Quantum Leap Engineering

Statistical Techniques used for Process Validation Studies

Nov. 1st and Nov. 2nd, 2018 | 8:30 am to 4:30 pm

Burlington, Massachusetts

This 2-day seminar will provide an understanding of FDA and ISO 13485 requirements for process validation with respect to statistical techniques. A Case Study will be used to demonstrate the statistical techniques used during the various stages of process validation (IQ, OQ and PQ).

Why Should You Attend:

Process validation is a requirement but knowing when to validate or revalidate a process is essential. If you do not validate you risk enforcement actions such as fines or recalls, but too much validation is costly in both time and money. This seminar will focus on the statistical techniques used for this important topic for those who are new to quality or new to process validation. It will:

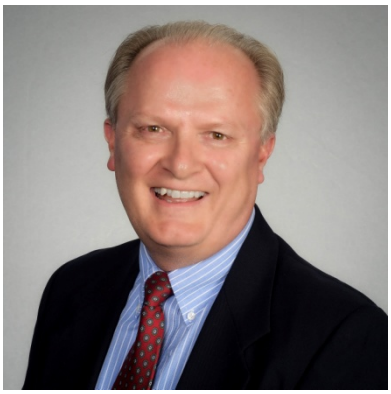
- Cover the statistical requirements for process validation from FDA Guidance for Industry- Process Validation: General Principles and Practices and ISO 13485.
- Discuss when process validation and revalidation are necessary or desirable.
- Provide an overview of what is required for process validation.
- Provide a Case Study to demonstrate the statistical techniques used during the various stages of process validation (IQ, OQ and PQ).
- Provide a sample Standard Operating Procedure for Statistical Methods and Analysis.

Learning Objectives:

- What is the Difference between Verification and Validation
- Understand what process validation is
- Learn about process validation guidelines
- Understand when to validate processes and what processes to validate
- Understand the statistical techniques used to perform process validation

(Additional Course Description on the Back of this Sheet)

Presenters



Jerry - M.S. Statistics, has spent 35+ years as a statistical consultant in the Medical Device industry. He has experience participating on cross-functional teams that included engineering, manufacturing, quality and medical professionals to development new products that meet regulatory requirements. Jerry also developed and delivered statistical training to thousands of engineers and scientists to perform, interpret and report process validations.

Sean, P.E., LSSMBB, has over 30 years of operational, quality and engineering experience. He specializes in training and implementing Productivity and Quality Programs (Lean and Six Sigma, Automation). Sean has a Master's degree in Engineering, is a graduate of the Business Management Program from MIT's Sloan School, is a registered Professional Engineer (PE) and a Lean-Six Sigma Master Black Belt.

Areas Covered in the Seminar:

- Difference between Verification and Validation
- What is process validation
- Process validation guidelines
- How to determine if a process requires validation
- What processes should be validated
- Review of Statistical Software to assist in the Analysis
- Process validation outline
- IQ – Installation Qualification
- OQ – Operational Qualification (Design of Experiments)
- PQ – Performance Qualification (Measurement System Analysis, Capability Studies)
- Process monitoring (Control Charts, Sampling Plans)

Who Will Benefit:

This seminar will provide valuable assistance to all personnel in:

- Quality Engineering
- Manufacturing/Design/Process engineers
- Test Engineers
- Quality Managers new to medical devices or process validation
- Operations/Manufacturing Managers
- Product Program Managers

Host Company:

Quantum Leap Engineering

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REGISTRATION
Cost: $1,295.
Visit www.QuantumLeapEng.com to register