2-day In-person Seminar:

Statistical Techniques for Medical Device Manufacturers

By: Dan O’Leary, President at Ombu Enterprises, LLC

Location: April 17-18 | Houston, TX

SPEAKER

Dan O’Leary, President at Ombu Enterprises, LLC

Dan O’Leary has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs. He has a Masters Degree in Mathematics, focusing on logic and number theory. His professional experience relates to quality, regulatory, reliability, and operations management.

Dan is a regular speaker at international conferences including ASQ, ISM, and RAMS. Dan teaches courses in reliability methods, medical device regulations and practices, statistical methods, management systems (ISO 9001, FDA QSR, & ISO 13485), and project management. Dan is an ASQ Certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; he holds an APICS certification in Resource Management.

LEARNING OBJECTIVES

Upon course completion participants will be able to:

✔️ Learn the sections of FDA QSR that require statistical techniques.
✔️ Understand how to apply the FDA tools to develop a clear understanding of the requirements.
   ✔️ Regulation
   ✔️ Preamble
   ✔️ Small Entity Compliance Guide
   ✔️ QSIT
   ✔️ Warning Letters
✔️ Understand the set of statistical techniques in ISO/TR 10017
✔️ Learn how to implement and apply the ISO/TR 10017 statistical techniques.
The FDA’s Quality System Regulation (QSR) requires device manufacturers to identify valid statistical techniques to “establish, control, and verify the acceptability of process capability and product characteristics.” Some manufacturers are not clear about what this means, while others employ statistical techniques but remain nervous about this means.

Similarly, sampling plans must be valid, documented, adequate, and reviewed based on changes.

In addition, statistical methodology, as part of CA & PA, is required to identify recurring quality problems based on data system analysis. A similar requirement applies to servicing analysis.

In addition, the requirement for process validation with a “high degree of assurance” is a requirement for process capability and product characteristics, i.e., a statistical technique.

These four areas often create a patchwork of techniques without a coherent approach. This seminar will help you resolve the problem.

The seminar starts with an understanding of the regulations through a variety of sources. Each application of statistical techniques starts with the regulatory requirements and is augmented by the preamble, where FDA addressed the comments it received on the proposed QSR. FDA published an extensive manual to help manufacturers implement the regulations. The seminar analyzes the objectives in the Quality System Inspection Technique (QSIT) and then turns to Warning Letters to help understand the issues.

COURSE DESCRIPTION

AGENDA

Day One: 8.00AM – 4.00PM

- Statistical Techniques in FDA QSR
- Tools to help understand the regulations
  - QSR Sections
  - Preamble
  - Small Entity Compliance Guide
  - QSIT
  - Warning Letters
- ISO/TR 10017 and what it tells us
- Working with the statistical techniques
  - descriptive statistics
  - hypothesis testing
  - measurement analysis

Day Two: 8.00AM – 3.30PM

- Working with the statistical techniques (continued)
  - time series analysis
  - statistical process control
  - process capability analysis
  - regression analysis
  - reliability analysis
  - sampling
  - statistical tolerances

WHO WILL BENEFIT

All medical device manufacturers that apply FDA QSR or ISO 13485:2003:

- Quality Managers
- Quality Engineers
- Quality Assurance and Quality Control
- Regulatory Affairs Managers
- Regulatory Affairs Professionals
- R&D Managers
- R&D Engineers
- Product Design and Development
- Operations Managers
- Production Managers and Supervisors
- Manufacturing Engineers
- Risk Managers
- Complaint system team members
- CAPA team members
Dan O'Leary displayed complete and total Mastery of the subject in this presentation, and in his answers to the questions asked from him.

- Quality Manager, Parker Hannifin Corp

I enjoyed Dan’s course very much. The Instructor and materials were excellent and the information he taught will be very helpful to my company.

- Compliance Coordinator, Diagnostica Stago, Inc

I have attended webinars from ComplianceOnline but this “Live” one was incredible. This seminar was excellent.

- Quality Engineering Manager, ConvaTec Inc

It was well organized event by ComplianceOnline. Communication was good. Presenter was very knowledgeable. Practical application of directives, standards, regulations are very helpful.

- Manager, Quality Assurance, Instrumentation Laboratory

It was well organized event by ComplianceOnline with good subject matter and knowledgeable instructor.

- Director of Operations and Quality, NDI Medical LLC

I appreciate the knowledge given at this seminar. Speaker is very experienced and I found good talent here. I am very happy with first class reference sheet.

- Sr. CAPA Specialist, Johnson & Johnson Vision Care Inc

Knowledgeable speaker with great real life examples and discussions.

- Quality Director, Lifecore Biomedical

It was my first conference with ComplianceOnline and experience was good. Love the reference material and flash key.

- Quality Director, Lifecore Biomedical
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Seminar Topic: **Statistical Techniques for Medical Device Manufacturers**

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