COBBLESTONE

COURSE ID 0042

Packaging Pharmaceuticals, Medical Devices and Combination Products

DIRECTED BY

Jan Gates, **President/Advisor Packaging Engineer, PackWise Consulting MSU, Bachelor of Science in Food Science and Master of Science in Packaging**

12 Hours

ACCREDITED COURSE

- Packaging Materials
- Defects and Risks
- Packaging System Qualification and Validation
- Product Lines
- Shipping Lanes
- Workshop

about the course

The importance of a product's primary package cannot be overstated. From material selection to closures, to stability, to the packaging process itself, a multitude of critical decisions must be made in order to develop a quality package. Shortcomings or a lack of understanding in any of these important considerations can render a final package unacceptable.

No pharmaceutical, medical device, cosmetic, or personal care product enters the marketplace without a package. This package not only ensures the product stability but can also ensure proper dosing or enhance product appearance. With the multitude of packaging options available, it can be a daunting task to select the best package option without extensive knowledge of the benefits and disadvantages for various options.

This 12-hour intensive, accredited, course will address how packaging for pharmaceutical, medical devices, combination products and other regulated products are developed. The course will explore how to design for excellence by considering regulatory and product requirements, materials use and handling, storage, and shipping risk factors.

The importance of specifications and testing will be emphasized. The requirements for production testing and distribution hazards will be reviewed from a product, manufacturing, and potential regulatory standpoint.

The current packaging requirements to satisfy regulatory authorities will be examined from a

worldwide perspective. Recent concerns on counterfeiting effects and methods being used to reduce potential issues will also be addressed.
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 in order to fully participate.

who should attend

This training is designed for personnel involved with packaging for pharmaceuticals, medical devices/combination devices, cosmetics, and personal care products. Departments may include:

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

Individuals involved with finished package integrity and material would also benefit from this course. Active participation and questions are encouraged throughout the course presentation.

learning objectives

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

- Apply an overview level of understanding regulatory requirements in the US and Europe for packaging and testing.
- Identify and use basic packaging design and development tools.
- Assess, compare, and select packaging materials and specifications for use.
- Specify packages that meet requirements for filling, closing, protection, warehousing, and distribution.
- Assess packaging material stability requirements testing.
- Contribute to prevent & solve packaging problems with materials/machinery interfaces and shipping challenges.
- Promote sustainable packaging choices for use.

course outline

Introductions and Learning Objectives Review
Overview of the US FDA and EU Regulations/ Guidance Documents

- **Agency and Industry Guidelines for Packaging Materials**
- **Pharmaceutical Packaging Essentials & Regulatory Requirements**
  - **Testing**
  - **Documentation**
  - **Statistical rationale**
  - **Risk assessments**
  - **Training**
  - **Other information**
  - **End Use Testing & Human Factors**
  - **Quality by Design**

Serialization and UDI Overview
Packaging Design & Development Process

- **Product fragility**
- **Logistics and Distribution Testing**
- **Specifications**
- **Stability Testing Risk Assessments**
- **Statistics**
- **Risk Assessments and Defect Catalogues**

Packaging Materials

- Plastics
  - Types, composition
  - Additives, Migration, Permeation
  - Sterilization Effects
- Flexible Packaging
  - Types, Uses: films, foils, laminates
  - Physical Properties
  - Seals and Testing
- Glass
  - Types, composition
  - Coatings
  - Defects
  - Sterilization Effects
- Trays and Blisters
  - Materials
  - Sealing
- Closures and Closure Systems
  - Types
  - Child resistant
  - Torque
- Labels
  - Materials
  - Printing
- Folding Cartons
- Corrugated

Process Validations and Distribution Challenges

- Overview
  - Equipment Installation and Operation Qualification (EIOQ)
  - Packaging Operation Qualification (OQ)
  - Packaging Process Qualification (PQ)
- Packaging Pre-requisites for OQ and PQ
  - Quality: inspection procedures, raw materials, material/machine interfaces
- Simulated Distribution Conditioning
- Temperature Testing
- Common Issues

Packaging Sustainability

- The "Right" Material(s)
- International Standards
- US/States/Counties/Cities
- Environmental Health and Safety Companionship

Problem Solving and Techniques

- Definitions
- Writing
- Root Cause Analysis
- CAPAs

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 packaging 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 in 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 X contact hours, or X CEUs. For further information, visit www.iacet.org