TWO DAYS WORKSHOP ON

Statistical Techniques for Medical Device Manufacturers

Date: 30 November 2017 - Friday, 01 December 2017
Location: San Francisco, CA

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". When device manufacturers analyze CA & PA information, they must also use "appropriate statistical methodology". In addition, sampling plans must be valid, documented, adequate, and reviewed based on changes.

by

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Dan is the President of Ombu Enterprises, LLC, a company offering training and execution in Operational Excellence, focused on analytic skills and a systems approach to operations management. Dan 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; is an ASQ certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; and is certified by APICS in Resource Management.

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". When device manufacturers analyze CA & PA information, they must also use "appropriate statistical methodology". In addition, sampling plans must be valid, documented, adequate, and reviewed based on changes.

Some manufacturers are not clear about all of this. Others are nervous about creating a sufficient approach to make good decisions and satisfy the regulations. The result may be a patchwork of techniques without a coherent methodology. This workshop helps resolve the problem.

Why Should you Attend
Statistical techniques are powerful methods for medical device manufactures since they can help improve efficiency and effectiveness. Many techniques apply in a variety of situations. This workshop explains how to evaluate the situation, determine the correct technique and apply it. In addition, since there are regulatory requirements, the workshop includes the necessary documentation to satisfy audits and inspections.

Learning Objectives
The workshop starts with an understanding of the regulations including QSR, ISO 13485:2003, and ISO 13485:2016. It also includes the methods regulators use to check compliance including the Quality System Inspection Technique (QSIT), FDA Warning Letters, and the Medical Device Single Audit Program (MDSAP).

The FDA regulations don't provide a catalog of available techniques or their application. This is the role of ISO/TR 10017:2003 Guidance on statistical techniques for ISO 9001:2000. While this guidance was written for ISO 9001:2000, it is easily applicable to FDA QSR, ISO 13485:2003, and ISO 13485:2016.

The guidance document provides a list of statistical techniques and explains how each applies to particular ISO 9001:2003 clauses. Mapping these applications to FDA QSR, ISO 13485:2003, and ISO 13485:2016 is straightforward and provides a robust approach to help a manufacturer identify the appropriate methods.

The workshop explains the many of the techniques, shows how they apply using medical device examples, and includes exercises for participants to solidify understanding.
AGENDA

Day 1 (8:00 a.m. - 8:30 a.m: Registration Process)

Part A - Statistical Techniques in the Regulations
- FDA QSR
- ISO 13485:2003
- ISO 13485:2016
- The Quality System Inspection Technique, QSIT
- The Medical Device Single Audit Program, MDSAP
- FDA Warning Letters

Part B - Identifying Statistical Techniques
- The Problem and a Solution
- Using ISO/TR 10017:2003
- Using GHTF/S3/N18:2010

Part C - Descriptive Statistics
- Data Types
- Measurement Scales
- Common Descriptive Statistics
- Graphical Methods
- Statistical Distributions
- Some Common Distributions

Part D - Hypothesis Tests
- The Concepts
- Comparing a Mean to a Standard
- Comparing Two Means
- Paired t-Test
- Other Applications

Part E - Regression Analysis
- The Concepts
- Linear and Non-linear Methods
- Using Excel
- Residuals

Day 2 (9:00 a.m: Workshop Start)

Part F1 - Attribute Sampling Plans
- Sampling Plan Concepts
- ANSI/ASQ Z1.4
- Single Sampling Plans
- Double and Multiple Sampling Plans
- c=0 Sampling Plans

Part F2 - Variables Sampling Using Z1.9
- Normality Assumptions
- Acceptance Sampling Concepts
- ANSI/ASQ Z1.9 Methods
- Comparative Sample Size

Part G1 - SPC Variables Charts
- x-bar and R Charts
- x-bar and s Charts
- I and MR Charts
- OC and ARL Curves
- Calculating Control Lines
- Interpreting the Results

Part G2 - SPC Attributes Charts
- p Charts
- np Charts
- u Charts
- c Charts
- OC and ARL Curves
- Calculating Control Lines
- Interpreting the Results

Part H - Process Capability Analysis
- Cp and Pp
- Cpk and Ppk
- Interpreting the Results

Part I - Measurement System Analysis (MSA)
- Measurement Analysis
- The Components of Variability
- Applications to Metrology

All medical device manufacturers that apply FDA QSR, ISO 13485:2003 or ISO 13485:2016
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, CA&PA team members
**PRICE/REGISTER**

**Single Registration**

Price : $1,395.

**GROUP REGISTRATIONS**

Call Toll Free (201)-871 0474 if you have any queries.

Special Group Discount
Buy for 3 Attendees - Get 1 Extra Attendee for free
Buy for 5 Attendees - Get 2 Extra Attendees for free

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**VENUE**

**Location:** San Francisco, CA

**Venue/Hotel:**
Sheraton Fisherman’s Wharf Hotel
2500 Mason Street, San Francisco, CA 94133

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**Terms & Conditions to Register for the Workshop**

Your registration for the workshop is subject to following terms and conditions. If you need any clarification before registering for the workshop call us at (510)-857-5896 or email us at customersupport@onlinecompliancepanel.com

**Payment Process**

Payment is required 2 days before the date of the conference. We accept American Express, Visa and MasterCard. Make checks payable to PMA Conference Management (our management company).

If you are paying by check, the check should be payable to HOLKOI LLC and mailed to: 38780 Tyson Lane Suite 210 Fremont California 94536

The registration fee includes: The workshop; all related course materials; tea/coffee and lunch on both the days

**Cancellations and Substitutions**

For online registration, use your American Express, Visa or MasterCard.

In case you find difficulty in registering, call us at (201)-871-0474 or sent an email to register@pmaconference.com. We will help you to register hassle-free.

Any cancellation request received at least 10 calendar days prior to the start date of the event will receive a refund with a $200 administration fee deduction. No cancellations will be accepted - nor refunds issued - within 10 calendar days from the start date of the event.

On request (before the commencement of the workshop) a credit for the amount paid minus administration fees ($200) will be transferred to any future Online Compliance Panel event and a credit note will be issued. Substitutions may be made at any time.

Onsite registrations are also possible. However we accept only credit card payments and check payments. Conference material will be issued on the spot depending on the availability. In case it is not available we will send the material by post after the conference is over. In the event, Online Compliance Panel cancels the workshop; the company 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.

**Conference Photograph / Video**

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**Documents to Carry**

Online Compliance Panel will issue an electronic event pass to each registered candidate once the registration is confirmed. Please bring the pass to the venue of the event.