Troubleshooting Softgel Capsules: Formulation Design and

Terms and Conditions

Payment: Tuition payable in US funds net of all charges. Payment is due at time of registration or upon receipt of invoice. If payment has not been received two weeks before the course, a credit card will be required to guarantee registration.

Discounts/Rates: To receive the Early-Bird tuition rate, payment is required at time of registration and/or BEFORE early registration tuition expires or the regular tuition rate will apply. If choosing invoice/wire transfer, payment must be received prior to expiration of early registration tuition or the regular tuition rate will apply. All tuition prices are a per person rate. To qualify for the Group Rate discount, registration must be for two or more enrollments registering at the same time, from the same company, for the same course. Please note: Group Rate Discount cannot be combined with any other discount. Multiple discounts not applicable.

Cancellations/Substitutions/FEES: ALL cancellations must be in writing and emailed to: info@cfpa.com. All cancellations are subject to a $300.00 cancellation fee. Applicants may cancel up to four (4) weeks prior to the course start date for a refund less cancellation fee. Applicants that cancel less than four (4) weeks prior to the course will be issued a credit less cancellation fee that can be used towards a future course or one year from the date of issuance. If you do not cancel and do not attend you are still responsible for the full payment. If for any reason, CfPA decides to cancel this course, we are not responsible for any expenses, hotel or other costs incurred by the registrant. Program content, schedule and instructors are subject to change without notice. Substitutions are permitted at any time, must be in writing and emailed to Customer Service at info@cfpa.com.

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Accreditations/Recertifications

Who We Are

The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately 450 short courses in 15 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more. Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory concepts to advances and sophisticated U.S. and European regulations. CfPA courses are offered in a variety of formats – Public offering, Client Site and Online – to fit you or your company’s training needs.

Accredited Educational Provider (AEP) programs are approved for continuing education credits under the related ANSI/OSHA/OSHAC standards and are approved to meet the US DoT, US DoE, Army Corps of Engineers, US Air Force, US Navy, FAA and NCBR requirements for CEUs.

The Center for Professional Advancement (CfPA) has been approved as an Accredited Provider by the International Association for Continuing Education and Training (GACET), 12100 Sunset Hills Rd., Suite 130, Reston, VA 20190. In obtaining this approval, CfPA has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. CfPA is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEUs will be awarded for participation in CfPA’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.

CfPA is the leader in Continuing Education and Training (IACET), continuing education accrediting; has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. CfPA is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEUs will be awarded for participation in CfPA’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.

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Who Should Attend
This broadly based course is intended for operators, troubleshooters and all scientists and technologists concerned with the development and processing of softgel capsules products and with related regulatory affairs. 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:
- Formulating
- Engineering Support
- Quality Assurance
- Validation
- Regulatory Affairs
- Manufacturing/Production
- R&D
- Marketing
- Purchasing

Learning Objectives
Upon completion of this course, you will be able to:
- Describe the basic design, development and processes involved in the manufacture of contemporary softgel encapsulated products

Course Description
The main aim of this course is to review the science relating to softgel encapsulated pharmaceutical and nutritional products. The course begins with a consideration of the basic aspects of softgel manufacturing process, progresses through raw material/ingredients and their properties to the formulation of these ingredients for softgel both the fill and the shell materials to meet the needs of the manufacturing process. Experimental designs and QbD is considered in determining robustness of the product/process. The program concludes with key aspects of the evaluation of finished products and the investigation and troubleshooting to solving problems.

Formal sessions of the course are supplemented with informal discussion periods between lecturers and course participants. The course includes both formal lecture/discussion sessions and hands-on laboratory sessions.

Softgel Capsules: Formulation Design and Troubleshooting

Course Outline
13 May 2016 • Amsterdam, the Netherlands | Offering# 1605-204
08.00: Registration/Continental Breakfast
08.30–08.45: Introductions and Course Overview/Review of Learning Objectives
08.45–09.30: Softgel Design, Testing and Terminology
- Introduction to softgels: Value of softgels, types
- Basics of ribbon chemistry and seal formation
- Process components: Setup, and in process adjustments
- Material and Ribbon evaluation: Gelatin bloom strength, viscosity, pH
- Ribbon testing: Bench preparation, stress- strain and permeation of ribbon
- Making of bench shell samples for testing, Film applicator/casting
- Testing: Elongation, tensile strength, vapor penetration
- Softgel evaluation: Uniformity of dose, appearance, moisture, firmness, hardness and burst strength
- Final product testing: Disintegration, dissolution
09.45–10.45: Understanding The Softgel Process:
- Rotary Die Process: Description, timing/alignment, pump type/ role/accuracy
- Separation of chemistry from process and in process controls/ adjustments
- Preparing the melt, Importance of time, viscosity, pH, temperature
- Medicine preparation, delivery, pumping
- Ribbon: Thickness, temperature, consistency. Choice of lubricant; amount and function
- Tooling Design, setup and positioning: Roll, wedge, die cup capacity and sealing designs
11.00 – 12.00: Softgel Process (Continued)
- Process setup and machine startup verification, making aircocks.
- Understanding the form fill and seal process
- Drying steps: Effect of drying rate; Humidity and temperature requirements, drying optimization
- Lubricant removal and printing
13.00–13.45: Softgel Shell Design/Ingredient Selection for Shell
- Ingredients for shell, fill and surface
- Sol to gel and sheet forming strategies
- ICIS vs Trans and Amorphous gelatin
- Structural ingredients for shell: Properties of gelatin: Types, sources and molecular weight: Change of properties with pH, temperature, moisture, addition of plasticizer, time, added ions; Role of Ti, Trm, Ts band Tg in process and functionality of shell

14.00–14.45: Development of Softgel Capsule Formulation
- Formulating best fill for therapy: Hydrophobic, hydrophilic, dispersions, vs suspension fills
- API system design: Aqueous, lymphatic, P-glycoprotein inhibition targeting, other considerations
- Three type fill designs: Solventy, dispersions and combinations
- Targeting volume for die cup size
- General rules of fills
- Building a formula of choices: Example combinations
- Use of HPE, pH compatibility with fill
- Fill ingredients, Interaction and compatibility rules
- Focus on migration prevention and prevention of leakers
- Focus on an example Softgel formulation: Solventy, micellar to invivo testing
- Stability evaluation and softgel dynamics, crossinglink issues
- Formulating SEEDs
- Formulating the shell components to match fill
15.00–16.15: Softgel Problems Investigation/Troubleshooting
- Active content: Weight uniformity, loss to shell, reactions with shell
- Leakage: Seal, Thickness, fill targets vs die cup, ribbon, land cutting/whole seal
- Qualification of new rolls: Verification of setup/ design; Lubricant efficiency
- Appearance and defect resolution
- Disintegration and dissolution test failures;
- Investigation of dynamic changes; Migration; Sweating, blooming
- Proactive inspection for defects; Process Optimization of Softgel
- Optimization: DOE modeling and design considerations
16.15–16.30: Wrap up/Discussion/ Assessment Opportunity

Breaks will be approximately every hour. Two in morning and two in the afternoon.

Client Site
Training at your site and at your convenience. For further information, please contact Client Site Programs: Direct Dial (USA) +1/732 238 1600, ext. 4547; or fax +1/732 238 9113; or E-mail clients@cfpa.com.

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A convenient and cost-effective way to experience our accredited training, easily access the knowledge you need through the Internet. For a list of upcoming courses visit www.cfpa.com/online-training.

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Course Co-Directors
Dr. Cecil W. Propst is Director, Scientific Affairs for Team Engineering Service, a formulation, and engineering support firm located in Kalamaing MI. He was Director of R&D (Grand Haven site) at SPI Pharma until semi retirement in 2015. He served as Director of Quality Assurance and Technical Services at Fleming and Company, and before that, 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 SMTKline Beecroam; Director, Quality Assurance for Norrill Thayer (a Revlon Company); and Group Leader/Product Development and Manager/Quality Control for Lewis Howe Company. He also serves as a consultant in the area of product development and process investigations for the chemical, diagnostic, food, engineering and beverage industries.

Ronnie Bayless, is a Special Projects Scientist for CaptekSoftgel International, a softgel capsule contract manufacturer. Prior to joining Captek he was a consultant/owner in the area of Softgel development/processing for Bayless Technologies, Inc. Mr. Bayless has over 25 years of practical, hands-on experience in many areas of polymer science from Research and Development to solving manufacturing process problems. He specializes in the areas of paintable and pharmaceutical softgel technologies, medical polymers, and polymer characterization and is experienced in employing scientific methods to develop new technologies, new products, and processes including complete implementation into manufacturing and the application of Statistical Process Control and Design of Experiments methods to improve process quality.

Course Location
This course will be held at the Crowne Plaza Amsterdam City Centre. Participants must, however, make their own reservations; the cost of hotel accommodation is not included in the course fee. Hotel information will be included with your acceptance.

Crowne Plaza Amsterdam City Centre
Nieuwewijserd Vanborghaudstraat 5
1012 RC Amsterdam, The Netherlands
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- Located in downtown area, near shopping, dining and local attractions

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