Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Complaint and Recall Management: A Compliant, Lean Program

Boston, MA

March 22nd & 23rd, 2018

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~~

Register for 10 attendees

Price: **$8,222.00** You Save: $6,728.0 (45%)*

~~$14,950.00~~

ENROLL

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



Jeff Kasoff

Director of Regulatory Affairs,
Life-Tech, Inc

Jeff Kasoff, RAC, CMQ/OE, LBB is the Principal Consultant at Lean to Quality, LLC. He has more than 30 years of experience in Quality and Regulatory management. Over that time, Jeff has implemented and overseen quality system operations and assured compliance, at all sizes of company, from start-up to more than $100 million in revenue. This multi-faceted experience makes Jeff uniquely qualified to address compliance issues across the entire range of company sizes.



Overview :

Complaint handling is likely one of the more cross-functional parts of your quality system: Customer Service may receive your customer complaints, Sales and Marketing may need to reach out to the customer for additional information, Regulatory Affairs may determine whether the complaint is reportable, QA may perform the root cause investigation, R&D or Manufacturing Engineering may need to be involved in the corrective action, and Quality Engineering may need to trend the complaints! This session will include the requirements for all of the above responsibilities, which will include defining, documenting, and implementing a complaint-handling system

Agenda:

Day One

Lecture 1: Introduction

Lecture 2: Complaint Handling

- Regulatory Overview: FDA, ISO 13485 (including 13485:2016)
- Definitions
- Application of Definitions
- The Value of "Non-complaints"
- Complaint Triage and Handling
- Complaint Investigations
- "Closing" Complaints
- Contents of Complaint Form
- Complaint Review and Trending
- Implementation of Risk Management into Complaint Handling
- Common Pitfalls and How to Overcome Them
- Exercise: Complaint or Non-complaint?

Why you should attend:

Complaint Handling is one of the more cross-functional aspects of your QMS, not to mention it being clearly the most customer-facing. To that end, many different functions will benefit from this presentation:

- Customer Service (your "complaint taker")
- Regulatory personnel
- Quality Engineering personnel
- Sales and Marketing personnel
- Customer Service personnel
- R&D personnel
- Manufacturing Engineering
- Executive Management
- Consultants
- Quality system auditors

Day Two

Lecture 1: Adverse Event Reporting

- Regulatory Overview: FDA, MDD
- MDRs
  - Reporting Process
  - Reporting Requirements
- Vigilance Reports
  - Reporting Process
  - Reporting Requirements
- Exercise: Reportability of Events

Lecture 2: Recalls / Field Corrective Actions

- Regulatory Overview: FDA, MEDDEV, Health Canada
  - FDA Regulations
  - EU Requirements
  - Competent Authority Reportable Event
  - Reporting Requirements
- Corrections and Removals
- Market Withdrawal and Stock Recovery
- Recall Classifications
- Roles and Responsibilities

Lecture 3: Q&A - Conclusion

Learning Objectives:

This seminar contains a streamlined review of the regulations, allowing the majority of time to be spent on a detailed focus on critical process requirements for compliance with the regulations. Jeff will also call from his 30+ years of experience in this area to put forth recommendations for methods of documentation that are straightforward and compliant. Among these recommendations are contents of complaint records, root cause investigations, and corrective actions.

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