Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Bullet Proof 510(k) and Latest FDA Proposed Changes to the Process

Chicago, IL

November 10th & 11th, 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)

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 :

This Two-day course is a primer and overview to the premarket notification process, i.e., a 510(k). A 510(k) is a premarket submission made to FDA to demonstrate that your device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to PMA. There are three types of Premarket Notification 510(k)s that may be submitted to FDA: Traditional, Special, and Abbreviated. The Special and Abbreviated 510(k) methods were developed under the "New 510(k) Paradigm" to help streamline the 510(k) review process. Product modifications that could significantly affect safety and effectiveness are subject to 510(k) submission requirements under 21 CFR 807 as well as design control requirements under the Quality System (QS) regulation.

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: Introduction and Regulatory Background

- There is no 510(k) form; however, 21 CFR 807 Subpart E describes requirements for a 510(k) submission.
- Current trends with the 510(k) process.

Lecture 2: The Process

- Who is Required to Submit a 510(k)
- When a 510(k) is Not Required
- When a 510(k) is Required
- Locating and justifying the Predicate
- Substantial Equivalence and demonstration of SE to another legally U.S. marketed device
- How to Prepare Submissions
- 510(k) Submission Methods
- List of forms associated with Premarket Notification 510(k) submissions
- Deciding When to Submit a 510(k) for a Change to an Existing Device
- What happens if FDA requires additional information and data and your responsibilities

Day Two

Lecture 3: Interactive Q&A, Wrap-Up and Adjourn

- Q&A with all participants and attendees
- Group discussion and review of recent 510(k) clearances and proposals and recommendations between FDA and industry
- Discussion Points: some of the recommendations have included, but not limited to, redefining fundamental terms, limiting use of predicates, greater authority to rescind 510(k)s, etc.
- 510(k) Frequently Asked Questions
- Attendees and participants should be prepared to address any issues and challenges as experienced on behalf of their company in this open-forum and interactive session

Who Will Benefit:

- CEOs &CFOs in medical device companies
- VPs, Directors and Heads of Regulatory Affairs
- VPs, Directors and Heads of Clinical Affairs
- Senior and line Marketing and Sales Management
- Regulatory Consultants
- Risk Managers
- Engineering & R&D
- Professionals involved with premarket notification to the FDA
- R&D personnel involved in approving the design of medical devices
- Medical device sales and marketing personnel
- Production & Operations

Objectives:

- Know the differences between the Traditional, Special and Abbreviated submissions
- Understand Substantial Equivalence and how it is applied
- Who is required to submit the application to FDA
- Where to submit the 510(k) and what to expect with the review and approval process
- When it is and is not required if you are a device company
- Exemptions to the submission process and special considerations
- How to locate a "predicate" device and go through the content and format of the 510(k)
- Understand the De Novo process and the expectations for possibly marketing a low risk device

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

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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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