CAPA: A Critical Quality System Requirement

The Role of Corrective Action and Preventative Action in Your Quality System

Wednesday, February 1, 2017  11:00 a.m.–12:30 p.m. (ET)
Course ID # 2570  Available On-Demand starting 2/2/17

who should attend

This webinar will provide a great resource to Pharmaceutical, Biotechnology and Medical Device Industries personnel within the following departments:

• Quality Control Personnel & Management
• Regulatory Affairs Personnel & Management
• Manufacturing Personnel & Management
• Quality Assurance Personnel & Management
• Supplier Quality Personnel & Management
• Senior Management

However, if you are already familiar with CAPA and its requirements, you may recommend this webinar to anyone in your company that may require additional knowledge about this subject.

learning objectives

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

• Explain the requirement of 21 CFR Part 211 and 21 CFR Part 820.100, FDA Guidance’s and other regulatory bodies’ compliance requirements applicable to CAPA.
• Describe the differences between CAPA and SCAR, their impact to product release turnaround time as well as the advantages of the different tools that are used for CAPA investigation (manual versus electronic CAPA investigation systems) and best practices within the industry.
• Discuss the different types of electronic CAPA systems, advantages and disadvantages of different systems and what to look for when choosing an electronic CAPA system.
• List the basic requirements of a quality system investigation, current trends and how to design a compliant and efficient quality investigation system (CAPA) in order to avoid FDA findings relating to Quality Systems Investigation.

course description

There has been several form 483’s and warning letters being issued to companies by the FDA as it relates to CAPA investigation because of insufficient or incomplete quality systems procedures applicable to corrective action and preventative action programs (CAPA). Addressing an FDA form 483 with findings associated with CAPA systems must be performed adequately, complete and must provide enough details within the CAPA procedures to ensure an effective CAPA investigational procedure. All failure, deviation or out of specification investigations must be adequately documented, corrected, prevented and checked for corrective action effectiveness through the use of a compliant CAPA investigational system and program. The result of a product investigation impacts the quality of the cGMP manufactured product label claim, to avoid it from being termed “adulterated” by the FDA which may result in product recalls, complaint and further actions by the FDA.

This 90-minute accredited training will benefit manufacturers of cGMP products in designing an effective, robust and compliant CAPA investigation system in order to avoid FDA or other regulatory bodies’ inspection findings in these areas.  It will also be a great resource to Quality Assurance, Manufacturing, Regulatory Affairs and Quality Control personnel and management within the Pharmaceutical, Biotechnology and Medical Device companies.

Review of Learning Objectives

Module 1: CAPA Requirements, Regulations and Application
• Understanding requirements of 21 CFR Part 211 and 21 CFR Part 820.100.
• Definition, application tools and types of CAPA (Differences between CAPA and SCAR) to include manual and electronic CAPA systems as well as the advantages and disadvantages of each type.

Module 2: Electronic CAPA Investigation System (Choosing a the Right CAPA Investigation Program)
• Types of Electronic CAPA Investigation Systems/Programs and Critical Aspects of the Initiation Evaluation of a CAPA Investigation System/Program
• Important Considerations during the Evaluation of an Electronic CAPA System/Program and how to choose the right system to work with

Module 3: Designing a Compliant and Robust CAPA Investigation Program
• Impacted Departments, Roles Associated with CAPA, Completing a CAPA investigation and Regulatory Requirements of a Complaint CAPA Investigation System/Program

Question and Answer Session
Charity Ogunsanya: (Owner/CEO), Pharmabiodevice Consulting LLC
Charity Ogunsanya has more than 23 years of extensive experience within the Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology and Medical Device Industries and has been the Microbiology, Sterility Assurance, Contamination Control, Aseptic processing, Quality Control Subject Matter Expert (SME) for multiple fortune 100 companies.
She has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and is currently in the Advanced Academic Master’s Biotechnology Program at the Johns Hopkins University with concentration in Biotechnology/Biodefense. She is the CEO/Owner of her consulting firm named Pharmabiodevice Consulting LLC. Her consultancy provides support to Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology and Medical Device Industries.

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. Enter Course ID# 2570 into Search. To register click Register Now.
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.
System Requirements: PC-based attendees: Windows® 7, Vista, XP or 2003 Server/Macintosh®-based attendees: Mac OS® X 10.4.11 (Tiger®) or newer

Accreditations/recertifications for this course

The Center for Professional Advancement has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), 11130 Sunrise Valley Drive, Suite 350, Reston, VA 20190. 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. The Center for Professional Advancement is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEU will be awarded for participation in The Center for Professional Advancement’s courses at the rate of .1 CEU per contact hour. CEU will be awarded only upon successful completion of the entire course and 70% accuracy in the required Learners’ Assessment. This course offers a total of 1.5 contact hours or .2 CEUs (CEUs rounded up).

Who we are—“Celebrating 50 Years”

The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately 450 short courses in 15 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 to fit your or your company’s training needs:

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Virtual Attendee: Ideal for those who need the training but cannot attend in person. For more information visit: www.cfpa.com/virtualattendee

Courses of interest

- Best Practices for Investigating Deviations and Non-Conformances–An Online Course
course ID# 2699
- Conducting Effective Quality Audits
course ID# 1681
- Design Control and Product Validation
course ID# 1900
- Developing and Maintaining an Effective Complaint System
course ID# 1834
- Documentation Management and Control
course ID# 1866
- How to Conduct Robust Root Cause Investigations for CAPA
course ID# 2089
- Implementing a Change Control Quality System Successfully–An Online Course
course ID# 2694
- Medical Device: Meeting Development and Global Regulatory Challenges
course ID# 2092

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.
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