COBBLESTONE

COURSE ID 3105

Introduction to CAPA Management

A Critical Quality System Requirement

DIRECTED BY

Laura Jeannel., Senior Quality Consultant, Farbridge Pharma Consulting

60 MINUTE

ACCREDITED COURSE

- CAPA and Regulatory Requirements for Pharmaceuticals and Medical Device
- Corrective and Preventive Actions – Definitions and Meanings
- Writing Effective CAPA Plans
- Initiating and Implementing CAPAs
- CAPA Reviews
- CAPA Closure
- CAPA Effectiveness and Follow-Up
- Trends and Insights

about the course

There have been several form 483s 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, and completely and provide enough details within the CAPA procedures to ensure an effective CAPA investigational procedure. All failures, deviations, 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, complaints, and further actions by the FDA.

In this introductory 60-minute accredited training, we will discuss and highlight to GMP professionals the importance of writing effective CAPAs from initiation, implementation, closure, effectiveness, and follow-up. It will be a great resource for professionals to build and strengthen their CAPA Management program into a proactive and preventive system for Quality Management Systems. Additionally, key case examples will aid personnel in identifying the most effective means to continuously develop effective CAPAs for an enhanced and more robust program.

Experience top-notch training LIVE from an industry expert that goes beyond traditional lectures. You will engage in an interactive and stimulating learning experience that will help develop the skills needed to excel in the field.

Those attending the LIVE training event must have a webcam on their computer equipped with a microphone and speakers/headset to fully participate.

who should attend

This entry-level training will provide a great resource to Medical Device, Pharmaceutical, and Biologics Industries personnel within the following departments:

- Quality Assurance
- Manufacturing
- Validation
- Quality Control
- Facilities

learning objectives

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

- Initiate, complete, and perform effective writing skills for CAPA Management
- Define key differences between Corrective Actions and Preventive Actions
- Identify key implementation in a targeted manner in a multi-tasking environment
- Show closing complete and robust CAPAs to prevent recurrence
- Define CAPA Effectiveness
- Evaluate Trend Management while building a proactive and preventive system as a key component to the Quality Management System

course outline

Review of Learning Objectives

Module 1: (40 min)

- CAPA and Regulatory Requirements for Pharmaceuticals and Medical Device
- Correction and Preventive Actions and their meaning
- Writing Effective CAPA Plans and implementation

Case Examples

Module 2: (20 min)

- CAPA Reviews and Closure
- CAPA Effectiveness and follow-up
- Trends and insights

Case Examples

Break-out session

Question and Answer Session

Assessment Opportunity

course instructor

Laura Jeannel, Senior Quality Consultant for Farbridge Pharma Consulting, is an experienced Quality Assurance professional leading as a former Quality Director and key consultant for >20 years. During her career, she has led major pharmaceutical companies in establishing, executing, and continuous improvement for sustainable Quality Management Systems. Ms. Jeannel has been responsible for the launch of multiple complex projects in pharmaceuticals, biologics, cell and gene, and medical devices.

She is a recognized trainer for key Quality Systems and pragmatic solutions for building positive partnerships for continuous improvement.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1 contact hour or .1 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)
Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS-established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.

The American Society for Quality (ASQ)
The American Society for Quality (ASQ)-Recertification Opportunities
Cobblestone is committed to enhancing the ongoing professional development of Quality professionals and other stakeholders through appropriate learning activities and programs. Many Cobblestone courses offer training that may help obtain required ASQ recertification education units.
For more information, visit: www.asq.org