Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Implementing ISO 13485:2016

Raleigh, NC

April 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 the 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 is certified by APICS in Resource Management.

Overview :

The final version of ISO 13485:2016 is now available and companies should be planning their implementation. There are significant changes from the earlier version; they will require major modifications to the Quality Management System (QMS). The new version has better alignment with FDA's QSR, but there are still major differences that create issues for effective QMS implementation.

This workshop covers the differences from the 2003 version to the 2016 version and offers practical implementation advice to update your QMS. Participants will also learn the differences with QSR and understand how to resolve them. The workshop uses extensive examples and exercises to help clarify the concerns.

Agenda:

Day One

Lecture 1: Overview of ISO 13485:2016

- Summary of the differences between ISO 13485:2003 and ISO 13485:2016
- High level comparison with FDA QSR

Lecture 2: Regulatory Framework

- Transition period for certificates
- Canada - MDSAP v CMDCAS
- EN ISO 13485:2016 and the MDD
- The new QMS audit findings/nonconformance grading system
- Implications of the EU's Medical Device Regulations

Lecture 3: Management Responsibility

- Quality Policy and Objectives
- Responsibility and Authority
- Internal Quality Audits
- Management Review

Lecture 4: Resource Management

- Competence and Training
- Infrastructure
- Work Environment and Contamination Control

Lecture 4: Design and Development

- Design Planning
- Design Inputs and Design Outputs
- Design Verification and Design Validation
- Design Review
- Design Transfer
- Design Changes
- Design Files

Day Two

Lecture 1: Supplier Management

- Selection
- Purchasing Information
- Written Quality Agreements
- Purchased Product Verification

Lecture 2: Production Processes

- Production Control
- Installation and Servicing
- Identification and Traceability
- Control of Nonconforming Product

Lecture 3: Process Validation

- When to Validate
- Validation Requirements
- Software Validation

Lecture 4: Monitoring and Measuring

- Control of Equipment
- Processes and Products
- Data Analysis
- Complaint Handling

Lecture 5: Corrective and Preventive Action

- Corrective Action
- Preventive Action

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
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What You will get

1. Learning Objectives
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Contact Information: Event Coordinator

NetZealous LLC, DBA GlobalCompliancePanel
161 Mission Falls Lane, Suite 216,
Fremont, CA 94539, USA
Toll free: +1-800-447-9407
Fax: 302 288 6884
Email: support@globalcompliancepanel.com

www.globalcompliancepanel.com

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

Look forward to meeting you at the seminar

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