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.

Who Should Attend:
Senior/Executive Officer, Director, Manager, Supervisor, Engineer, Consultant, Auditors, etc.

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 (additional 50 words):

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 complaint 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.