Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

FDA Inspection: Do's and Don'ts

Boston, MA

December 8th & 9th, 2016

9:00 AM to 6:00 PM

Price

(Without Stay) Price: **$1,295.00**

(Seminar for One Delegate)

(With Stay) Price: **$1,695.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees (With stay)

Price: **$4,323.00** You Save: $4,152.00 (49%)*

~~$8,475.00~~

ENROLL

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

David R Dills

Regulatory Affairs & Compliance Consultant,

David R. Dills, Regulatory & Compliance Consultant with more than 24 years of hands-on experience and a proven track record within the FDA regulated industry, has an extensive regulatory and compliance background with Class I/II/III and IVD devices, pharmaceutical operations, and manages activities within the global regulatory and compliance space. He manages quality, regulatory and compliance projects with multiple competing priorities having a direct impact on site operations and commercial opportunities and develops strategies for governmental approval to introduce new products to market, provides guidance on regulatory and compliance requirements and prepares/reviews worldwide submissions/dossiers/technical files and addresses global regulatory requirements.

Overview :

Many regulated companies preparing for FDA inspections are not prepared and the outcome can be negative as we see all the time with enforcement actions. This seminar provides the fundamentals and the ground rules on how to prepare for and survive an FDA inspection no matter if you are a Class I, II, III device or a pharmaceutical or biologics manufacturer. This presentation will review and emphasize the do's and don'ts and cardinal rules as to interviewing, how to respond, reviewing documentation, etiquette, use of certain words, body language, responding to questions/requests, etc., and certainly replying to 483's and Warning Letters.

Seminar Pricing Includes (With Stay)

- Samsung Galaxy Tab 4
- 2 Days Stay
- Pick-up and Drop Facility (Nearest Airport)
- Break-Fast and Lunch
- High Tea
- Pack of 3 Webinars will be provided which has been done in the past on similar subject

Agenda:

Day One

Lecture 1: How a firm should prepare for an FDA inspection

Lecture 2: Ways to train employees in view of the inspection

Lecture 3: How to ensure that required documentation is in place

Lecture 4: How to interact with the investigator-DO's and DON'T's

Lecture 5: What companies should do when the inspection ends

Lecture 6: How to reply to 483's and warning letters

Lecture 7: Legal implications of non-compliance

Lecture 8: Post inspection actions

Who Will Benefit:

- This seminar will provide valuable assistance and guidance to all regulated companies that are preparing for FDA inspections. The employees who will benefit include:
- All levels of Management for all departments
- QA/QC/Compliance/Regulatory Affairs
- Information Technology/Marketing & Sales
- Engineering/Technical Services/Validation
- Consultants
- Operations and Manufacturing

Day Two

Lecture 1: Why inspections are conducted and by what statutory authority

Lecture 2: The emphasis on systems-based inspections...and the IOM and other crucial FDA reference documents

Lecture 3: What is subject to FDA purview and what's off-limits

Lecture 4: Understand and apply the do's and don'ts and comprehend that preparation is the key to success

Lecture 5: What are the prohibited "Acts" and the enforcement categories that you need to deal with

Lecture 6: What you need to know and do to prepare for, during and even after the inspection...and why your inspection response team is key

Lecture 7: The company's Inspection Plan (SOP) can make or break the inspection depending on how to use it and training your personnel

Lecture 8: How to respond to findings and facilitating the documentation and remediation process...and reaching final closure

Lecture 9: Define clear responsibilities, roles and goals for personnel involved in SOP development

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