ComplianceOnline
The Largest GRC Advisory Network

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.

COURSE DESCRIPTION

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 identity 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.

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

TESTIMONIALS

"Dan OLeary 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."

Registration Form

Registration Information:

- **Register Online**. Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-888-717-2436.
- Call +1-888-717-2436 or Fax your PO: 650-963-2556.
- Pay your check to (payee name) "MetricStream Inc" our parent company and Mail the check to: ComplianceOnline (MetricStream, Inc), 2600 E. Bayshore Road, Palo Alto, CA 94303.
- Please fill this form with attendee details and payment details and fax it to 650-963-2556

GROUP REGISTRATIONS

Send Your Team for Maximum Benefit Get your team up to speed!

2 Attendees	-	Get 10% off
3 to 6 Attendees	-	Get 20% off
7 to 10 Attendees	-	Get 25% off
10+ Attendees	-	Get 30% off

Call Toll Free +1-888-717-2436
if you have any queries.

Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ +1-888-717-2436 or email us @ editor@complianceonline.com

Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($200) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Seminar Topic: Statistical Techniques for Medical Device Manufacturers

Date & Location: .....

Attendee Details:

Register for 3 and 4 person gets a free pass.

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization .....

.....

Address .....

.....

City .....

State ..... Zip.....

Country .....

Phone ..... Fax .....

Payment Options

☐ Check enclosed, payable in U.S. funds to ComplianceOnline (MetricStream, Inc.)

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....

Total amount $ .....

Signature .....
(Signature required on credit card and bill-me orders.)

Print name.....

☐ Bill me/my company $ .....

Purchase order # .....
(Payment is required by the date of the conference.)

Please fill this form with attendee details and payment details and fax it to 650-963-2556

ComplianceOnline
The Largest GRC Advisory Network
www.complianceonline.com
2600 E. Bayshore Road Palo Alto, CA 94303
Ph: +1-888-717-2436 | Fax: 650-963-2556