Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Why is FDA at my Facility, and What do I do During an Inspection

Baltimore, MD

April 6th & 7th, 2017

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~~

ENROLL

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

David R Dills

Global Regulatory Affairs & Compliance Consultant,

David R. Dills, Global Regulatory Affairs & Compliance Consultant currently provides regulatory affairs and compliance consultative services for early-stage and established Class I/II/III device, IVD, biopharmaceutical, cosmetics and nutraceutical manufacturers on the global landscape, and has an accomplished record with more than 27 years of experience

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. Emphasis is placed on the company's SOP on dealing with inspectors and knowing how to be prepared, proactive...and being able to defend and justify... and what it takes to achieve a favorable outcome.

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

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

Who Will Benefit:

Departments :

- Top and Middle Management
- Quality Assurance/Management
- Compliance Management
- Manufacturing
- Laboratory
- Regulatory Affairs
- Information Technology
- Marketing & Sales
- Operations
- Research & Development

Who Will Benefit:

Types of facilities:

- Manufacturing facilities
- Contract manufacturing facilities
- Distributors
- Packaging, Labeling
- API Suppliers
- Laboratories
- Importers
- Documentation Management

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
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What You will get

1. Learning Objectives
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6. Special price on future consulting or expertise services.
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8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
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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

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