Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

# Supplier Management in FDA - and ISO-regulated Industry

San Diego, CA

September 14th & 15th, 2017

9:00 AM to 4:00 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~~

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 has more than 30 years 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. Jeff has also been primary liaison with FDA inspectors and notified body auditors, giving him first-hand experience with the most common issues surfaced by regulatory agencies.

## Overview :

Supplier qualification and assessment is required in both the QSR regulations and ISO standards. Many companies spend a great deal of time and money in pursuit of compliance. Many companies can spend significantly less time and money, and still be in control of their suppliers and in compliance with the regulations. This class will review the QSR and ISO requirements for supplier evaluation, including defining the types of suppliers that require evaluation. The QSR/ISO requirements for supplier assessment will be defined as well. Attention will be paid to inclusion of risk management in across both supplier qualification and assessment, implementation of which will allow your company to devote value-added resources to these efforts.

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## Agenda:

### Day One

Lecture 1: Introduction

Supplier Selection

- •Review of FDA requirements
- •Review of ISO requirements
- •Types of suppliers that must be qualified
- •Defining critical suppliers
- •Outsourced processes

Lecture 2: Supplier Selection (cont)

- •Recommended Practices
- •Documentation requirements
- •Use of Risk Assessment
- •The Quality Agreement
- •Common Pitfalls

Lecture 3: Supplier Assessment

- •Review of FDA requirements
- •Review of ISO requirements
- •Case Study: A Hypothetical Supplier Assessment
- •Recommended Practices

Lecture 4: Supplier Assessment (cont)

- •Documentation requirements
- •Use of Risk Assessment
- •Common Pitfalls

Why should you attend:

Notified bodies and the FDA cannot require your suppliers to meet the quality system regulations, so they must make sure you are exercising sufficient control over those suppliers. You must make sure your supplier management and system meets all required regulations and guidance documents, especially for outsourced processes such as contract manufacturing, sterilization and testing, and also for critical suppliers. Sure, you depend on your suppliers to provide you with goods and services

### Day Two

Lecture 1: Supplier Nonconformance

- •Types of supplier nonconformances
  - ◦ Best Practices for Handling
  - ◦ Best Practices for Notification
  - ◦ Trending
  - ◦ Evaluation of Supplier Response
  - ◦ Tracking effectiveness

Lecture 2: Supplier Nonconformance (cont)

- •Supplier Corrective Action Requests
  - ◦ Pre-notification?
  - ◦ Best Practices for Issuance
  - ◦ Followup
  - ◦ Evaluation/Acceptance of Supplier Response
  - ◦ Tracking effectiveness

Lecture 3: Workshop

- •Acceptability of Supplier Responses

Lecture 4: Q&A - Conclusion

Areas Covered in the Session:

- Supplier Selection
  - ◦ Review of FDA requirements
  - ◦ Review of ISO requirements
  - ◦ Types of suppliers that must be qualified
  - ◦ Defining critical suppliers
  - ◦ Outsourced processes
  - ◦ Recommended Practices
  - ◦ Documentation requirements
  - ◦ Use of Risk Assessment
  - ◦ The Quality Agreement
  - ◦ Common Pitfalls

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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
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
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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

**GlobalCompliancePanel**