CfPA
THE CENTER FOR PROFESSIONAL ADVANCEMENT
FOUNDED 1967

Celebrating 50 YEARS 1967-2017

NEW! Best Practices for Manufacturing Active Pharmaceutical Ingredients

Meeting Today's Production, Control, and Regulatory Challenges

September 12–14, 2017 | New Brunswick, NJ

Directed by: **Richard G. Einig, Ph.D., RAC, CQA,** Pharmaceutical Quality Assurance Consultant

Course Topics Include:

– Worldwide Regulatory Impact
– Life Cycle Focus
– Enhanced Manufacturing Approach
– Supplier Relationships
– Discussions from case studies
– Group Workshop

course description

This 3-day **intensive** course prepares attendees to meet the challenges they face in the heavily regulated pharmaceutical industry. API manufacturers must be aware of local, regional and national regulatory agencies' enforcement activities that are applied to API production and develop a strategy to compete successfully in the current world economy. Manufacturing in the 21st century is shifting from manual processes that depend on subjective decision-making to automated processing that provide greater control and flexibility. This new paradigm focuses on product life-cycle from development activities to commercial production and finally product discontinuation.

The initial topic discussed is management's roles within the organization and outside of the organizational structure that contribute to the success of the operation. Other topics focus on the various manufacturing functions using classical, enhanced or a combination approach. Risk management is an important tool in the decision making process related to quality and production systems development that emphasizes patient safety and helps to maintain a healthy regulatory environment. Throughout the program there are interactive class exercises. On the last day of the course, participants are put into small groups and each group receives a list of simulated regulatory observations based on actual inspections. The groups evaluate the observations and then prepare a written response to the regulatory authority explaining their activities to remediate the deficiencies. The exercise is a valuable opportunity to develop approaches with your colleagues and build lasting contacts.

SAVE $200-Register & Pay by 12 June

www.cfpa.com

who should attend

This course is designed to inform those experienced in Active Pharmaceutical Ingredients (API) manufacturing about the shifting paradigm due to globalization and enlighten those who are entering a career in this exciting field of API manufacturing:

- Pilot and commercial production
- QA/QC
- Technical services
- Regulatory affairs
- Process development
- Validation
- Regulatory agency investigators

The presenters discuss the many ways that roles and responsibilities for individuals and departments are changing now to achieve a successful and compliant API operation in the 21st century

learning objectives

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

- Develop an operational strategy to compete in the worldwide economy
- Compare your current operation to recent industry practices and initiatives
- List worldwide regulatory requirements and enforcement activities
- Design and operate efficient niche manufacturing facilities
- Build a quality culture that contributes to overall operational performance

course outline

First Day

08.00: Registration/Continental Breakfast

08.30: Introduction and Review of Learning Objectives

08.45–10.00
Worldwide Regulations and Guidances:
- ICH Documents concerning API Manufacturing and Control
- WHO, PIC/s and Other Guidance
- GAMP, PDA and Other Interpretive Guidance
- Industry and Regulatory Policy

10.30–12.00: Role of Management in a Commercial Operation:
- Resource Considerations
- Product Selection
- CMO Selection
- Partnering with Drug Product Operations

13.00–13.45:
Interactive Exercise with Case Studies

13.45–14.30: Role of Development in Fulfilling the Corporate Mission
- Scalable Process
- Analytical Methodology
- Critical Process Attributes and Parameters
- Follow-up during Start-up

15.00–16.30: Role of Technical Services
- Technology Transfer
- Statistics for Risk-based Operation
- Process Analytical Technology
- Automation

16.30–17.00: Interactive Exercise with Case Studies

Second Day

08.30–10.00: Role of Warehouse, Engineering and Maintenance:
- Supplier/Vendor Relationship
- Automated Warehouse Operation
- Links to Manufacturing and Quality Control
- Functional Facility Design
- Outsourcing Warehousing, Engineering and Maintenance Services

10.30–12.00: Role of Production
- Batch and Continuous Processing
- Outsourcing Processing and CMO Agreements
- Sterile and Potent Compound Processing
- Biotechnology Processing

13.00–13.45:
Interactive Exercise with Case Studies:

13.45–14.30: Role of Validation
- Risk Based Validation Approach
- Processes
- Analytical Methods
- Computer Systems

15.00–16.30: Role of the Quality Unit:
- Oversight and Risk Management
- Quality Assurance/Quality Control
- Quality Systems
- Outsourcing

16.30–17.00:
Interactive Exercise with Case Studies

Third Day

08.30–10.00: Auditing API Facilities and Preparing for and Managing a Regulatory Inspection:
- Type, Purpose, and Preparations
- Performance and Follow-up
- Vendor-Customer Relationship
- The Authority, Approach, and Variability of Regulatory Investigators
- Pre-inspection Audits
- Pre-inspection Planning
- Responding to Observations During and After the Inspection

10.30–12.00: Group Workshop-Practicing What We Discussed:
- Simulated regulatory observations based on actual inspections will be given to small groups for evaluation and the preparation of written responses to the regulatory authority explaining.their activities to remediate the deficiencies.
  This workshop is an excellent means to share individual experiences and views and to bring into focus the operational and regulatory issues covered in the course. The responses will be presented to all course participants for discussion and constructive critique.

13.00–14.15:Group presentations for prepared responses to simulated regulatory observations.

14.30–15.00: Wrap-Up with Question and Answers

Assessment Opportunity

course director

Richard G. Einig, Ph.D., RAC, CQA is a consultant specializing in the pharmaceutical and veterinary medicine industries. His experience spans over twenty years in senior management of quality, regulatory, and development units of large international companies and start-up "biotechs". He has worked internationally with innovator and generic dosage form companies, medical device manufacturers and research organizations.

Dr. Einig participated in developing the PhRMA Bulk Pharmaceutical Committee's Guidance on Production of Drug Substance, and is an invited speaker at domestic and international meetings on quality and processing of pharmaceutical products.

Dr. Einig is a member of the American Chemical Society as well as a member and carries certifications from the American Society for Quality, the Regulatory Affairs Professional Society, and the Institute for Independent Business. He received undergraduate and graduate degrees in Chemistry from St. Louis University, MBA from Webster University, and Ph.D. from Missouri University.

additional faculty

Michael Day has a thirty year career associated with process development and manufacturing in the pharmaceutical business. He was responsible for U.S. API production for Hoechst-Celanese Corporation and manager of Technical Services for Searle/Pharmacia/Pfizer at the Augusta, Georgia facility. He has extensive experience in the area of technical transfers and associated quality systems that supported commercialization of those products. He is currently consulting and teaching in the pharmaceutical arena.

course location

This course will be held in the Amsterdam area. Specific hotel information will be sent to you in your final confirmation package which will be emailed to you approximately three (3) weeks prior to the course start date. Please note that participants must make their own hotel reservations; the cost of the hotel accommodations is not included in the course fee. We recommend that travel/hotel arrangements not be made until final confirmation email is received.

- **Located in downtown area, near shopping, dining and local attractions**

accreditations/recertifications for this course

The Center for Professional Advancement (CfPA) has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), 11130 Sunrise Valley Drive, Suite 350, 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. This course offers a total of 18 contact hours, or 1.8 CEUs.

who we are—"Celebrating 50 Years"

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 new advances and cutting-edge technology, and current U.S. and European regulations. CfPA courses are offered in a variety of formats to fit you or your company's training needs:

In Person: Away from responsibilities, participants are immersed without distraction
Client Site: Training at your site and at your convenience. For further information, please contact Client Site Programs: +1/732.238.1600, ext. 4547 or E-mail clientsite@cfpa.com
Online: A convenient and cost-effective way to experience our accredited training. For a list of upcoming courses visit www.cfpa.com/onlinetraining
Virtual Attendee: Ideal for those who need the training but cannot attend in person. For more information visit: **www.cfpa.com/virtualattendee**
Virtual Recorded: Watch the recorded version of the Live In Person course. For more information visit: **www.cfpa.com/virtualattendee**

tuition

Early Bird–Save $200–(Must register and pay by 12 June 2017)	$2510
Regular Tuition	$2710

Group Discount: Register 2 or more from the same company, at the same time, for this course and receive a 10% discount off each registration. Tuition payable in US funds net of all charges includes continental breakfast, luncheon, breaks and course notes.
Note: Payment is due 2 weeks prior to course or at time of registration.

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how to register

- Online: www.cfpa.com enter Course ID# into Search. Click Register Now button. Group Rates Available: Save 10% on 2 or more attendees.
- Call Customer Service at 732-613-4500 or email: info@cfpa.com
- Fill out the registration form and email it to: info@cfpa.com

registration form

Best Practices for Manufacturing Active Pharmaceutical Ingredients course id# 2742 /course offering# 170724EU2742

instructions:

Please complete Registrant Information, Course Information and Payment Sections. Submit one form per individual registrant.

☐ Check here if group discount applies (two or more enrollments for the same course, from the same company)

All fields MUST be completed in order for registration to be accepted.

registrant information

Registration Type: ☐ In Person Attendee ☐ Virtual Attendee (Live or Recorded)

Prefix: ☐ Ms ☐ Miss ☐ Mrs ☐ Mr ☐ Dr ☐ Prof

First Name_____ Last Name_____Designation (i.e.Phd, Jr)_____

Email Address _____ Alternate Email (copy sent here as well) _____

Title_____

Your position in the organization is (please check one)

☐ Corporate ☐ Line Operational ☐ Managerial/Supervisory ☐ Staff ☐ Consultant

Your primary job function is (please check one)

☐ Clinical Practice ☐ Project Management ☐ Design Engineering ☐ Quality Control Assurance

☐ Environmental Safety ☐ Research & Development ☐ Legal or Regulatory Affairs ☐ Technical Information Services

☐ Manufacturing & Operations ☐ Training and/or Education ☐ Marketing or Sales ☐ Other _____

*Primary industry that best describes your area of interest (select maximum of 2)

☐ Analytical Chemistry
☐ Biopharmaceuticals/ Biotechnology
☐ Chemical/ Process Engineering
☐ Clinical/ Non-Clinical
☐ Cosmetics/ Personal Care/ Household Products
☐ Environmental and Safety Technology
☐ Food Technology
☐ Mechanical/ Design Engineering
☐ Medical Devices/ Diagnostics
☐ Packaging Technology
☐ Petroleum Technology
☐ Pharmaceutical Technology
☐ Technical/ Project Management

contact information

Company Name _____

Address _____

Zip/Postal Code_____ City_____ Country_____

Phone _____ Fax _____

course information

Course Title_____

Course ID#/Offering#_____

Tuition

Tuition_____

*How did you hear about us? ☐ Email ☐ Postcard ☐ Colleague ☐ Google Search ☐ Social Media

☐ Trade Show ☐ Advertisement ☐ Course Director ☐ Course Brochure ☐ Other _____

discount code

Discount Code _____

payment information

☐ Credit Card

☐ Visa ☐ Mastercard ☐ American Express ☐ Discover

Card #: _____ Exp. Date: _____ Security Code: _____

Cardholder Name: _____ Signature: _____

Billling Addess (if different from above)

Address _____

Zip/Postal Code_____ City_____ Country_____

☐ Wire Transfer ☐ Purchase order (PO# if applicable _____)

☐ Send Invoice ☐ Check: Payable in US funds to: **The Center for Professional Advancement**

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. The Virtual Attendee Option does not qualify for Early Bird pricing. 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 up to 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 airfare, 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.

Confirmation Letters: Before each course begins, all registrants will receive written Final confirmation including detailed information regarding course location – VIA EMAIL. We recommend that travel/hotel arrangements not be made until final confirmation package is received. If confirmation is not received two weeks prior to the course please contact Customer Service at info@cfpa.com.

Course photography / video: By registering and attending a CfPA course, you agree to have your photograph and/or video taken at the course venue, and you do not have any objections to CfPA using these photos and/or videos for marketing or any other CfPA Course and/or promotional purposes. You agree to release CfPA from any kind of claims arising out of copyright or privacy violations. All questions regarding this matter should be sent to Customer Service at info@cfpa.com.

Please note: English will be used in all lectures and course notes. For questions/more information contact Customer Service at 732-613-4500 or info@cfpa.com.

☐ I have read and agree to CfPA's Terms and Conditions