

# FDA Quarterly Briefing—April 2009

Location: Your Computer Offering # 0904-701 Priority Code: 520

Future briefings—first Tuesday of each Quarter: July 7, 2009; October 6, 2009

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 with an expert who can help you assimilate the information and answer your questions.

## WHO SHOULD ATTEND

This course presented by CfPA in conjunction with

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, you will be able to:

- Explain the newest FDA concepts regarding certain allowable deviations within the design or medical devices and production processes
- Summarize FDA's newest efforts regarding Off Label Drug use
- Describe the basics of the updated approach to Process Validation including Q8, Q9 and Q10

## 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. The topics are:

### Module 1: New Administration:

- How will the Obama administration change FDA and regulation?
- What are Tom Daschel's plans for top level changes in personnel and philosophy?
- What new policies will emerge?
- What previous strategies will survive?

### Module 2: Shake Up in Medical Devices:

- Has the Medical Devices group approved some products without adequate testing?
- What new 510(k)/PMA requirements will emerge?
- What changes are coming in the approval process?

### Module 3: FDA/EMEA Harmonization:

- Risk Based (Q8, Q9, Q10) and Quality by Design new approaches
- The fundamental philosophical differences between FDA and EMEA
- Steps backward (and tiny steps forward) toward harmonization
- How to make dual submissions

### Question and Answer Session

## TUITION AND REGISTRATION

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

Register at [www.cfpa.com](http://www.cfpa.com). Enter **Course Offering #0904-701** 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. Only registered participants will receive accreditation.

For more information see reverse side 



# CfPA

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## COURSE DIRECTOR

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**Dr. Sandy Weinberg**, Associate Professor of Health Care Management (Regulation) at Clayton State University, part of the Georgia State University System; retired regulatory professional from the drug, device and vaccine industries.

Dr. Sandy Weinberg, is currently a professor of Health Care Management in the School for Professional Studies at Clayton State University, part of the Georgia State University System. He is teaching and researching Regulation and Biodefense. Dr. Weinberg is a consultant to the FDA regulated industries and is a former consultant to the FDA and other international regulatory agencies including Health Canada, NIH, CDC, EMEA and the Swiss Ministry of Health.

He has been a leader in the field of system validation for more than twenty years, and a practitioner in regulatory submissions, auditing, international liaison and biodefense vaccine development. Dr. Weinberg is the author of numerous books and articles, including *The GALP Regulatory Handbook*, *The Handbook of System Validation*, *Good Laboratory Practice Regulations*, and *The Handbook of Drug Regulatory Submissions*. His most recent articles include "Cost Effective Validation for LIMS" and "Conforming to Part 11 Regulations".

Dr. Weinberg is a member of the Board of the KEMA Registered Quality (ISO 9000 Certifier) in the United States and the Netherlands. Recently retired, Dr. Weinberg was Senior Director for Biodefense at GE Healthcare and Vice President of Tikvah Therapeutics; as well as an investor in and Board member of several international biomedical companies.

Working as a consultant, Dr. Weinberg provides auditing and advisory services in regulatory areas. Recent projects include the auditing and certification of a chromatography control system; a business development and fund raising project for a biodefense vaccine company; an Orphan Drug submission; and the validation of a Laboratory Information Management System. Much of Dr. Weinberg's practice is centered in the US, Western Europe and Israel.

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## ACCREDITATIONS

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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.

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## WHO WE ARE

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The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately three hundred and fifty short courses in 18 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more.

Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory concepts to new advances and cutting-edge technology, and current U.S. and European regulations. CfPA courses are offered in a variety of formats – Public offering, Client Site and Online- to fit you or your company's training needs.

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## ABOUT WILEY-BLACKWELL

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Wiley-Blackwell was formed in February 2007 as a result of the acquisition of Blackwell Publishing Ltd. by John Wiley & Sons, Inc., and its merger with Wiley's Scientific, Technical, and Medical business. Together, the companies have created a global publishing business with deep strength in every major academic and professional field. Wiley-Blackwell publishes approximately 1,400 scholarly peer-reviewed journals and an extensive collection of books with global appeal. For more information on Wiley-Blackwell, please visit [www.blackwellpublishing.com](http://www.blackwellpublishing.com) or <http://interscience.wiley.com>.

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## COURSES OF INTEREST

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- **21 CFR Part 11: Strategies for Cost Effective Compliance Using a Risk-based Approach**  
course id# 2225
- **Applied cGMPs for Pharmaceutical and Allied Industries**  
course id# 610
- **Clinical Testing Plan and Submissions – a TWO Part Course- An Online Course**  
course id# 2242
- **Introduction To Pharmaceutical cGMP-An Online Course**  
course id# 2244
- **Orphan Drug Application and Submission**  
course id# 2223
- **Pharmaceutical cGMP-Quality Systems-An Online Course**  
course id# 2245
- **Practical Steps to Understanding ICH Q9-An Online Course**  
course id# 2160

### 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](mailto: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.

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## TERMS AND CONDITIONS

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**\*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.