



CfPA

The Center for Professional Advancement

Accredited Technical Training Worldwide

PO Box 7077, East Brunswick NJ 08816

Phone 732-238-1600 • Fax 732-238-9113

ON-DEMAND Quarterly Reports FDA QUARTERLY BRIEFING/July 2008

Location: Your Computer Offering # 0807-728 Priority Code: 520

New FDA guidelines, regulations, and interpretations emerge constantly from the agency that controls almost a third of the US economy. Keeping up with these changes is a constant challenge. Join CfPA each quarter for the latest FDA guidelines – 90 minutes every quarter with an expert who can help you assimilate the information and answer your questions.

WHO SHOULD ATTEND

This course is designed for professionals in the pharmaceutical, device and biologics industries. It will be especially beneficial to:

- Regulatory/QA Managers
- Directors and VPs
- Planning Executives anticipating FDA changes

LEARNING OBJECTIVES

Upon completion of this training, participants will be able to:

- Apply the new FDA public advertising guidelines
- Incorporate emerging FDA revisions to GMP and 21 CFR Part 11
- Implement initiatives related to new FDA Post Market Surveillance Requirements

COURSE DESCRIPTION

This quarter's briefing is a careful distillation identifying the three most important new initiatives, regulatory changes and innovations from the FDA, and places them in context for the pharmaceutical, biological and device professional. This 90-minute accredited online training is divided into three sections, each section devoted to a new FDA regulation or initiative. Ample time has been allotted to answer your questions. The topics are:

Public Advertising Guidelines:

- Congressional mandate
 - 2007 Act
- Problems and value of public advertising
 - Information dissemination
 - Public demand, over-use
- FDA monitoring
 - Shift from FTC
 - Expertise gap
- Emerging guidelines
 - Clarity
 - Information without "sales pitch"
 - Dangers and side effects

GMP and 21 CFR Part 11 Revisions:

- Harmonization with EMEA GAMP4/5
 - GAMP4= cGMP+Part11
- Updating of GMPs in automated environment
 - More than ten years since last update
 - Risk factors
- PAT
 - Automation of QA function
 - Potential for remote monitoring

Post Market Surveillance Requirements:

- Extension of FDA focus
 - Reduce NDA/ANDA pressure
 - Increased most market surveillance
- Improved data collection and analysis
 - Active rather than passive
 - Tracking use, side effects
 - Possible post clinical studies (Phase V?)
- Concerns over off label use
 - Reconciling distribution volume
- Post NDA/ANDA submission and review
 - New FDA responsibility
 - New submission guidelines

Question and Answer Session

COURSE DIRECTOR

Dr. Sandy Weinberg Independent Consultant to FDA Regulated Industries, has consulted for the FDA, Health Canada, NIH, CDC, EMEA and the Swiss Ministry of Health

ACCREDITATIONS



The Center for Professional Advancement has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102. In obtaining this approval, The Center for Professional Advancement has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. As a result of their Authorized Provider membership status, The Center for Professional Advancement is authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards.

REGISTRATION

TUITION* – **Single Rate: U.S. \$295.00 per person** **Group Rate: U.S. \$245.00 per person****

Register at www.cfpa.com. Enter **Course Offering #0807-728** into **Quick Jump**. To register use **Priority Code: 520**.

For Questions and Information call Customer Service at 732-613-4500.

Please Note: Multiple participants are not authorized to share access provided to a single registrant, a single dedicated seat license must be purchased for each individual. CfPA reserves the right to cancel access or collect the group rate payment if this requirement has been violated.

ABOUT ON-DEMAND:

Our pre-recorded on-line training courses are available for viewing at your convenience at your computer. Register for a CfPA on-demand course, your registration will be processed within two (2) business days, after payment and registration are complete you will receive an email from olinetraining@cfpa.com with your password to access the on-demand course. You will have two (2) business days to view the course. You MUST complete all polls and the course evaluation to receive your accreditation certificate for this course.

TERMS AND CONDITIONS

***Payment:** Tuition payable in US funds net of all charges. Payment is due at time of registration in the form of a credit card. Please contact CfPA's Customer Service for other payment options.

****Group Rate:** The Group Rate is for two or more enrollments, up to five registering from the same company at the same time. For groups of six or more, please contact Customer Service for group pricing. **Cancellations/No Show: "Live"** - Registrants may cancel up to two working days prior to the course start date and will receive a letter of credit to be used towards a future course up to one year from date of issuance. No credit will be issued for no-shows and/or cancellations less than two working days prior to the course. : **"On-Demand"** - No refund or credit will be issued for no-shows and/or cancellations of on-demand training courses. CfPA is not responsible for any outside related costs incurred by registrant's cancellation.