FDANEWS PRESENTS THE

AN INTERACTIVE WORKSHOP FEATURING 11 HANDS ON EXERCISES

MEDICAL DEVICE COMPLAINT MANAGEMENT | Building a Robust System to Meet Global Requirements

PRESENTED BY OMBU ENTERPRISES AND FDANEWS

FEB. 25-26, 2015 | WYNDHAM BEACON HILL, BOSTON, MA

YOUR INSTRUCTOR

Dan O'Leary
President
Ombu Enterprises, LLC

"Very informative and on point. This lecture was amazing and spot on. We covered a lot in two days. Dan's approach was great and he is good at helping employees at all levels."

—Shivani Persad, Associate Complaint Coordinator, Fresenius Medical Care

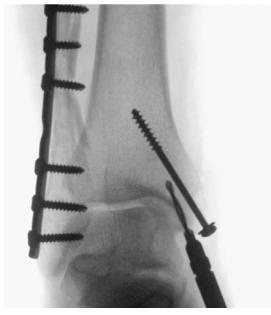
You start with hypothetical complaints, and then trace them through the regulatory system. First comes the presentation explaining the issues and illustrating them with regulations, guidance documents, Warning Letters, etc. These are followed by interactive exercises liberally spread over two days.

You find yourself out of your chair and engaging with devicemakers like yourself — from the EU, Canada and all across the US — confronting and solving shared problems.

At the conclusion of each small-group exercise, you take a test. But not to worry —you can't fail. Answers are provided, plus proven solutions to take home and apply in your operation. We know of no other workshop providing such fine-grained level of interactivity, not to mention solutions you can put into effect — at once.

Attendees to this all-new workshop will learn:

- The role of Unique Device Identification (UDI) in complaints and adverse event reporting
- Regulatory reporting requirements in three major markets: US, EU, and Canada
- Understanding why the source of a complaint (Facebook, Twitter, email, phone call) is not your chief concern — it's how to handle the communication
- The proper use of corrective action in complaint management, including statistical analysis
- Developing a complaint classification system that links to the risk management file
- Analysis methods to help determine the impact of design changes on regulatory requirements
- How to distinguish between enhancements and recalls, following the FDA guidance.
- Recall requirements in the US, EU, and Canada.



Day 1

WEDNESDAY, FEB. 25, 2014

8:00 a.m. – 9:00 a.m. | **REGISTRATION AND CONTINENTAL BREAKFAST**

9:00 a.m. – 10:15 a.m.

Part A – The Intersection of Complaints and the Regulatory Structure

- Understanding the Quality Management System (QMS) in the US, EU, and Canada
- Distinguishing records and reports to regulatory agencies (content, trigger, and timing)
- How and why the FDA conducts inspections and the guiding documents they use
  - Quality System Inspection Technique
  - Compliance Program 7382.845 Inspection of Medical Device Manufacturers
- Using sampling plans as part of the Medical Device Directive (MDD) audit

Exercise – FDA Inspection Levels
Exercise – QSIT sampling plans for records

10:15 a.m. – 10:30 a.m. | **BREAK**

10:30 a.m. – 12:00 p.m.

Part B – How Newly Enacted Unique Device Identification Will Impact Complaints

- Overview of the US regulations regarding UDI
- What are Device Identifiers and Production Identifiers — and how do they differ
- Understanding the GUDID and the information you need to supply

Exercise – Creating a new Device Identifier

Part C – Servicing: The Front Line for Complaints?

- Definition of servicing — is your definition and regulators' the same?
- How servicing relates to other QMS elements?
- Producing service records and linking them to complaints
- Tips, tools, and techniques for analyzing service records; what should you be looking for?

Exercise – Analyze a small set of service records using quality tools

12:00 p.m. – 1:00 pm | **LUNCH BREAK**

1:00 p.m. – 2:30 p.m.

Part D – Complaints

- Definition of a complaint —distinguishing regulatory complaints from customer service complaints
- Comparing and contrasting QSR vs. ISO 13485 definitions
- Successfully developing and managing complaint classification systems
- Fully understanding complaint system interrelationships, it's harder than it appears

Complaints and corrective action
- Complaints and MDRs
- Complaints and EU Vigilance
- Complaints and risk management (ISO 14971:2007)

- Complaint system flowchart
- Determining the required content for complaint records

Exercise – Analyze customer reports to determine if they are a complaint and potentially reportable

2:30 p.m. – 2:45 p.m. | **BREAK**

2:45 p.m. – 4:30 p.m.

Part E – Medical Device Reports (US)

- Understanding the criteria for reporting
- Establishing the MDR event files that serve their purpose and stand up to FDA scrutiny
- Identifying Designated Individuals
- MDR system interrelationships
- Examining the nexus between MDRs and complaints
- Getting to know the types of MDRs (30 day and 5 day)
- Reporting MDRs — paper or electronic
- Records required for the MDR system — what you must have

Exercise – Initiate a Medical Device Report

Part F – Medical Device Reports in the EU and Canada

- Understanding the criteria for reporting
- The regulatory structure in the EU (MDD and MedDev)
- The regulatory structure in Canada
- Role of the Notified Body in the

Vigilance System

- Role of the MDD Authorized Representative in the Vigilance System

Exercise – Analyze an adverse event to determine when to report

4:30 p.m. | SESSION WRAP-UP, END OF DAY ONE

Day 2

THURSDAY, FEB. 26, 2014

8:30 a.m. – 9:00 a.m. | CONTINENTAL BREAKFAST

9:00 a.m. – 10:15 a.m.

Part G – Corrective Action and Preventive Action (CA&PA)

- The difference between corrective action (CA) and preventive action (PA)
- Understanding CA&PA interrelationships in the QMS
- The CA&PA flowchart —implementing it in your QMS
  - CA&PA verification and validation
  - CA&PA effectiveness review
  - CA&PA records — opening, closing and managing the records effectively
- Tips, tools and techniques for complaint analysis; what should you be looking for?

Exercise – Analyze complaints as quality data to identify quality problems

10:15 a.m. – 10:30 a.m. | BREAK

10:30 a.m. – 12:00 p.m.

Part H – Design Changes

- Understand the role of change in the design control system
- Design change interrelationships —the five important considerations
  - When a production change is a design change
  - Does the design change create a new Device Identifier?
  - Does the design change require an updated 510(k)?
  - Does the design change impact the Risk Management File?
  - Is the design change an enhancement or a recall?
- The design change flow chart shows the picture
- Design change records —tips for maintaining the Design History File (DHF)

Exercise – Classify changes as a design change or a production process change

12:00 p.m. – 1:00 pm | LUNCH BREAK

1:00 p.m. – 2:30 p.m.

Part I – 510(k) Changes

- When a design change requires a pre-market notification change
- 510(k) change process interrelationships
- 510(k) change records and reports
- FDA's 1997 guidance document — 17 years old, but still applicable today
- The 2012 law and FDA's plan — what's the latest and what's on the horizon

Exercise – Analyze design changes to determine if they require a revised 510(k)

2:30 p.m. – 2:45 p.m. | BREAK

2:45 p.m. – 4:30 p.m.

Part J – Corrections and Removals (C&R)

- Defining the terms — a source of constant confusion
- Understanding how the C&R regulations relate to the QMS
- Distinguishing enhancements from recalls – the FDA guidance and its theory
- C&R records and reports — distinguishing between the requirements
- Overview of the integrated system and how to make it work for you
- Bringing all the pieces together — best practices for building C&R procedures that work
- The link between C&R reports and recalls
- Recalls caused by suppliers

Exercise – Evaluate proposed field actions to determine if they are a correction or a removal

4:30 p.m. | ADJOURN WORKSHOP

It was a very methodical approach, enjoyed the examples."

—Randall Lenz, CQT Consultant / QE, Stryker Instruments

a Robust System to Meet Global Requirements

11 Comprehensive Exercises You Can't Afford to Miss!

Your mentor is Dan O'Leary, a 30-year veteran of device quality compliance and five-star presenter. Mr. O'Leary is a master at working with devicemakers large and small to apply proven methods that build end-to-end complaint management systems. Register today to take advantage of these exclusive interactive exercises.

1. **FDA 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.

2. **QSIT Sampling Plans for Records —** 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.

3. **Creating a New Device Identifier —** The UDI regulations require manufacturers to create Device Identifiers (DI) for each version or model as well as Device Identifiers for each packing level. They must be included in the complaint records, Medical Device Reports, and Correction & Removal files. This exercise helps participants understand when a change creates a new Device Identifier (DI).

4. **Analyze a Small Set of Service Records Using Quality Tools —** 820.200 requires manufacturers to analyze service records using statistical techniques applicable for data analysis in 820.100. In some cases, servicing, complaints and MDRs are tightly coupled. This exercise introduces a small data set and gives participants an opportunity to apply techniques.

5. **Analyze Customer Reports to Determine If They Are a Complaint and Potentially Reportable —** The definition of complaint in medical device regulations is technical, and requires analysis to determine when a report alleges a "regulatory complaint". In addition, complaints must be evaluated to determine which ones could lead to a Medical Device Report. This exercise provides examples that help participants distinguish among the various cases.

6. **Initiate a Medical Device Report —** In the US, some complaints are reported to the FDA as a Medical Device Report. This exercise uses an example problem and offers participants an opportunity to see how the information relates to the fields in the MDR form.

7. **Analyze an Adverse Event to Determine When to Report —** In the EU, some are reported using the Manufacturer's Incident Report form from MEDDEV 12.2-1 on the Vigilance System. This exercise uses an example problem and offers participants an opportunity to see how the information relates to the fields in the MDR form.

8. **Analyze Complaints as Quality Data to Identify Quality Problems —** Medical device manufacturers expect to receive complaints at some rate. The manufacturer must track the rate for different kinds of complaints, for risk management post-market surveillance and for EU vigilance reporting. This exercise provides an opportunity for participants to determine a baseline rate, a trigger point, and determine if the rate is still acceptable.

9. **Classify Changes as a Design Change or a Production Process Change —** QSIT informs the FDA investigator that Production and Process Changes could be Design Changes. This exercise provides participants an opportunity to classify changes and provides insight into the decisions to make in the QMS.

10. **Analyze Design Changes to Determine If They Require a 510(K) —** Every design change for a 510(k) device must be evaluated to determine if it is significant enough to update the 510(k). This exercise provides some situations for participants to analyze.

11. **Evaluate Proposed Field Actions to Determine If They Are a Correction or a Removal —** Whenever a manufacturer changes a product in the field, there must be an evaluation to determine if the change is a correction or a removal. In addition, there must be an evaluation of reportablility. This exercise provides practice in making those evaluations.

ABOUT YOUR INSTRUCTOR

Dan O'Leary

Dan O'Leary is President of Ombu Enterprises, LLC, an education, training and consulting company focusing on Operational Excellence using analytical skills and a systems approach to operations management. Dan has more than 30 year's experience in quality, operations and program management in regulated industries, including aviation, defense, medical devices, and clinical labs. He holds 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.

Ombu Enterprises, LLC

Ombu works with manufacturing companies, offering training and execution in operational excellence. Focusing on the analytic skills and systems approach of operations management, Ombu helps companies achieve efficient, effective process and regulatory compliance.

"Very informative and could pull documentation in support of information provided. I have high confidence in the information he provided. Great up to date information. I liked asking specific questions and getting his opinions."

—Linda Todd, Sr. Post Market Surveillance Analyst, Spectranetics

"Dan is a wealth of knowledge in regards to all aspects of medical device regulations."

— Kanan Bhavsar, PV Clinical Trial and Drug Safety Specialist, Merck

COURSE BINDER MATERIALS

- Full slides from the PowerPoint presentations
- A copy of each interactive exercise worksheet as well as answer keys
- An annotated version of MDR sections regulation based on recent Warning Letters
- An Excel worksheet that helps analyze the FDA regulations. It has a series of questions that start with a complaint and follow the reporting and record keeping decisions to help understand the integrated requirements spread across different parts of the regulations.
- Reference documents:
  - FDA guidance on Medical Device Reporting
  - FDA draft guidance on Medical Device Reporting
  - Comparison of MDR Rule Changes
  - FDA guidance on Enhancements and Recalls
  - Comparison Part 7 and Part 806 definitions
  - FDA guidance document on 510(k) changes
  - MEDDEV document on the Vigilance System
  - Health Canada document on Medical Device Problem Reporting

WHO SHOULD ATTEND

- Quality Managers
- Regulatory Affairs Managers
- Engineering Managers
- Quality Engineers
- Design Engineers
- Project Managers involved in design and development
- Specialists assigned to complaints, corrective actions or medical device reporting
- Recall coordinators
- Medical staff evaluating risk, safety or effectiveness
- General/corporate counsel

The materials are excellent and a great handout to be used in any organization. Dan really put a lot of work into the materials and workshop."

— Cheryl Landrum, Quality Analyst, Kimberly Clark

FDANEWS PRESENTS THE

Register Today!

MEDICAL DEVICE COMPLAINT MANAGEMENT

Building a Robust System to Meet Global Requirements

☐ **Yes!**

Sign me up for the **Medical Device Complaint Managment Workshop**

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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. Hotel may require 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.

Dates/Location:

Feb. 25-26, 2015

Wyndham Boston Beacon Hill
5 Blossom Street, Boston, MA 02114

Toll Free: (800) 937-8461 or
+1 (617) 742-7630

www.wyndhambeaconhill.com

Room rate: $179.00 plus 14.45 percent tax
Reservation cut-off date: Feb. 3, 2015
GROUP CODE – 02246838FDA

TUITION:

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

CANCELLATIONS/ 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 from 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.

TWO OR MORE 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 +1 (703) 538-7600 for details.

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