COBBLESTONE

COURSE ID 1358

Pharmaceutical Process Development

Formulation Scale-Up of Solid, Semi-Solid, Liquid & Sterile Dosage Forms, Quality by Design, Clinical Supply Manufacture, and Regulatory Considerations

DIRECTED BY

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12 Hour

ACCREDITED COURSE

- Solid Dosage Form
- Technical & Regulatory Considerations
- Liquids, Emulsions, and Suspensions
- Lyophilization
- Quality by Design (QbD)
- Clinical Supply Manufacture

about the course

This 12-hour course is designed to provide a basic understanding of the significant process development effort involved in taking an R&D laboratory formulation to commercial production. This course will focus on two main areas:

1. How to develop a pilot process suitable for scale-up to commercial production.
2. Factors to consider during scale-up and technology transfer to take a product from formulation development to the production floor.

The course will review topics such as process flow and equipment selection. Regulatory considerations, such as documentation and a need for pilot scale products to be representative of commercial production, will be discussed.

Various technologies available for manufacturing dosage forms will be reviewed in the context of scale-up parameters. These will include processing methods for mixing, granulation, compression, and coating of solid dosage forms, as well as processing methods for solutions, emulsions, suspensions, and sterile parenteral products.

This training is ideal for those new to this area but will also benefit those who are experiencing problems with existing development or process activities.

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 course is intended for personnel in process development, technical service, and pilot plant groups within the pharmaceutical industry. This includes personnel responsible for the manufacturing of dosage forms for clinical studies. It will also be of value to personnel in:

Research and Development	Analytical Services
Product Development	Manufacturing
Production	Quality Assurance
Regulatory Affairs	CMC Projects

learning objectives

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

- Determine the critical project management and regulatory issues to be considered for process development of dosage forms such as tablets, capsules, liquid orals, parenterals, scale-up of the process to manufacturing scale and transfer of technology from R&D to production
- Assess the associated regulatory issues, equipment selection, cost considerations, and critical need for coordination between R&D, Process Development, Production and Quality Assurance groups in the successful process development of drug dosage forms.

course outline

Review of Learning Objectives

Process Development, Key Issues and Concepts

- Technical & Regulatory Considerations
- Project Management & Coordination

Factors to Consider in Process Development and Scale-up

- Quality by Design (QbD Concepts)
- Case Study

Solid Dosage Forms-Mixing, Granulation

- Equipment Selection
- In-process Tests

Solid Dosage Forms-Compression, Encapsulation, Coating

- In-process Tests
- Critical Process
- Attributes

Liquids, Emulsions and Suspensions

- Disperse System Technology
- Milling and Mixing Equipment
- Critical Product & Process Parameters
- Equipment Selection

Parenteral Dosage Forms

- Small Volume Parenterals Scale-Up
- Development of Sterilization Processes

Lyophilization

- Scale-up Considerations
- Equipment Selection
- Sterile Validation

Clinical Supply Manufacturing

- Scale-up Considerations
- GMP Requirements
- Critical/Non-Critical Change

Question and Answer Session
Assessment Opportunity

course instructor

Mike Yelvigi is Principal and Managing Partner at Center for Pharmaceutical Integration LLC, which provides consultation service to the industry in the area of CMC support &Technology Integration and Transfers (mergers & acquisitions). He retired as Sr. Director and Head of CMC Therapeutic Area Management function at Pfizer/Wyeth Inc. NY. He had responsibility for co-ordination of CMC activities related to drug substance synthesis, drug product formulation, analytical development, and regulatory filing for several therapeutic areas. He has over thirty years extensive experience in pharmaceutical formulation, process development/scale-up, process validation, manufacturing and pre-approval inspections and has successfully launched several products globally. Earlier to this, he was Head of Process Development and clinical supply group at Hoffman-La Roche Company, New Jersey. Other companies he has worked with include Parke Davis (USA), G.D Searle and Organon Inc. He obtained his undergraduate degree in Pharmacy from Bombay University and graduate degree in Pharmacy, from Philadelphia College of Pharmacy.

He is an adjunct Assistant Professor of Pharmaceutics at the School of Pharmacy, University of Mississippi. He is an active member of AAPS, ISPE, AAiPS, FIP and has lectured at many symposiums in the pharmaceutical technology, drug development areas. He was the Chairperson of the AAPS Manufacturing Science & Engineering section and is also an Executive committee member of the Industrial Pharmacy Section of FIP. He is an editorial board member of Pharma Times journal.

additional faculty

Jay Rheingold, Founder of Drug Product Solutions, LLC, provides consulting on pharmaceutical development and manufacturing activities. Dr. Rheingold is currently Vice President, Pharmaceutical Development at SQ Innovation. Dr. Rheingold received his B.S. in Biology from the State University of New York and his M.S. and Ph.D. in Pharmaceutical Sciences from the University of Connecticut.

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