COBBLESTONE

COURSE ID 3125

NEW!

In-depth Look into Softgel Formulation, Manufacturing and Troubleshooting

DIRECTED BY

Cecil Propst, Managing Director at Propst Consulting Services

6 Hours

ACCREDITED COURSE

- Gelmass and fill making
- Critical design and process controls for rotary die process
- Softgel drying and drying optimization
- In-process and finished product testing
- Defect investigations/defect resolution
- Shell ingredients and formulation
- Fill ingredients/formulation
- Bench: Gelmass/ribbon/fill development/ Compatibility
- Pilot development and transfer
- DOEs for process parameters/Shell chemistry

about the course

Softgels are widely popular dose forms for liquid that represent the most important oral form for less than 5 milliliters of liquid. Additionally, softgels are vital as a lipid delivery system, enhancing both solubility and permeation of Active Pharmaceutical Ingredients (APIs) by targeting the lipid absorption route. Softgels may appear to be a simple, two-part system, shell and fill. However, softgels are far more complex requiring both an understanding of the science behind the ingredient selection, formulation balance, and compatibility, while also requiring expertise in manufacturing, sealing, and drying to produce an acceptable finished product.

In this 6-hour, fully accredited training, participants will identify the full scope of the softgel process. The first 3-hour session covers the manufacturing process and the resolution of defects. The second 3-hour session covers the ingredients, formulation, bench, and pilot development phase of the softgel development/investigation process.

Participants attending the live training can ask questions and interact with the instructor. Thus, it is recommended to have a webcam on their computer as well as a microphone and speakers/headset to fully participate.

who should attend

The training has been designed for professionals working in both the pharmaceutical and dietary supplement industries who are interested in the manufacturing process and resolution of softgel defects associated with the manufacturing process. Those familiar with the process and troubleshooting but who wish to develop a basic knowledge of shell and fill formulation will find this training extremely valuable. Understanding the practices applied at the bench, small scale and production levels is a key to product success. These practices will be addressed during this training event.

The material will be presented in such a way as to be of value to a varying level of expertise. This course will especially benefit those in:

- Regulatory Affairs
- QA/QC
- Manufacturing
- Suppliers
- R&D
- Validation
- Engineering

learning objectives

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

- Describe the basic design, controls, and processes involved in the manufacturing of contemporary softgel encapsulated products.
- More effectively investigate and eliminate manufacturing defects during development and production.
- Describe the strategy involved in ingredient selection/ formulation development for softgel shell and fills.
- Create plans/effective practices to develop and scale up formulations to manufacturing levels.

course outline

Review of Learning Objectives

Session One:
Module One: Softgel Process (90 minutes)

- Overview of Process
- Melt Making: Process, Controls, Transfer Systems
- Rotary Die Forming Process
- Machine setup options; timing
- Critical design and controls
- Softgel drying and drying optimization
- Polishing

Module Two: Softgel Testing, Problems, and Defect Resolution (90 minutes)

- In-process and finished product testing
- Firmness, hardness, burst strength, moisture
- Rupture, Disintegration, and Dissolution Testing
- Focus on defect resolution
- Appearance/ Deformed: Shape/ Dimensional/ Color
- Resolving leakers
- Structure: Firmness, brittleness/Cracked, Sticky, adhesion issues
- Setting up an Action Sheet for Defect resolution (Leakers)

Session Two:
Module One: Development of Softgel Formulations (120 minutes)

- Softgel ingredients

- Targeting solubility: Solvency, transition matching, emulsification
- Chemistry matching
- Example: Oil fill, Oil-based DOE
- Molecular pairing: (Improved permeation)
- Hydrophilic formulation in steps...
- SEDD formulation for improved bioavailability
- Creating a stable suspension:

Module Two: Pilot and Small-Scale Development Methods (60 minutes)

- Understanding gelatin chemistry and its impact on the process
- Effect of shell additives
- Issues with the migration of ingredients
- Preparing samples of Gelmass on a bench for testing
- Studying properties and dynamics of GelMass and Ribbon
- DOE for shell composition (Water and plasticizer)
- Fill, lube, and ribbon compatibility
- Small-scale batches vs bench preps

Question and Answer Session

Assessment Opportunity

course instructor

Dr. Cecil W. Propst is Managing Director at Propst Consulting Services, a formulation and engineering support LLC located in Norton Shores, MI. He was the Director of R&D (Grand Haven site) at SPI Pharma until 2015. He served as Director of Quality Assurance and Technical Services at Fleming and Company and, before that, as President of Manufacturing Chemists. His duties included system design, product and process development, and regulatory affairs. Previously, he served as cGMP Facilities Director for the University of Maryland at Baltimore, in connection with the University's SUPAC contract with the FDA. Dr. Propst also served as Director of Technical Development for Stellar Manufacturing; Director of Quality Compliance for SmithKline Beecham; Director of Quality Assurance for Norcliff Thayer (a Revlon Company); and Group Leader/Product Development and Manager/Quality Control for Lewis Howe Company. He serves as a consultant in the area of product development and process investigations for the chemical, diagnostic, food, engineering, and beverage industries.

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 6 contact hours or .6 CEUs. For further information, visit www.iacet.org

AIC- American Institute of Chemists

Cobblestone is committed to enhancing the ongoing professional development of Cost Engineering professionals and other stakeholders through appropriate learning activities and programs. Many Cobblestone courses offer training that may be helpful in meeting the AACE continuing education requirements for recertification as a Certified Chemist, Certified Chemical Engineer, or Chemical Technician.
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