Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Uncovering and Managing Successful Post Market Compliance for Medical Devices

Philadelphia, PA

October 25th & 26th, 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.*

Rita Hoffman

Owner, Regs & Recall Strategies

Ms. Hoffman is the Principal Consultant/Owner of Regs & Recall Strategies, LLC, and a consulting firm providing regulatory insight focusing on industry assistance on FDA compliance issues. Ms. Hoffman has been consulting with FDA firms on post marketing issues for the past 6 years. She enjoys teaching firms on how to think like and FDA Officer and shares her skills on her past experiences both in and out of FDA.

Prior to working as a consultant, Ms. Hoffman spent more than 37 years with the FDA. She retired in 2011 after holding the position of recall branch chief for the Center for Devices and Radiological Health (CDRH). She was responsible for oversight and review of all medical

Why you should attend:

Customer satisfaction plays a significant role in measuring a product's postmarket performance. It is an indicator of how effective the product performance is managed. Both the quality system regulation (QSR) and the International Organization for Standardization (ISO) require procedures and processes to monitor and control your post market problems. The complaint-handling mechanism not only collects feedback from unsatisfied customers, but also provides means for failure investigations and subsequent corrective and preventive actions (CAPA).

Medical Device Reporting (MDR) and recall compliance involve regulatory obligations and proper and timely reporting. Failure to properly report events and take corrective and removal actions can cause costly problems for a manufacturer and can be life threating for consumer.. The number of device companies having their recall classified as a Class 1 (most severe) has surged in the past three years. Additionally, product liability and financial risks are staggering when companies fail to properly

Agenda:

Day One

Lecture 1 (90 Mins):

- Complaint Handling and FDA Expectations

Lecture 2 (90 Mins):

- Medical Device Reporting Procedures (MDR) Procedures and Regulations
- MDR reporting by firm, agents and exemptions

Lecture 3 (90 Mins):

- Standard Operating Procedures,
- Guidance Documents Update and eMDR Discussion
- Ways FDA works with Counterparts
- What to expect from the Inspector

Lecture 4 (90 Mins):

- Recalls, Definition and Legal Authority Overview
- Being Recall Ready

Areas Covered in the Session:

- Understand how to comply with complicated Compliant Handling, MDR and Recall requirements
- Firms MDR reporting and FDA's handling of MDR reports
- Company preparation in the event of a Recall, recall strategy, notification letter and communicating with the FDA
- Minimize your risk of regulatory enforcement actions
- Assist with the creation and maintenance of effective procedures for handling complaints, reportable events and recalls
- Understand the relationship and interaction with other quality system elements as they relate to complaints and reportable events
- Walk-through of case examples
- Step-By-Step guide to designing Standard Operating Systems for communicating process for firm's success

Day Two

Lecture 1 (90 Mins):

- Corrective and Provetive Actions
- Health Hazard Evaluations

Lecture 2 (90 Mins):

- 806 Reporting
- Developing Effective Strategies and Communicating and Negotiating with FDA Notifications Letters and Press Releases

Lecture 3 (90 Mins):

- Silent Recalls and Product Enhancements
- Product Retrieval, Status Reports
- Effectivness Checks

Lecture 4 (90 Mins):

- Follow-up Planning
- Terminating a Recall
- Participating in a Mock Recall (Class Participation)
- Close out

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
2. Participation certificates
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7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
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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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