COBBLESTONE

COURSE ID 2590

Pharmaceutical Semi-Solid Dosage Form: Development, Manufacture & Scale-up

DIRECTED BY

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12 Hour

ACCREDITED COURSE

- Physico-Chemical Principles of Semi-Solid systems
- Chemical Engineering principles of Unit Operations
- Laboratory to commercial batch scale-up factors and risks
- Choosing the right excipients Application of Quality by Design (QbD) Principles to meet regulatory needs
- Risk Analysis Tools
- SUPAC Case Studies/Workshop
- Invivo-Invitro Assessment methods

about the course

For both prescription and OTC pharmaceuticals, a semi-solid dosage form is a very common delivery method for the drug product. But just because they are common does not mean that they are easy to develop and manufacture. In fact, there are a whole host of issues that can arise during development and manufacture that can result in marginal or unacceptable product.

This intensive, 12-hour accredited course will provide a set of theoretical and practical tools for pharmaceutical semi-solid formulation development either for prescription or OTC drugs. The selection of the correct raw materials and manufacturing processes needed to create stable semi-solid dispersed-phase products and to effectively solve problems arising during development will be addressed.

Troubleshooting existing commercial product problems will be emphasized. Emulsion and suspension behavior will be described along with current methods to analyze the behavior of dispersed phases and methods to measure and predict stability. Processing and scale-up issues specific to the type of equipment will be covered. Key emphasis will be placed on application of Quality by Design (QbD) principles and Process Analytical Technology (PAT). Risk analysis tools, key principles of process validation, technology transfers, and clinical manufacturing will be discussed. Chemical engineering aspects of Unit Operations will likewise 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

The course is designed for professionals engaged in pharmaceutical Semi-Solid dosage forms. It is intended for professionals who work in formulation development, raw materials selection, drug delivery systems, scale-up and manufacturing process, validation, clinical supply manufacture and quality testing. Such personnel include:

- Semi-Solid Formulation Scientists
- Manufacturing Supervisors/Engineers/Managers
- Pilot Plant Operation and Scale-Up
- Regulatory Affairs/Quality Control
- R&D Scientists/Technicians
- Project Managers/Business Development
- Manufacturing Operators
- CMC Project/Technology Transfer Staff

learning objectives

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

- Describe physico-chemical principles of semi-solid formulations
- List the critical project management and regulatory issues of semi-solid dosage forms development
- Describe the scale-up to manufacturing and transfer of technology from R&D to production
- Apply the Quality by Design concepts at R&D and scale-up
- Assess the regulatory issues, equipment selection, cost considerations, and critical need for coordination between R&D, Process Development, Production and Q/A groups
- Develop a pilot process suitable for scale-up to production
- List the factors to consider during scale-up and technology transfer

course outline

Review of Learning Objectives

Overview of Pharmaceutical Development Process

- Process Flow
- Regulatory Requirements & guidelines
- Documentation requirements
- Various semi-solid dosage forms

Semi-solid Dosage Forms. Physico-Chemical Characteristics. Part 1

- Types of emulsions & suspensions
- Formulation mechanisms and kinetics (thermodynamics)
- Emulsifier types and characteristics
- Suspension stabilizers
- Material Characterization Methods

Semi-solid Dosage Forms. Physico- Chemical Characteristics. Part 2

- Scale-up Factors
- Specifications
- Analytical Methods

- Stability requirements

Factors to consider in Process Development & Scale-up

Scale-up factors and issues
Mixing and homogenization Unit Operations
Understanding "Sameness" in semi-solids
Significance of "Dimentionless Numbers"
Equipment selection criteria

Quality by Design Concepts

- FDA/ICH requirements
- Current Practices
- Design of Experiments
- Risk Analysis
- Case study-Emulsion scale-up
- Case study-Group Exercise

Invivo-Invitro Assessment methods

- Human/Animal models
- Q1/Q2/Q3 similarity
- Challenges in obtaining FDA approvals

Technology Transfer

- Requirements
- Templates
- Success Factors
- Regulatory requirements

Question and Answer Session

Assessment Opportunity

course-co instructors

Mike Yelvigi is the founder & principal 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 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.

Dr. Kurshid Iqbal has over 25 + years of domestic and international experience in pharmaceutical product development. He has worked within the leading multinational pharmaceutical organizations, R.W. Johnson Pharmaceutical Research Institute, Hoffmann-La Roche and E.R. Squibb & Sons, and last as Sr. Vice President and CSO at KBI Biopharma, Inc. Dr. Iqbal earned his Ph.D. in Pharmaceutics from The University of Sciences, Philadelphia and has remained active in the field of biopharmaceutical formulation development, drug delivery and stabilization of proteins and peptides. Dr. Iqbal has published consistently in this field and has extensive experience in formulations products, drug delivery and product development of a variety of dosage forms, including sterile products, topicals, emulsions, and suspensions. He was responsible for filing several INDs, NDAs, and PLAs during his career with big pharma. He was elected as the section chair of the Biotech section of The American Association of Pharmaceutical Scientists, (AAPS) in 1992 and has remained active with the growth of this organization.

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.