An Interactive Workshop Featuring 11 Hands on Exercises
Presented by Ombu Enterprises and FDAnews

March 11–12, 2014 • Westin Waltham-Boston Hotel • Waltham, MA (Boston)

Medical Device Complaint Management

Building a Robust System to Meet Global Requirements

You start with a hypothetical complaint, then trace it through the regulatory system. First come lectures, then interactive exercises — 11 of them 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 will be 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
- Planning field actions and making regulatory reports

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.FDAnews.com/mdcomplaintmngmt or call (888) 838-5578

FDANEWS

DAY ONE: TUESDAY, MARCH 11

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 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)
- 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 — proven strategies that work for all companies
- 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 TWO: WEDNESDAY, MARCH 12

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
  - CAPA verification and validation
  - CAPA effectiveness review
  - CAPA 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 four 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)?

"I thought the presenter was thorough and provided real-world examples in order to enhance the presentation."

Isabel Hoverman, Quality Engineer, Orthofix, Inc.

- Does the design change impact the Risk Management File?

- 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

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

4:30 p.m.
ADJOURN WORKSHOP

"[Dan] has a great approach to teaching a group of professionals with very different backgrounds and experience."

Walter Domozych, Principle Quality Engineer, Boston Scientific

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.

TESTIMONIALS FROM PAST ATTENDEES

"[Dan is an] Excellent speaker. Great experience and examples. Interactive discussions in particular were very helpful."

Brian Ray, Senior Manager Risk Management, Welch Allyn

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

Randall Lenz, CQT Consultant/QE, Stryker Instruments

"The examples given were helpful, and the presentation was very easy to follow."

Karyn Schwitters, Regulatory Affairs Specialist, Anderson Packaging, Inc.

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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.

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

COURSE MATERIALS

- Full slides from the PowerPoint presentations
- Copies of each interactive exercise worksheet as well as an answer key for each exercise
- A copy of 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 draft guidance on Medical Device Reporting
  - FDA draft guidance on Corrections and Removals
  - FDA guidance document on 510(k) changes
  - MEDDEV document an the Vigilance System
  - Health Canada document on Medical Device Problem Reporting

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LOCATION 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. 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.

LODGING AND CONFERENCE VENUE:

March 11-12, 2014
Westin Waltham-Boston Hotel
70 Third Avenue
Waltham, MA 02451
Toll Free: (800) 937-8461
+1 (781) 290-5600
www.Westin.com/Waltham
Room rate: $189.00 plus 11.7 percent tax
Reservation cut-off date: Feb. 19, 2014

TUITION

Tuition of $1,797 includes all workshop sessions, workshop written materials, two breakfasts, one luncheon 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 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.

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.

FOUR EASY WAYS TO REGISTER

Online: www.FDAnews.com/mdcomplaintmngmt
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 ***Medical Device Complaint Management*** on March 11–12, 2014 in Waltham, MA

I understand the fee includes all workshop sessions, workshop written materials, two breakfasts, one luncheon and daily refreshments.

FDANEWS
300 N. Washington St., Suite 200
Falls Church, VA 22046-3431

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Attendee 2: Name _____ Title _____ Email _____

Attendee 3: Name _____ Title _____ Email _____

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