Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Preparing Premarket Submissions that secures U.S. FDA Clearances/Approvals: 510(k)/Pre-IDE/IDE and PMA

Los Angeles, CA

February 23rd & 24th, 2017

8:30 AM to 5:00 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.*

Subhash R Patel

Regulatory Affairs & Quality Compliance Consultant, MD Reg Consulting, LLC

Subhash Patel is an accomplished Regulatory Affairs Professional offering 30 plus year of experience in authoring, preparing and submitting more than 150 successful premarket submissions to U.S. FDA. He brings his expert knowledge and hands-on experience in developing a robust premarket submission that secures clearance or approval from U.S. FDA. He offers valuable tips and suggestions on what works and what doesn't form his own experience. He has presented numbers of technical papers at conferences and conducted plentiful training seminars in various countries.

Overview:

This workshop style training course is designed based on 30 year of regulatory affairs experience in preparing more than 150 successful U.S. FDA submissions for major medical device companies. In these 2 days, the following essential elements of U.S FDA premarket submissions will be covered:

- History and background of U.S FDA Laws and Regulations
- Classify Your Device
- Choose the Correct Premarket Submission for your device
- Compile the Appropriate Information for your Premarket Submission
- Author and Prepare your Premarket Submission
- Submit your Premarket Submission to the FDA
- Interact with FDA Staff during Review and Approval

AGENDA:

Day One

Lecture 1: An overview of U.S. FDA Premarket Regulations

- History and background of U.S FDA Laws and Regulations
- How to Classify Your Device
- Choose the Correct Premarket Submission for your device

Lecture 2: Premarket Notification 510(k)

- Applicable Laws, Regulations and Requirements for 510(k)
- Decide Type of 510(k)
- Compile the Appropriate Information for 510(k)
- Format and Content of your 510(k)

Lecture 3: Premarket Notification 510(k) - continue

- Suggestions on What to Include or Exclude into your 510(k)
- Tips on authoring a reader's friendly and convincing 510(k)
- Critical Review of your prepared 510(k) for acceptability

Lecture 4: Premarket Notification 510(k) - continue

- Determine risk and contingency plan for potential questions form the reviewer
- Points to Consider - Submit your 510(k) to FDA
- Interact with FDA staff during review and clearance of your 510(k)

Day Two

Lecture 1: Premarket Approval (PMA)

- Applicable Laws, Regulations and Requirements for PMA
- Decide Type of PMA
- Compile the Appropriate Information for PMA
- Format and Content of your PMA
- Suggestions on What to Include or Exclude into your PMA
- Tips on authoring a reader's friendly and convincing PMA

Lecture 2: Premarket Approval (PMA) - continue

- Critical Review of your prepared PMA for acceptability
- Determine risk and contingency plan for potential questions form the reviewer
- Points to Consider - Submit your PMA to FDA
- Interact with FDA staff during review and clearance of your PMA

Lecture 3: Investigational Device Exemption (IDE)

- Applicable Laws, Regulations and Requirements for IDE
- Purpose and Use of Pre-IDE to your advantage
- Compile the Appropriate Information for IDE
- Format and Content of your IDE
- Suggestions on What to Include or Exclude into your IDE
- Tips on authoring a reader's friendly and convincing IDE

Lecture 4: Post Market Requirements for Medical Devices

- Quality System (QS) Regulation/Medical Device Good Manufacturing Practices
- Mandatory Medical Device Reporting (MDR)
- Recalls, Corrections and Removals
- Medical Device Tracking
- Post Market Surveillance Studies (PSS) mandated under section 522 of the Federal Food, Drug and Cosmetic Act
- Post-Approval Studies (PAS) mandated as a condition of approval of a premarket submission - mostly premarket approval (PMA) application
- Points to consider - Third Party Inspection by Accredited Persons Program limited to manufacturers who meet certain conditions

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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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7. Special price on future seminars by GlobalCompliancePanel.
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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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