Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

# ISO 13485:2016 Implementation Workshop

Salt Lake City, UT

May 10th & 11th, 2018

9:00 AM to 6:00 PM

## Price

Price: **$1,295.00**

*(Seminar for One Delegate)*

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$3,885.00** You Save: $2,590.0 (40%)*

~~$6,475.00~~

Register for 10 attendees

Price: **$7,122.00** You Save: $5,828.0 (45%)*

~~$12,950.00~~

ENROLL

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

### Lena Cordie

*Quality & Regulatory Consultant,*

Lena Cordie has over 20 years of quality and project management experience including:

- 10 years in project management at Target Financial Services
- 11 years as Director of Operations at Key Surgical, a medical device company focused on sterile processing, personal protection, and OR products. In this position she was responsible for overseeing all quality and regulatory functions, production, product procurement, and order fulfillment.

## Overview :

The medical device industry is in the midst of major change, with the publication of the FDA's UDI Regulation, the first revision to the ISO Quality Management Systems standard in over a decade, and the upcoming changes to the EU's Medical Device Regulation expected to be passed later this year. All of these events have far reaching effects on Quality Management Systems so it is critical to understand what has changed with in ISO 13485: 2016 in order to create a comprehensive quality plan for your organization to ensure continued compliance and certification.

## Agenda:

### Day One

Lecture 1 : Anatomy of a Quality Management System

- Detailed review of all Clauses within the Standard
- Policies and Procedures designed to drive safety and compliance
- Supporting Documents and Databases covering operating procedures, staff training, and data management
- Operational Procedures guiding regulatory compliance, management involvement, and overall control of critical business functions
- Monitoring and measuring of quality processes and operational outcomes affecting product quality and patient safety
- Compliance and Improvement programs for audit, inspection, and clinical information

Lecture 2 : Gap Analysis of ISO 13485: 2003 to ISO 13485: 2016

- Increasing efficiency, cutting costs, and monitoring supply chain performance through increased supplier controls
- Increased requirements for design control
- Covering new requirements for complaint handling, regulatory reporting and unique device identification

Lecture 3 : Application of Risk

- Ensuring all operational procedures are following a risk based approach
- Discussion of risk mitigation techniques and implementation
- Identifying ways to make medical devices safer and more effective

# ISO 13485:2016 Implementation Workshop

### Day Two

Lecture 1 : Identification of Documentation Requirements

- Utilizing new Medical Device File requirements for each family or line of devices
- Reporting requirements to regulatory authorities
- Enhancing product design and development through validation and design transfer
- Preparing all necessary material for a Quality Report

Lecture 2 : Monitoring & Measurement of the QMS

- Validating software implementation into the manufacturing process and/or quality system
- Establishing evaluation procedures based on audit and quality reports
- Creating a system of checks and balances to analyze QMS success

Lecture 2 : Creating a Quality Plan for QMS Updates

- Obtaining senior leadership buy in to the new program
- Outlining how to review and improve processes across your organization
- Utilizing efficient reporting protocol and technology
- Identifying new or existing processes and documents affected by the changes
- Evaluating risks to the quality system associated with the QMS updates

Areas Covered in the Session:

- Gaining an understanding of the relationship between standards and quality management systems
- Understanding the basic principles of a quality management system
- Incorporating the Plan-Do-Check-Act approach
- Identifying the critical elements of a quality system
- Creating a documentation structure that is consistent with the system requirements

## 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
4. Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

## What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals

## 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

**GlobalCompliancePanel**