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.

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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.

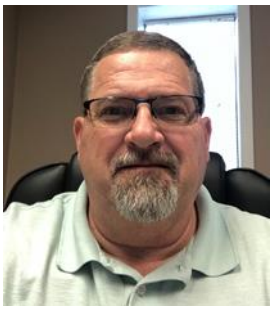
Session Abstract: The following is the proposed outline for the presentation:

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 and 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 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 3rd 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.

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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.