

Photo Not Yet Available

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

--Niela Is Different, Amazon

- Have been a speaker in ASQ conferences such as:

--20th Audit Conference 2011 – Reno, NV

--21st Annual Audit Conference 2012– Augusta, GA

--2012 National Quality Education Conference, Louisville, KY

--25th 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.

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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, Member # 00025666
- 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

Date: Thursday, October 17, 2019

Time: 2:45 – 3:30

Speaker Name: Stan Cherkasky

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

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 #: B5

Date: Thursday, October 17, 2019

Time: 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 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.

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