Global CompliancePanel

NetZealous

2-day In-person Seminar:

Advertising and Promotional Requirements for Drugs and Medical Devices

By: **David R. Dills** Regulatory Affairs & Compliance Consultant,

Location : San Diego | August 07-08, 2014

Location : Chicago | September 4-5, 2014

Course "**Advertising and Promotional Requirements for Drugs and Medical Devices**" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

About GlobalCompliancePanel:

GlobalCompliancePanel is a training source that delivers diverse, high quality regulatory & compliance trainings. These trainings are simple while being relevant and cost-effective while being convenient. GlobalCompliancePanel imparts knowledge of best practices across a broad range of user-friendly mediums such as webinars, seminars, conferences and tailored, individualized consulting. These help organizations and professionals implement compliance programs that meet regulatory demands and put business processes in place. Through our trainings, we bring together the regulators or experts on regulation on the one hand, with the community that needs to learn or be aware of those regulations, on the other.

Our services benefit the Medical Devices, Pharmaceutical, Bio Technology, Food Safety, Financial Accounting Standards, and IT Control & PCI Industries. Our clientele includes companies such as J&J, Pfizer, Sanofi Aventis, Pall Corp, Abbott, Merck, Bayer, and Roche, some of which are Fortune 500 companies.

Professionals who undergo trainings from GlobalCompliancePanel exhibit a vastly improved quality of life in which there is increased productivity and professional growth. Some 30,000 professionals have gained from more than 500 training courses we have conducted till now

David R. Dills , Statistical Consultant & Trainer, Ohlone College & SV Polytechnic .

John N. Zorich, has spent 35 years in the medical device manufacturing industry; the first 20 years were as a "regular" employee in the areas of R&D, Manufacturing, QA/QC, and Regulatory; the last 15 years were as consultant in the areas of QA/QC and Statistics. His consulting clients in the area of statistics have included numerous start-ups as well as large corporations such as Boston Scientific, Novellus, and Siemens Medical.His experience as an instructor in statistics includes having given 3-day workshop/seminars for the past several years at Ohlone College (San Jose CA), 1-day training workshops in SPC for Silicon Valley Polytechnic Institute (San Jose CA) for several years.several 3-day courses for ASQ Biomedical, numerous seminars at ASQ meetings and conferences, and half-day seminars for numerous private clients.. He creates and sells formally-validated statistical application spreadsheets that have been purchased by more than 75 companies, world-wide.

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.

The FDA regulates the promotion of prescription drugs, biologics, medical devices and biotechnology products to ensure that the information is not false or misleading. The FDA has for decades regulated traditional advertising for decades, published various guidance documents for industry and issued many violation letters. If the FDA determines that drug or medical device promotional material is false or misleading or lacking in fair balance as between benefits and risks, companies could be forced to implement costly corrective actions, such as remedial advertising, suffer damage to their reputations and incur monetary fines. Already, the government has collected billions of dollars in fines, forfeitures and disgorgements from drug companies for the alleged marketing of a product for unapproved, or "off-label," uses.

Course Outline:

Day One

Lecture 1: Required Elements of All Advertising and Promotional Materials for Drugs and Medical Devices

Lecture 2: Promotion, Labeling and Advertising

Lecture 3: Misbranding/Off-Label Information and Issues

Lecture 4: FDA Enforcement Surveillance

Lecture 5: Social Media

Lecture 6: Enforcement Tools

Lecture 7: The FDA has an escalating arsenal of enforcement tools from informal notices to formal administrative notices to civil actions and finally to criminal prosecution.

Lecture 8: Untitled Letter and the Warning Letters

Lecture 9: Seizures

Day Two

Lecture 10: Injunctions/Consent Decrees

Lecture 11: OIG/DOJ/False Claims Act and Other Acts and OIG Settlements/CIA's

Lecture 12: Physician Payments Sunshine Act

Lecture 13: The federal Anti-Kickback statute presents many potential pitfalls for medical device manufacturers looking to promote their products.

Lecture 14: Disclose risk information in prescription drug and medical device promotion appropriately and effectively to healthcare professionals and consumers

Lecture 15: Company Policies and Procedures

Lecture 16: AdvaMed Code of Ethics on Interactions with HCP's

Lecture 17: Integrating FDA compliance elements into Healthcare Compliance or Corporate Compliance programs and overview of the standards with HHS-OIG Guidance

Lecture 18: Recent Trends and Enforcement Actions

Global CompliancePanel

2-day In-person Seminar 2014

Pricing list:

Price for One Delegate pass Price: $1,295.00

August 07-08, 2014 | San Diego

Register now and save $200. (Early Bird)
Until July 11, Early Bird Price: $1,295.00
From july 12 to August 05, Regular Price: **$1,495.00**

September 4-5, 2014 | Chicago

Register now and save $200. (Early Bird)
Until August 08, Early Bird Price: $1,295.00
From August 09 to September 02, Regular Price: **$1,495.00**

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

What you 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

Payment Options:

- Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
- Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
- PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free 1800 447 9407 for the invoice and you may fax the PO to 302 288 6884
- Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free 1800 447 9407 for the wire transfer information

Who Should Attend:

- Project Managers
- Regulatory Affairs Management
- Regulatory Affairs Specialist
- Compliance Officer
- Compliance Specialist
- Clinical Affairs
- Quality Assurance Management
- Marketing & Sales
- Distributors/Authorized Representatives
- Legal Counsel
- Engineering/Technical Services
- Operations/Manufacturing
- Consultants
- Marketing Communications

Contact Information: Event Coordinator

Toll free: 1800 447 9407
Fax: 302 288 6884
Email: support@globalcompliancepanel.com

Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

Team GlobalCompliancePanel

NetZealous LLC, DBA GlobalCompliancePanel
161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA

Global CompliancePanel

2-day In-person Seminar 2014

Registration Form:

Please use this form to register online, using your American Express, Visa or MasterCard.

To get discounts on group attendance, please call us on1800 425 9409

Call us on 1800 447 9407 or fax your PO to 302 288 6884

Please pay your check issued from the payee to NetZealous LLC, our parent company, and mail it to NetZealous, 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA Please call us at 100 8425 9409 or email us at support@globalcompliancepanel.com Please fill this form out and include attendee and payment details in it and fax it to 302 288 6884

Terms and Conditions

Your registration for this seminar is bound by terms and conditions spelt out here. Please call or mail us if you have any clarifications or doubts on this issue.

Cancellations and Substitutions

If you wish to cancel your attendance at our seminar, the person who has registered for this seminar has to submit written cancellations through fax or email at least 10 calendar days before the date of commencement of the event. This will entitle her/him to a full refund minus a $150 administration fee. No cancellation request will be accepted or entertained and no refunds will be issued for requests made outside the stipulated period.

A request to this effect has to be sent by email or fax more than ten days before the commencement date of the seminar. After receiving this request, we will issue a credit for the amount paid with a deduction of administration fees of $150. This credit note will be transferred to a future GlobalCompliancePanel event, and a credit note will be issued towards this.

You are allowed to make substitutions at any time till the start of the event. The substituting person should be present well in time for the event with proper written communication and company identity.

If registering on the date of the seminar, please make sure you pay for the event using your credit card or check just before the start of the event. To such attendees, we may not be able to give the conference materials on the spot. In such an event; we will send the same after the conclusion of the seminar.

No-shows will not be reimbursed.

If GlobalCompliancePanel cancels an event, we will not be reimbursing any airfare, accommodation, other costs or losses that the registrants may have incurred. GlobalCompliancePanel reserves the right to change topics and speakers without notice.

Seminar Topic:.....

Date:.....

Attendee 1 : Name ..... Title ..... Email .....

Attendee 2 : Name ..... Title ..... Email .....

Attendee 3 : Name ..... Title ..... Email .....

Attendee 4 : Name ..... Title ..... Email .....

Company Information

Organization .....

Address .....

City ..... State ..... Zip.....

Country .....

Phone ..... Fax .....

NetZealous LLC, DBA GlobalCompliancePanel
161 Mission Falls Lane,
Suite 216, Fremont, CA 94539, USA
Phone: +1-800-447-9407

Toll free (US): +1-800-447-9407 / Fax (US): 302 288 6884

Payment Options

☐ Check enclosed, payable in U.S. funds to NetZealous LLC, DBA GlobalCompliancePanel

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....

CVV Number .....

Total amount $ .....

Signature .....

(Signature required on credit card and bill-me orders.)

Print name .....

☐ Bill me/my company $ .....

Purchase order # .....

(Payment is required by the date of the conference.)

Please fill this form with attendee details and payment details and fax it to 302 288 6884