Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Marketing, Advertising and Promotion of Pharmaceuticals and Medical Devices

Chicago, IL

May 18th & 19th, 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 in the areas of Regulatory Affairs, Compliance and Quality Systems. He has been previously employed, with increasing responsibilities by device manufacturers and consultancies, including a globally recognized CRO and has worked directly with manufacturers engaged in compliance remediation activities involving consent decrees, CIA's, warning letters, and customer generated compliance events, conducts QS, regulatory, compliance assessments/audits and FDA Mock Inspections for State of Readiness.

Overview :

The changing game for drug and device marketing, however, is governed by antiquated and inadequate rules created for traditional print and broadcast advertising by the Food and Drug Administration ("FDA"). How the FDA will deal with such advanced communication technology that can go "viral" and just as quickly disappear is the question that the industry is eager to have answered.

Agenda:

Day One

- Introductions and Background
- Advertising and Promotion Regulation Overview
- Required Elements of All Advertising and Promotional Materials for Drugs and Medical Devices
- Laws Governing Advertising and Promotion: FDA
- Promotion, Labeling and Advertising
- Misbranding/Off-Label Information and Issues
- In-Depth Analysis of Requirements for Advertising and Promotion
- FDA Enforcement Surveillance
- Social Media
- What must product claim ads tell you?
- What are ads not required to tell you?
- Does the law say anything about the design of ads for prescription drugs?
- Has FDA done research on DTC advertising?
- How can an ad violate the law?
- Who should I tell if I think that a prescription drug ad violates the law?
- What does FDA do if it determines that an ad violates the law?
- What is Off-Label and the consequences with HCP's?
- Off-Label Promotion
- Medical Education
- Why FDA has complete jurisdiction over prescription drug labeling and advertising, as well as all medical device labeling, but has limited jurisdiction over medical device advertising?
- FDA and FTC Enforcement
- The FDA has an escalating arsenal of enforcement tools from informal notices to formal administrative notices to civil actions and finally to criminal prosecution.

Day Two

- Untitled Letter and the Warning Letters
- Seizures
- Injunctions/Consent Decrees
- OIG/DOJ/False Claims Act and Other Acts and OIG Settlements/CIA's
- Physician Payments Sunshine Act
- The federal Anti-Kickback statute presents many potential pitfalls for medical device manufacturers looking to promote their products.
- Disclose risk information in prescription drug and medical device promotion appropriately and effectively to healthcare professionals and consumers
- Company Policies and Procedures
- AdvaMed Code of Ethics on Interactions with HCP's
- Integrating FDA compliance elements into Healthcare Compliance or Corporate Compliance programs and overview of the standards with HHS-OIG Guidance
- Recent Trends and Enforcement Actions

Recap of Day 1 and Day 2

Exercise on Day 2

- Interactive Discussions
- Review Regulatory and Compliance Documentation

Debrief/Adjourn/Wrap-Up

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
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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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