# Quality Sessions – Abstracts

**Quality Management System Review**
John Suedbeck, Merck

A quality management system (QMS) can be defined as a set of policies and process controls required for planning and execution (production/development/service) in the core business area of an organization. The QMS serves as the foundation of the organization, helping to meet requirements and to drive improvement.

While every organization has the latitude to design a QMS that best meets their unique requirements, most organizations associated with the pharmaceutical industry deploy the same basic processes. We will review some of these basic processes and discuss the key elements associated with each and show how they work to help an organization meet requirements, identify problems and drive improvement.

**"Know thy Data" – Statistical Techniques for Analyzing Data**
Tammy Triplett, Mayne Pharma

- Review types of data generated to monitor and control a manufacturing process (Critical Control Points) and Analytical Data
- Discuss methods that can be used to review the data
- Case Study: What is the Data telling us?

**ASQ Programs, Certifications, and Your Local Chapter**
John Suedbeck, ASQ Eastern Carolina Section 1126

Serving as a general introduction to ASQ and local section 1126, we will review ASQ and the programs offered. We will discuss certificates, degrees and certifications and how they come into play with many of the career paths associated with the pharmaceutical industry. We will link this to training and certifications offered by ASQ. We will review the organizational structure of ASQ section 1126, discuss the benefits of an active membership, and describe the programs and opportunities offered with a focus on meeting the needs of individuals and the community.

**Effective Root Cause Analysis**
Tammy Triplett, Mayne Pharma

- Review the steps of a Root Cause Analysis
- Review tools used aide in determine root cause
- Implementing effective Corrective and Preventive Actions

**Corrective and Preventive Actions**
Jerry Zemble, Purdue Pharma

Learn what drives a CAPA
Learn how to differentiate between a Corrective Action, a Correction and a Preventive Action
Learn what causes the origination of a CAPA
Learn the correct phases of a CAPA Workflow
Example Citations for improper/inadequate CAPA

**Sampling Types and Sampling Plans used in Pharmaceutical Industry**
Dan Carlson, ASQ Eastern Carolina Section 1126

A review and explanation of Sampling Types used in the Pharmaceutical Industry with advantages and disadvantages for the five types. The presentation with also include a discussion of sampling plans for attributes and variables per ANSI/ASQ Z1.4.