Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Overview of Device Regulation - FDA

Boston, MA

June 22nd & 23rd, 2017

8:30 AM to 5:30 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.*

Thomas E. Colonna

Founder, Biotech Consultant LLC

Dr. Thomas E. Colonna earned a bachelor of science in microbiology from the University of Sciences in Philadelphia (formerly the Philadelphia College of Pharmacy and Science), a Ph.D. in molecular biology from the Johns Hopkins University, and a law degree from the Georgetown University Law Center. In addition to his consulting activities, Dr. Colonna is the Director of the MS in Regulatory Science and MS in Food Safety Regulation programs at Johns Hopkins University.

Dr. Colonna provides consulting services in the scientific and regulatory aspects of a wide range of medical devices and biologics with particular expertise in the areas of in vitro diagnostics (ELISA-based, PCR-based, SNPs, microarrays, and pharmacogenomics), medical device software (including bioinformatics), and biotechnology-based products.

Overview :

This course provides a basic description of an FDA regulatory strategy for medical devices and explains the relationships between regulatory strategy and product development. It offers guidelines for developing successful strategies for medical devices, including definitions and classifications, elements of regulatory strategy, sources of regulatory intelligence, selection of development and product clearance/approval pathways.

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2-day In-person Seminar:

Overview of Device Regulation - FDA

Agenda:

Day One

Registration & Breakfast	8.30 am - 9.00 am
Lecture 1: Overview of FDA Medical Device Regulation	9 am - 10.30 am
Break	10.30am - 11.00 am
Lecture 2: Overview of FDA Medical Device 510(k) Premarket Notification Process	11.00 am - 12.30pm
Lunch	12.30 pm - 1.30 pm
Lecture 3: Overview of FDA Medical Device PreMarket Application Process	1.30 pm - 3.00 pm
Break	3.00 pm - 3.30 pm
Lecture 4: Overview of FDA Device Manufacturing Issues	3.30 pm - 5.00 pm
Lecture 5: Q & A	5.00 pm - 5.30 pm

Day Two

Registration & Breakfast	8.30 am - 9.00 am
Lecture 1: Overview of In Vitro Diagnostic Regulation	9 am - 10.30 am
Break	10.30am - 11.00 am
Lecture 2: Overview of Biomedical Software Regulation	11.00 am - 12.30pm
Lunch	12.30 pm - 1.30 pm
Lecture 3: Overview of FDA Medical Device Post-Market Surveillance	1.30 pm - 3.00 pm
Break	3.00 pm - 3.30 pm
Lecture 4: Overview of Device Regulatory Strategies	3.30 pm - 5.00 pm
Lecture 5: Q & A	5.00 pm - 5.30 pm

Why should you attend:

This course provides a basic description of an FDA regulatory strategy for medical devices and explains the relationships between regulatory strategy and product development. It offers guidelines for developing successful strategies for medical devices, including definitions and classifications, elements of regulatory strategy, sources of regulatory intelligence, selection of development and product clearance/approval pathways.

Who Will Benefit:

- Regulatory professionals working in the medical device field

Areas Covered in the Session:

- Describe the elements impacting the definition and classification of medical devices
- Determine the points to consider in the development of a regulatory strategy
- Define the tools for regulatory strategy development
- Recognize sources of regulatory and competitive intelligence
- Identify the elements of a regulatory plan
- Apply regulatory principles to develop a regulatory plan

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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