

Introduction to Softgel Manufacturing and Controls

DIRECTED BY

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ACCREDITED
COURSE

- The Rotary Die Process and Key Components
- Fill and Medicine Preparation
- Process Setup, Operation Controls, and Tests

about the course

Softgel dosage forms represent a modern take on the traditional tablet product, the most common type of pharmaceutical products produced. In the patient's hand, a softgel can seem like a simple product not knowing there are numerous complexities that go into its manufacture. But for the manufacturer, without a clear understanding of the science behind the ingredients or the expertise in the manufacturing process, unacceptable finished products may be produced.

This 2.5 hour accredited training course first covers the critical product/ process design components for Softgels and the rotary die process. After reviewing the design requirements, the process set up, in process controls and adjustments required to meet the product design objectives are considered. In process testing and process feedback adjustments are reviewed on a best practices basis. Aspects of formulation of fill and shell and material transfer systems are reviewed. The program concludes focusing on defect elimination: Leakers and investigating issues of content uniformity.

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 2-hour course is intended for all scientists and technologists interested in developing basic understanding of the critical process, materials and in-process test used in the manufacturing of Softgels for Pharmaceutical, Nutritional, and related industries.

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

learning objectives

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

- Describe the basic design, development, controls and processes involved in the manufacture of contemporary softgel encapsulated products
- Explain how to eliminate defects during production

course outline

Review of Learning Objectives

Module 1

- Softgel product and process design
- Shell and fill material requirements and preparation
- Shell forming process

Module 2

- Equipment and component description
- Process setup and timing
- In-process test and controls
- Critical controls and Defect elimination

Optional: 30-Minute 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 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, 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 **2.5** contact hours, or **.3** CEUs. For further information, visit www.iacet.org