Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Complaints, Adverse Event Reporting, and Recalls - An Integrated Approach

Philadelphia, PA

July 27th & 28th, 2017

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$4,485.00** You Save: $2,990.0 (40%)*

~~$7,475.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Dan O'Leary

President, Ombu Enterprises

Dan O'Leary is 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 certified by APICS in Resource Management.

Overview :

Medical Device manufacturers operate in numerous regulatory systems that often have different requirements and are not always consistent. The new ISO 13485:2016 emphasizes this problem. Manufacturers must identify their roles, identify the regulatory requirements for that role, and incorporate them into the quality management system.

The various jurisdictions, however, deal with post-market device issues in many different ways. The quality management system, QMS, needs three interlocking process: complaint management, adverse event reporting, and recalls. These processes also have supporting QMS processes such as corrective action and design changes.

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Agenda:

Day One

Lecture 1: The Regulatory Structure
- FDA QSR
- ISO 13485:2016 and regional variants
- ISO 14971:2007 and regional variants
- Implementing MDSAP
- The EU Medical Device Regulation

Lecture 2: Servicing
- Identification of problems
- Servicing data analysis
- Input to the complaint process

Lecture 3: Complaints
- Identifying complaints
- Evaluating complaints
- Investigating complaints
- Complaint data analysis
- Input to the corrective action process
- Input to the risk management process

Lecture 4: Corrective Action
- Developing the process
- Analyzing product and process information
- Determining subsequent actions
- Input to the design process
- Input to the risk management process

Lecture 4: Design and Design Changes
- Determining the need for a design change
- Documenting design changes
- Design change verification and validation
- Input to the risk management process
- Input to the pre-market submission process

Day Two

Lecture 1: Risk Management
- ISO 14971:2007 and regional variants
- Incorporating post-market information

Lecture 2: Updating Pre-market Submissions
- US - The 510(k) guidance
- EU - Technical files and design dossiers
- Canada - License changes

Lecture 3: Adverse Event Reporting
- US - MDR
- EU - Vigilance Reports
- Canada - Mandatory Problem Reporting

Lecture 4: Recalls
- US - Corrections and Removals
- EU - Field Safety Corrective Actions
- Canada - Recall

Who will benefit:
- Quality Directors and Managers
- Regulatory Directors and Managers
- Design Engineering Managers
- Sustaining Engineering Managers
- Risk Managers
- Complaint Specialists
- Adverse Event Reporters
- Corrective Action Specialists
- Recall Specialists

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Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
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What You will get

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Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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