COBBLESTONE

COURSE ID 1998

Annual Product Reviews/Product Quality Reviews

DIRECTED BY

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12 Hours

ACCREDITED COURSE

- Regulatory Requirements for Product Reviews
- Pharmaceutical Quality System (PQS) and the impacts on Product Review
- Product Review Content
- Recent Regulatory Activities
- Management Involvement in Product Review
- Product Review Process
- Quality System Review

about the course

Periodic Product Quality Reviews or Annual Product Reviews of drug products are required by the U.S., EU and Canada. The purpose of the annual product quality review course is to educate the participant in the regulatory requirements for the FDA Annual Product Review while demonstrating the power of the Periodic or Annual Product Review as a Quality Assurance and Quality Improvement tool. We will discuss how the Product Review supports the US, EU and Canadian GMPs while applying the ICH Q10, Pharmaceutical Quality System elements of Process Performance and Product Quality Monitoring, CAPA, Change Management and Management Review. Discussion will also include the impact of the FDA 2011 Process Validation guidance and the potential impact of the proposed FDA requirement for Quality Metrics on the Product Review.

This 12-hour accredited intensive course will discuss the comparative evaluation about similarities and differences of requirements associated with the manufacturing of the drug product in different countries.

Since this training is highly interactive, those attending the live training event must have a webcam on their computer as well as a microphone and speakers/headset to fully participate.

who should attend

This course is targeted toward professionals who are responsible for the preparation of the FDA Annual Product Review, or Product Quality Review, or the oversight of the preparation of the Product Quality Review. This annual Product Quality Review course also includes information that is pertinent to those who support process validation as defined in the FDA 2011 Process Validation Guidance and those who want to understand the potential impact of the FDA draft guidance on Quality Metrics on Product Reviews and the organization as a whole.

learning objectives

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

- Interpret the requirements for Annual Product Reviews.
- Outline the role of the Product Review in corrective actions, preventive actions, and continuous improvement.
- Outline systems that may be involved in the preparation of the product Review
- Classify the role of management in an effective Product Review Program.

course outline

Review of Learning Objectives

Regulatory Requirements for Product Reviews

- Paragraphs of US, EU and Canadian GMPs and pertinent guidances that require a Product Review
- Identify the specific expectations of each regulation.
- Expectations of management found in the regulations.

Impact of the Quality System

- Introduce ICH Q10, the Pharmaceutical Quality System (PQS).
- How each of the elements of the PQS impacts on the Product Review.
- Other Quality Systems and what can be learned from them.
    - The QSR (21CFR820)
    - ISO 9000
    - ISO 13485
    - Baldridge

Product Review Content

- Product Review Examples for Review
- The specific requirements for the content of the Product Review found in regulations and guidances.
    - US GMP
    - EU GMP
    - Canadian GMP
    - ICH Q7
    - GPG 7356.002
- How the periodic review of the Quality System is consistent with ICH Q10 and other contemporary Quality Systems
- Comparison of expected content in the regulations
    - Common areas
    - Geographical impact
    - Impact of time

Recent Regulatory Activities

- The FDA Process Validation Guidance and the FDA Quality Metrics Guidance.
- How the Product Review can satisfy the FDA expectation for Continued Process Validation.

- Risk management and the Product Review
- How the reporting of Quality Metrics can be integrated into the Product Review process.

The Expanded Role of the Product Review

- How recent guidances have raised the visibility of the Product Review and management involvement.
- The Product Review for multiple jurisdictions
- The Product Review for a virtual organization
- The Product Review and the Regulatory Inspection

Product Review Process

- Identify where the information required for the Product Review is maintained.

Overview of Product Reviews

- Tie together the Product Review and the Quality System Review
- The future importance of the Product Review.
- The Product Review and the Quality System Review as a tool for proactive continuous improvement.
- Discuss the preparation of the Product Review.
    - Individual preparer
    - Preparation by multi-disciplinary team
- Discuss roles and responsibilities within the organization that relate to the preparation of the Product Review.
- The Product Review for multiple jurisdictions
- The Review for a Product manufactured in multiple facilities

Management Responsibilities

- Review Management responsibility as discussed in the GMPs, ICH Q10, and the Quality Metrics Guidance.
- How management responsibilities relate to the Product Review.
- Identify the evolving expectations of the regulatory agencies as defined in recent guidances and demonstrated by recent regulatory observations.

Product Review – an interactive discussion

- Product Review Case Studies
- Product Review Regulatory Observation

Quality System Review

- Introduce the concept of the periodic review of the Quality System
- The Product Review and the Quality System Review as a tool for proactive continuous improvement.

Question and Answer Session

Assessment Opportunity

course instructor

Danielle DeLucy, MS, is the owner of ASA Training and Consulting, LLC which provides Pharmaceutical and Biologics companies with training and quality systems assistance to meet Regulatory compliance.

Before this role, Danielle had been in the industry for 20 years serving in numerous Quality Management Roles at Sanofi Pasteur, such as the Director of Product Quality, the oversight of Sterility Assurance practices, and providing QA oversight of numerous filling and packaging operations. Danielle began her QA career as a Quality Control Pharmaceutical Microbiologist at a contract laboratory where she performed various tests for their clients.
In the years after, she has held positions in the Quality management arena while increasing her

responsibility. She has helped to lead many Regulatory Health Inspections and was instrumental in the coaching process of her peers before any inspection. She has worked with companies such as Johnson & Johnson, Novartis, and Glaxo SmithKline to name a few. Currently, Danielle assists companies who are faced with warning letters, and consent decrees, and those wishing to improve compliance to establish more robust quality systems so that the company can succeed.

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.