Aug. 26-27, 2014 • Marriott Bethesda North Hotel and Conference Center
Bethesda, MD

An Interactive Workshop Presented by **FDAnews** and **Ombu Enterprises**

Innovative Process Validation Strategies For Medical Devices

Proving Your Processes And Documentation To The FDA

No other course teaches you the latest process validation strategies, proven statistical methods that meet FDA approval and the best ways to document your work. Not only will your operations run more smoothly, you'll have confident that you'll pass your next FDA inspection.

- Learn the three elements of FDA QSR's approach to process validation
- Understand and apply the traditional phases of process validation: IQ, OQ, and PQ
- Be aware of the regulatory issues and how an FDA investigator approaches process validation
- Review and analyze warning letters to avoid common problems
- Integrate process validation with risk management including risk reduction and production information collection
- Incorporate HACCP methodology to help improve your process
- Learn the statistical basis for process validation and apply the methods
- Develop designed experiments to explore the parameter space and set limits

Dan O'Leary, 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.

Visit www.DeviceProcessValidation.com or call (888) 838-5578

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WORKSHOP AGENDA

DAY ONE

8:00 A.M. – 9:00 A.M.
REGISTRATION AND CONTINENTAL BREAKFAST

9:00 a.m. – 10:15 a.m.
Process Validation Concepts

- When to validate a process
  - A cogent Warning Letter
- How to validate a process
- Contrasting Process Output Verification and Process Validation
- The Regulatory Definitions of Process Validation
- **Exercise** – Setting Process Parameters: Participants will analyze a hypothetical process to determine the input parameters and whether the process should be validated.
- **Exercise** – Selecting a Sampling Plan: Participants will analyze a hypothetical process and identify the characteristics the influence the choice of sampling plans.

10:15 A.M. – 10:30 A.M. BREAK

10:30 a.m. – 12:00 p.m.
The Requirements Framework

- QSR Requirements
- Status of the Guidance Documents
- ISO 13485:2003 Requirements
- The guidance ISO/TR 14969:2004
- GHTF Guidance Document

12:00 P.M. – 1:00 P.M. LUNCH BREAK

1:00 p.m. – 2:30 p.m.
The Regulatory Approach

- Understanding the FDA Regulations
- Using the Quality System Inspection Technique (QSIT)
  - QSIT Sampling Plans
- Warning Letters – Learning form Others
- **Exercise** – Determine the Inspection Level: FDA Investigators plan the extent of their inspections based on the levels in the Program Compliance Guide. This exercise provides participants an opportunity to apply these ideas and understand the factors that determine the depth of the inspection.
- **Exercise** – Determine The Number of Records to Inspect: When an FDA investigator asks for records, the number reviewed is determined by a sampling plan in QSIT. This exercise explains how the investigator classifies the records, and estimates the error rate; it is not Z1.4 acceptance sampling.
- **Exercise** – Analyze Warning Letters: This series of exercises uses process validation problems raised in Warning Letters. Participants analyze the problem, write a problem statement, determine the cause, and recommend corrective action.

2:30 P.M. – 2:45 P.M. BREAK

2:45 p.m. – 5:00 p.m.
Installation Qualification (IQ)

- The QSR Requirements
- The ISO 13485 Requirements
- Equipment and OSHA Standards
- Utilizing Total Productive Maintenance (TPM)
- Measuring Equipment Effectiveness
- **Exercise** – IQ Checklist: Participants will use the example in the GHTF guidance document to determine if all the essential elements for Installation Qualification are covered.
- **Exercise** – Determining Equipment Effectiveness: Participants analyze the utilization of equipment to determine its effectiveness, using a common technique from Total Productive Maintenance (TPM).

5:00 P.M.
SESSION WRAP-UP END OF DAY ONE

DAY TWO

8:30 A.M. – 9:00 A.M.
CONTINENTAL BREAKFAST

9:00 a.m. – 10:15 a.m.
Statistical Methods (Part 1)

- How to describe a process using statistical terms
- Using Statistical Process Control (SPC)
- How to measure process capability
- Integrating sampling methods
- **Exercise** – Descriptive statistics: Participants analyze some data sets and use the data to calculate descriptive statistics.
- **Exercise** – Setting up an SPC chart and monitoring a process: This exercise sets up the control lines to use in x-bar & R charts.
- **Exercise** – Calculating process capability: Participants calculate process capability indices used to determine the ability of a process to meet its specifications.
- **Exercise** – Calculating the binomial distribution: Sampling plans often use the binomial distribution as their basis. This exercise provides practice in doing the calculations to illustrate the underlying concepts.
- **Exercise** – Choosing sampling plan parameters

10:15 A.M. – 10:30 A.M. BREAK

10:30 a.m. – 12:00 p.m.
Statistical Methods (Part 2)

- Understanding the concepts of designed experiments
  - Fractional Factorial Designs
  - Resolution
  - Aliases
- The principles of robust design
- How to apply statistical tolerances
- **Exercise** – Determine a DOE alias: In fractional factorial DOE, some of the results have an alias. This exercise shows how to determine the aliases in a design.
- **Exercise** – Layout a half-fraction DOE: This exercise gives the participant an opportunity to lay out a fractional factorial design based on a full factorial design.

12:00 P.M. – 1:00 P.M. LUNCH BREAK

1:00 p.m. – 2:30 p.m.
Operational Qualification (OQ)

- How to use DOE to set the process limits
- Understand how to set the warning limits and action limits
- Analyzing a worked example

2:30 P.M. – 2:45 P.M. BREAK

2:45 p.m. – 4:45 p.m.
Performance Qualification (PQ)

- Understanding the role of PQ
- Analyzing a worked example

The Process in Production

- Learning how to apply HACCP principles
- Understand the impact on Risk Management
- **Exercise** – Applying HACCP Principles: HACCP is a powerful tool that is underutilized in process validation. This exercise demonstrates its application to a process.

4:45 P.M. – 5:00 P.M.
SUMMARY, CONCLUSIONS, AND LESSONS LEARNED

5:00 P.M.
ADJOURN WORKSHOP

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COURSE MATERIALS

- Slides from PowerPoint presentations
- Case studies that demonstrate the concepts of process validation
- Interactive exercise worksheets and the answer keys
  - Reference Documents
  - GHTF guidance on process validation
  - QSR Guide chapter on design control
  - QSR Guide chapter on process validation
  - QSR Guide chapter on buildings and environment
  - QSR Guide chapter on equipment and calibration

WHO SHOULD ATTEND

- Project managers involved in design and development
- Design engineers
- Quality engineers
- Manufacturing engineers
- Quality auditors
- Production managers
- Production supervisors
- Scientists involved in device R&D and manufacturing
- Training personnel
- General/corporate counsel
- Production engineers
- Risk management specialists

WHAT YOUR COLLEAGUES HAVE TO SAY

"[Dan] has a great approach to teaching a group of professionals with very different backgrounds and experience."
WALTER DOMOZYCH, Principle Quality Engineer, Boston Scientific

"I thought the presenter was thorough and provided real-world examples in order to enhance the presentation."
ISABEL HOVERMAN, Quality Engineer, Orthofix, Inc.

"The examples given were helpful, and the presentation was very easy to follow."
KARYN SCHWITTERS, Regulatory Affairs Specialist, Anderson Packaging, Inc.

"It was a very methodical approach, enjoyed the examples."
RANDALL LENZ, CQT Consultant / QE, Stryker Instruments

YOUR EXPERT INSTRUCTOR

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. Dan is now President of Ombu Enterprises, LLC, a consultancy focused on operational excellence and regulatory compliance serving small manufacturing companies. 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.

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LOCATIONS AND HOTEL ACCOMODATIONS

To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the **FDAnews** Workshop to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rates, and space is limited. Hotels may run out of discounted rates before the reservation cutoff date. The discounted rate is also available two nights before and after the event based on availability. The hotel may require the first night's room deposit with tax. Room cancellations within 72 hours of the date of arrival or "no-shows" will be charged for the first night's room with tax.

Lodging and Conference Venue:
Aug. 26-27, 2014
Bethesda North Marriott Hotel & Conference Center
5701 Marinelli Road
North Bethesda, MD 20852
Toll free: (800) 859-8003 • Tel: +1 (301) 822-9200
www.bethesdanorthmarriott.com
Room rate: $169 single or double (plus 13 percent tax)
Hotel reservation cutoff date: Aug. 4, 2014

TUITION

Tuition of $1,797 includes all workshop sessions, workshop written materials, two breakfasts, two luncheons and daily refreshments.

CANCELLATIONS AND SUBSTITUTIONS

Written cancellations received at least 21 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 21 calendar days of the start date of the event. A credit for the amount paid may be transferred to any future **FDAnews** event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, **FDAnews** 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.

TEAM DISCOUNTS

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Call (888) 838-5578 for details.

FOUR EASY WAYS TO REGISTER

Online: www.DeviceProcessValidation.com
Fax: +1 (703) 538-7676
Phone: Toll free (888) 838-5578 (inside the U.S.) or +1 (703) 538-7600
Mail: **FDAnews,** 300 N. Washington St., Suite 200 Falls Church, VA 22046-3431 USA

☑ **YES!** I want to attend **Innovative Process Validation Strategies For Medical Devices** on Aug. 26—27, 2014, at Marriott Bethesda North Hotel & Conference Center, Bethesda, MD for $1,797 per attendee.

FDANEWS
300 N. Washington St., Suite 200
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