COBBLESTONE

COURSE ID 1789

Packaging Process Validations: Pharmaceutical and Medical Device

DIRECTED BY

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9
HOURS

ACCREDITED COURSE

- Using Protocols
- SOP's
- Process controls
- Documentation for IQ, OQ, and PQ
- Workshops

about the course

The integrity of a package depends on the qualification of the packaging equipment, the packaging process, and consistent performance throughout the commercial packaging run. No matter how well the container/closure has been developed, it cannot protect the product as designed if it is not properly sealed and packed. The packaging process validation ensures that packages are sealed and packed correctly.

This intensive, 9-hour accredited course provides an in-depth overview for packaging validation practices. The training will help ensure the product packaging conforms to its predetermined specification. Targets include consistent quality to the consumer, compliance with regulatory requirements, safety, cost effectiveness, financial and other company benefits. Controlled processing from translated user requirements to measurable packaging specifications is discussed. There is emphasis on practical ways to implement packaging validation, using protocols, SOP's, planning, statistics, process controls and other tools. The Validation-Master Plan, protocols, templates for IQ, OQ, and PQ are described.

who should attend

This training is especially designed for personnel involved with packaging process validations for pharmaceutical and medical devices packaging. Active participation and questions are encouraged throughout the course presentation. Professionals in the following departments will benefit greatly from this training.

- Package Engineering
- Product Development
- Supplier Development
- Supply Chain/Logistics
- Manufacturing
- Quality/Quality Assurance

learning objectives

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

- Apply and understand an overview level of regulatory requirements for packaging validation in the US and Europe.
- Identify elements required to execute a packaging process validation.
- Specify requirements for validating a final closure packaging machine.
- Contribute to achieving consistent quality for a packaging system.
- Identify elements and responsibilities needed for executing a packaging process validation.
- Prepare protocols, templates, documents, and contribute significantly to the validation exercise

course outline

Introduction and Learning Objectives
Review

- Why Validate
- Regulations
- Quality
- Definitions
- Overview

Packaging Systems Validating

- Medical Devices versus Pharmaceutical versus Combination Devices
- Packaging Line Examples
- Distribution Systems
- Sterile Barrier Systems
- Thermal Systems

Before Starting a Packaging Validation

- Defining the Validation to complete
- Flowcharting the system
- Risk Assessments
- Defect Catalogs
- Defining the business risks
- Sample Sizes

Test Method Validations

Packaging Materials

- Glass, Plastics, Laminates, Coatings, Metal
- Paper, Paperboard, and Corrugated
- Labels and the three aspects
- Specifications

Human factors testing, overview

Introduction–Guide to Process Validation

- Definitions and Terms in Validation
- Protocols, SOP's, VMP, IQ, OQ, PQ
- Change Control
- Verification/Validation
- Responsibilities–Vendors, project team, management, consultants

Production Lines

- Equipment Installation
- Equipment Operation
    - Impulse sealers
    - Hot bar sealers
    - Hot plate sealers
    - Torque equipment
    - Other Equipment

Shipping Lanes

- Carrier
- Locals
- Testing

Shipping Lanes

- Ambient
- Controlled temperature

Documentation

- Regulatory Requirements
- Communication
- Flow Charts, Matrix, Training Templates
- Validation Master Plan (VMP)
- Developing Universal Templates

Question and Answer Session
Assessment Opportunity

course instructor

Jan Gates, has 30+ years of experience in package engineering for foods, pharmaceuticals, detergent, and medical devices with a BS in Food Science and MS in Packaging from Michigan State University. Her work includes individual contributions and leading teams for packaging material and systems design and development. The packaging design and development have been completed to meet regulatory, product protection, and customer use requirements; also, included are production optimization, validation, and minimal packaging for sustainability. She has previously worked for Bristol Myers Squibb, Conagra, Lever Brothers, Dade Behring, and Abbott Vascular. She currently works as a consultant in her company PackWise Consulting and with Adept Packaging.

Ms. Gates works with ASTM D10 and F02 committees for rigid/flexible packaging and environmental package testing. She is also working as a US representative on various ISO TC 122 committees for packaging tests, vocabulary, labeling, and temperature-controlled product shipment. She was a task group lead with AMMI on a US guidance document for compliance with ISO 11607-1/-2 (packaging for terminally sterilized medical devices). The AMMI TIR 22 document has been converted into ISO/TS 16775.

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 9 contact hours, or 1.2 CEUs. For further information, visit www.iacet.org