Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Applying U.S. FDA Laws and Regulations to Each Phase of Total Product Life Cycle (TPLC)

Philadelphia, PA

May 25th & 26th, 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 supported by comprehensive knowledge of U.S. FDA laws and regulations and 30 year of extensive experience working within in the U.S. FDA regulated industries. In these 2 days, the following essential topics will be covered:

- Total Product Life Cycle and Your Medical Device
- An Overview of U.S. FDA Medical Device Regulation
- Regulations for Design and Product Development
- Premarket Notification 510(k) and Premarket Approval (PMA)
- Regulations for Production & Process Control
- Readiness for FDA Facility Inspection

AGENDA:

Day One

Lecture 1: Total Product Life Cycle and Your Medical Device

- Understand various definitions of Total Product Life Cycle
- Importance for define TPLC for your own medical device
- Practice Exercise: Define TPLC of your own medical device
- Building Regulatory Strategy considering TPLC

Lecture 2: An Overview of U.S. FDA Medical Device Regulation - Part 1

Lecture 3: An Overview of U.S. FDA Medical Device Regulation - Part 2

Lecture 4: Regulations for Design and Product Development

- Research & Development
- Design Development and Control
- Prototype Product Development
- Design Verification
- Design Validation
- Design Transfer to Manufacturing/Production
- Helpful Hints and Suggestions

Day Two

Lecture 1: Premarket Notification - 510(k) and Premarket Approval (PMA)

- Determine Class of your Medical Device for Regulatory Controls
- Exemption form Premarket and QS
- Regulation requirements
- Premarket Notification - 510(k)
- Premarket Approval - PMA
- Investigational Device Exemption - IDE for clinical studies
- Preparation of Premarket Submissions
- Helpful Hints and Suggestions

Lecture 2: Regulations for Production & Process Control - Part 1

- Purchasing & Supplier Controls
- Document Control
- Device Identification and Traceability
- Acceptance & Nonconforming Product Control
- Labeling & Packaging Control
- Helpful Hints and Suggestions

Lecture 3: Regulations for Production & Process Control - Part 2

- Corrective Action and Preventive Action (CAPA)
- Records - Device History Record, Device Master Record, QS Record
- Complaint Files including Medical device Reporting (MDR)
- Post Market Reporting Responsibilities
- Helpful Hints and Suggestions

Lecture 4: Readiness for FDA Facility Inspection

- FDA Authority & Practices
- FDA Compliance Program Policy, Strategies and Approach
- Prepare and Stay Focused during Inspection
- Responding to FDA Form 483 Observations
- Responding to Warning Letter
- Planning and Managing Remediation Project & Activities
- Additional Regulatory Actions

Global CompliancePanel

2-day In-person Seminar:

Applying U.S. FDA Laws and Regulations to Each Phase of Total Product Life Cycle (TPLC)

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