COBBLESTONE

COURSE ID 2752

Introduction to Batch Record Review

DIRECTED BY

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60 MINUTE

ACCREDITED COURSE

- Master Batch Records and Contents
- Requirements for Master Batch Records for FDA and EU
- Reviewing a Master Batch Record
- Issuance of the Master Batch Record and Reconciliation
- Manufacturing Batch Record Review for content by QA
- QA Review and Disposition

about the course

Regulatory Agencies require firms to have written procedures in place to document production and process controls, better known as batch records. Additionally, there must be written procedures for a batch record review process to demonstrate compliance. A strong batch record review system is essential to properly document all critical and operational process parameters that go along with the production and manufacture of pharmaceuticals, biologics, medical devices, etc.

In this introductory 60-minute accredited training, we will identify and discuss Master Batch Records (MBR), regulatory requirements, and key steps for issuance, batch record review, reconciliation, and final QA disposition. Several examples and case studies of best practices will be demonstrated to emphasize how an effective batch record review is conducted based on current quality/regulatory requirements.

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 online training is designed for professionals in the Pharmaceutical, Medical Device, and other life science industries. It will be especially valuable to the personnel and management, including senior management, in these areas:

- Quality Assurance
- Quality Control
- Facilities
- Manufacturing
- Validation Professions in GMPs and Pharmaceuticals

learning objectives

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

- Define Master Batch Record and its contents
- Identify MBR regulatory requirements
- Show Effective Batch Record Review
- Demonstrate effective turnaround time for Batch Record Review for in-house and CMO oversight
- Outline Responsibilities for QA Disposition, oversight, and continuous improvement.

course outline

Review of Learning Objectives

Module 1: (40 min)

- Master Batch Records defined
- Construct Effective Batch Records that ensure right first time
- Build a streamlined organization and flow of Batch Records from Issuance, Use, Review and Disposition

Case Examples

Module 2: (20 min)

- Evaluate several case examples
- Batch Record Disposition and its importance
- Performing Trends and Continuous improvement for turnaround time and effectiveness

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's recertification education units.
For more information, visit: www.asq.org