over time working on social responsibility and sustainability is that the guidance from ISO 26000 is the right thing to do for all of those interested parties involved.

**Speaker Bio:** Dennis Welch has spent his career helping businesses build management systems beginning with QS-9000 in 1995. He has been the risk management auditor for Madison Precision Products for the last three years and built a social responsibility system that won their OEM customer's prestigious sustainability award. Dennis is currently retired, but still consults with companies to build management systems.

### ASQ Audit Division Organizational Chart

