Innovative Process Validation Strategies for Medical Devices:
Proving Your Processes and Documentation to the FDA
Presented by Ombu Enterprises and FDAnews
Aug. 26-27, 2014 – Bethesda, MD

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**

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.
Exercises – 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.
Exercises – 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.
Exercises – 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**