COBBLESTONE

COURSE ID 3122

GMP Change Control Process

DIRECTED BY

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12 Hours

ACCREDITED COURSE

- Definition of Change
- Regulatory Requirements
- Change Control Process
- Classification of Change
- Roles
- Assessment and Risk
- Compliance and Non-Compliance
- Regulatory Examples

about the course

Change Control is a requirement of all regulatory agencies and authorities worldwide. It is a critical GMP function that must be addressed daily. The value of identifying and tracking change is to prevent unintended consequences, remain in proper process alignment, and avoid any alteration of the products' Safety, Identity, Strength, Purity, and Quality (SISPQ). Many aspects of an operation are affected by change control making it imperative to properly assess, analyze, risk assess, and plan for the change requested as part of the change control process.

This fully accredited 12-hour course will provide an in-depth examination of what constitutes a change, who is responsible, and who participates in each step of the process. This course also covers the US FDA terms and exclusions regarding change control that have been implemented over the past few years.

Included in this course are change control exercises, so that the participants can practice identifying and implementing knowledge learned with our subject matter expert.

Those attending the LIVE training will have the opportunity to ask questions during the session. It is highly recommended to have a webcam on their computer as well as a microphone and speakers/headset to fully participate.

who should attend

This course has been developed to meet the training needs of both beginners and experienced professionals involved in Quality Assurance/Quality Control, Regulatory Affairs, Development, and Manufacturing that participate in change control processes within the following industries:

- Pharmaceutical Science
- Research & Development
- Cosmetics
- Biologics
- Medical Device
- Veterinary Drug Products

learning objectives

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

- Define and explain Change Control and the process
- Identify and show what to do when change occurs
- Outline the requirements of Change Control including verification
- Utilize the appropriate process in initiation, follow through, and closure of a change
- Review and discuss examples of Change Control
- Develop a Change plan
- Plan and utilize the Change Control process and associated documentation

course outline

Review Learning Objectives
The Definitions of Change
Regulatory Requirements for Change Control

- Domestic & International
- International review of Change Control requirements
- Regulatory response and Change Control

Origins of Change
The Process of change

- When to initiate a Change Control
- The formality of Change Control
- Cost/Benefit Analysis of Proposed Changes
- Proper Justification for Changes
- Change Control Assessment
- The paperwork of Change Control
- Associated forms
- Notifications of Change

Planned and Unplanned

- Deviations and Change Control
- Modification and Change Control
- When to consider the Change Control process

Classification of Change

- Like for Like
- Like in Kind
- SUPAC/BACPAC application
- Design Change

Application of Change

- Pharmaceutical & Medical Device
- MDR and ISO
- Quality System Requirements

Responsible Roles

- Those involved.
- Task assignment
- Everyone's responsibilities

Qualification and Validation

- Deep dive into maintaining the validated state

The Change Control Plan

- Change Management Plan
- Project Management of Change

Managing Change

- The Change Control Board
- Management and Change

When to initiate change

- Risk Assessment in Change Control
  - Quality Risk Tools
  - Impact of Change
- Change Review and Verification.
- The close out of Change Control
- Brief discussion on Computer Programs
- Compliance and Non-Compliance

3- 4 Exercises in Change Control requiring evaluation, team discussion, presentation, and review (participation in discussions is for live attendees only)

Assessment Opportunity

course instructor

Mr. Angelucci is a pharmaceutical professional with over 30 years' experience in Quality Assurance, Quality Control, Regulatory Affairs, Validation, consent decree remediation as well as cGMP Compliance in the Medical Device and Pharmaceutical industries.
He has worked for several well-known companies including Johnson & Johnson, Bristol-Meyer Squibb, Pfizer, Schering Plough, and Merck. His experience has been either as a direct employee or as a contracting consultant while employed at Foster Wheeler and Aker Kvaerner. As a consultant Mr. Angelucci has worked at various project locations domestically and in Europe and Asia. With these firms he has been involved with auditing, GMP training, Bio-tech consulting as well as FDA audit and PAI readiness training and participation.

Mr. Angelucci is a degreed engineer with two master's degrees in engineering, holds industry certifications with ASQ as a CQE, CQA and CPGP. Previously He was the ASQ Philadelphia chapter Education Chair. In addition, he holds a PMP certification through the Project Management Institute. He has published numerous articles on the subjects of Validation and compliance and has been a speaker to industry groups such as ISPE, IVT, DIA, PDA, ASQ and CFPA.

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 12 contact hours, or 1.2 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.