

**Presentation Abstracts**

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**Out of Another @#S%&\* Crisis A presentation by Dr. Deming (impersonation) and Mike Micklewright**  
**Mike Mickleright, Quality Quest, Inc.**

The United States is in more need of Dr. Deming's teachings than Japan was in the 50's.

Dr. W. Edwards Deming, oftentimes was known as the Prophet of Quality, but many people fail to understand his impact and influence on waste reduction, the early Lean movement, and the resurgence of Japan's quality and productivity. Learn from Dr. Deming (as personified by Mike Micklewright) about his 14 Points and how, because they are principles, they are never-ending and more applicable today than ever before. Learn from Mike Micklewright how Dr. Deming would view today's business and quality world in comparison to his 14 Points and his viewpoint on today's trends in Lean, Six Sigma, Lean Six Sigma, Root Cause Analysis, and ISO 9001. Learn about Dr. Deming, the man, the prophet, and his principles and how they so much impacted the Lean movement.

**Making Decisions with Probability Distributions**  
**David LeBlond, Abbott Laboratories**

A basic review of continuous and discrete probability distributions useful in decision making. Density, mass, and cumulative distribution function concepts and formulae as well as random number generation and some practical examples will be discussed. Implementation and use in EXCEL will be demonstrated.

**Adverse Event Measures for Process and Data**  
**Matthew Hettinger, Mathet Consulting, Inc.**

An adverse event is any undesirable experience associated with the use of a medical product in a patient. It is critical that these events be reviewed, analyzed, monitored and reported in an accurate and timely way in the interest of public safety. A requirement for these processes are valid measures and measurements.

This presentation will first review the basics of measures including the definition / specification of a measure, assignment to some characteristic of interest, scales, collection, use in analysis and interpretation of results. This information will then be applied to drug-related clinical trials with a focus on adverse events. Examples of adverse event measures will be presented along with measures associated with adverse event processes and data. As adverse event measures, and the data associated with those measures, are a small part of the total set of measures and data generated and collected on the road to producing a new drug product, adverse event measures and data will be placed in the context of the whole.

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**Six Sigma Applied to the Pharmaceutical and Medical Device Industries.  
Wayne Taylor, Taylor Enterprises, Inc.**

Learn about Six Sigma and the role of Six Sigma in the Pharmaceutical and Medical Device Industry. Six Sigma is an evolution of Total Quality Management and other previous quality initiatives. Learn what Six Sigma offers that is new and the lessons it teaches. While Six Sigma is an initiative for reducing cost, improving quality and making other improvements, it has important lessons for Process Validation, CAPA root cause investigations and PAT.

**Electronic Assembly in Manufacturing for Class 2 and 3 Medical Devices  
Leo Barry, Plexus Corporation**

This presentation was developed for and presented to the FDA twice in the past year as part of Personnel training. It focuses on quality system requirements applied to complex manufacturing of class 2 and 3 medical devices.

An introduction to this process, with examples of minimum standards and best practices applied to this process, and an overview of process quality management demonstrates how quality is sustained throughout the Plexus Corporation. Slides, short videos, speaker presentations and props give hands-on familiarity with seven core competency operations: materials, surface mount, plated through hole, high level assembly, test / inspection, rework, and shipping. Minimum standards and best practices are identified throughout. Short discussion after each section reviews the purpose of that process, potential defects, and related controls.