

Regulation of Marketing and Promotion of Prescription Drugs Course # T37

October 25 - October 26, 2010

Start - 8:00 Finish - 5:00

Hotel Information:

Hyatt Arlington
1325 Wilson Boulevard
Arlington, VA 22209
(703) 525-1234

Rate: \$ 239

Deadline for Group Rate: 2010-09-11

Registration Rate:

\$1,495.00 Register by 09/11/10

\$1,695.00 Register after 09/11/10

Cancellation Date: 10/26/10 (Cancellation fee is determined by date cancelled.)

Continuing Education Credit:

ACPE: 0708-0000-10-034-L03-P (1.4 CEU)

Initial Release Date: N/A

CBRN: N/A

CME: 14 Hours of Category 1 Credit

VNA: 07-04-01 14 Contact Hours

Course Description:

This course will be held at:
The PERI Training Facility
1616 N Fort Myer Drive Suite 1430
Arlington, VA 22209

Day 1: 8:00 AM - 5:00 PM

Day 2: 8:00 AM - 5:00 PM

This course presents industry and FDA experts on current issues regarding FDA regulation of promotional activities such as direct-to-consumer advertising, pharmacoeconomics, scientific exhibits, off-label communications as well as trends in FDA enforcement; learn how new developments in product liability and application of Anti-Kickback laws and regulations will effect your ability to market and promote prescription drugs. Walk away with best practices in complying with the Federal Food, Drug & Cosmetic Act, the Anti-Kickback Statute and the new PhRMA Code on Interactions with Healthcare Professionals and how to fashion a message about your product.

Who Should Attend:

Personnel in marketing, sales, advertising, public affairs, regulatory affairs and legal departments should attend. Individuals in outcomes research, clinical affairs, and compliance with responsibility for review of marketing activities would also find this beneficial.

Educational Objectives:

Upon completion of this course, participants should be able to:

- Explain the key public policy factors affecting the regulatory environment
- Describe legal and regulatory requirements, appropriate professional and industry guidelines and current trends
- Recognize the views and positions of the major players: The U.S. Food and Drug Administration, The American Medical Association, The Inspector General of Health and Human Services, The U.S. Congress and others

Key Topics:

- FDA Regulation of Promotional Activities
- Complying with the Federal Food, Drug & Cosmetic Act
- The FDA Perspective on Marketing and Promotion of Prescription Drugs
- PhRMA Code on Interactions with Healthcare Professionals
- Regulation of Product Promotion ¿ There¿s More Than Just The FDA
- Product Liability Implications
- Focus on Direct-to-Consumer (DTC) Advertising
- Pharmacoeconomics: What You Can and Can¿t Do
- The New Standards of Commercial Support: An Overview

Course Director(s):

Danielle Drissel, Esq
Attorney At Law
Hogan & Hartson