Accredited Technical Training for the Pharmaceutical, Biopharmaceutical, and Medical Device Industries

January – May 2009 Europe Course Offerings

Course Topics in this Catalog Include:

• Analytical Methods Validation for FDA Compliance
• Conducting Effective Quality Audits
• Good Laboratory Practices (GLP)
• ISO 13485, ISO 9001 and QSR Regulations for Medical Device Companies
• Packaging of Pharmaceuticals
• Pharmaceutical Technology Transfer
• Root Cause Investigation for CAPA
• Vendor and Contract Supplier Qualification

CfPA Courses Offer:

• Topics from Introductory to Advanced
• Access to Leading Industry Experts
• An Informative and Interactive Learning Environment
• Practical Knowledge You Can Use to Improve Job Performance
• Application Oriented Real Life Case Studies
• Accreditation and Certification
• Traditional Classroom and Online Training Options

www.cfpa.com
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For 40 years CfPA has been meeting the needs of professionals in the life-sciences industries with the most comprehensive selection of accredited technical training programs available anywhere.

Our curriculum of over 350 courses in 18 industries cover basic to advanced topics in Regulatory, Quality Assurance, Manufacturing, and Research. Choose a course from a variety of formats to fit your professional lifestyle: public, client site or online.

We look forward to seeing you at an upcoming course.

Online Training
CfPA's Online Training program offers a new way to experience CfPA's Accredited Technical Training and is the perfect complement to our public and client site courses. Now you can easily access the knowledge you need through the Internet to improve your performance on the job and increase your value to your employer. For more information on upcoming Live and On-Demand courses, visit our website at:

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Analytical Methods Validation for FDA Compliance  

20–22 April 2009 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for individuals who have the responsibility for establishing the integrity of analytical methods for active pharmaceutical ingredients (APIs) or finished pharmaceutical dosage forms. This course will benefit individuals in:

• R&D • Quality Assurance • Quality Control • Technical Operations

Regulatory affairs personnel responsible for the review of such data will also benefit from this course.

Course Summary: One of the most critical factors in developing and marketing pharmaceutical drug substances and drug products today is ensuring that the analytical methods used for an analytical process can generate valid data upon which business and regulatory decisions can be made. FDA, ICH and USP have each recognized the importance of this to the drug development process and have separately expanded method validation requirements in recent years. However, with only limited guidance, industry has been left to interpret how to adequately comply with the regulations.

Whether involved in method development, method validation, method optimization or method transfer, this course will provide a broad understanding and “hands-on” knowledge of the method validation process and the difficulties encountered in validating methods to comply with today’s upgraded FDA CDER requirements. Lectures will include not only theoretical basis and practical applications, but actual validation examples of HPLC, GC, UV/Vis, AA, and titration methods for small organic molecules. Some of the more common mathematical and statistical treatments of validation data will also be discussed. Because of the tremendous effort that can be expended in conducting validation studies, efficiency of experimental design and documentation will be stressed throughout the discussions.

Although the general principles in this course may be applied to methods for testing biological molecules and medical devices, the focus of this course is on the validation of methods for the analysis of small molecules.

Course Co-Directors:
J. Mark Green, Ph.D., Principal Investigator, Bristol-Myers Squibb Medical Imaging
David E. Wiggins, Associate Director of Analytical/Stability R&D, Schering-Plough Consumer Health Care Products

Tuition:
Early Registration (SAVE $200): U.S. $2345 ($2235 with Group Rate*) (Must register and pay by 23 February 2009)
Regular Registration: U.S. $2545 ($2435 with Group Rate*)

Calibration in the FDA Regulated Industry

9–10 March 2009 • Dublin, Ireland

Who Should Attend: This overview course is intended for individuals in all industries, but specifically individuals in FDA regulated industries, who are responsible for establishing, maintaining, operating a calibration program, and audit of calibration activities, including:

• Quality Assurance • Quality Control • Technical Support
• Quality Engineering • Facilities and Equipment Maintenance
• Research and Development

Course Summary: The regulations covering manufacture and control of drug products and medical devices require that firms have a program for the calibration of test and measurement equipment. A requirement for calibration is also defined in ISO 9000 and a Quality System for a calibration laboratory is described in ISO 17025. Calibration is a good business and science practice followed in all industries that require measurements for process monitoring and control. The program must include the elements of: calibration intervals, scheduling, specific calibration procedures, limits of accuracy and precision and remedial action in the event that the instrument does not meet established requirements.

This course addresses the regulatory and business requirements for calibration as an element of a Quality System and how these requirements support the increasing application of process monitoring and sophisticated laboratory instrumentation, along with the maturing discipline of calibration in the regulated industries. It includes a discussion of a compliant calibration program and concludes with a discussion of a model calibration procedure.

Course Director:
Dr. Jerry Lanese, President, The Lanese Group, Inc.

Tuition:
Early Registration (SAVE $200): U.S. $1640 ($1560 with Group Rate*) (Must register and pay by 12 January 2009)
Regular Registration: U.S. $1840 ($1760 with Group Rate*)

Please note course topics, dates, and locations subject to change. Please refer to our website for the most current information.
Complaint Handling and MDR Reporting for Medical Devices

ID: 1834  Offering #: 0905-405

18–20 May 2009 • Amsterdam, The Netherlands

Who Should Attend: This practical program will be of benefit to all medical device personnel involved with their company’s Complaint Handling Systems including personnel responsible for the following:

- Implementation of the System
- Management of the System
- Receiving and Documenting Complaints
- Investigating Complaints
- Regulatory Compliance
- MDR Reporting
- Product Performance Monitoring
- Internal Auditing
- Training

Course Summary: Complaint handling systems have come under intense scrutiny by the FDA in recent years. This course will examine the current industry FDA environment and seek to provide you with knowledge and tools for survival. It will provide a step-by-step guide to the setting-up, operation, management and auditing of a Complaint Handling System for today’s medical device industry environment.

There will be case studies in which various examples of complaint systems will be presented. Pragmatic, simple, statistical trend methods will be reviewed and attendees will utilize what they learn in a series of workshops.

Course Director:
Jim Colyn, President, Jim Colyn & Associates Quality Consulting

Tuition:
Early Registration (SAVE $200): U.S. $2545 ($2435 with Group Rate*) (Must register and pay by 23 March 2009)
Regular Registration: U.S. $2345 ($2235 with Group Rate*)

Conception, Design and Implementation of Plant Safety Systems

ID: 1672  Offering #: 0904-204

6–8 April 2009 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for those who are actively involved in the design and/or operation of industrial plant safety systems; for those concerned with day-to-day operation of manufacturing facilities; and for those that would benefit from an understanding of potential risks (and options available to reduce those risks), which are inherent in operating chemical plants. This includes but is not limited to:

- Technologists
- Engineers
- Technicians
- Managers

Course Summary: The intent of this course is to address the three aspects of plant safety system design:

- Identification of hazards which have the potential to cause or lead to undesirable events as well as quantification of risk associated with those hazards using Layers of Protection Analysis (LOPA).
- Definition of the process design intent to eliminate, mitigate or safely respond to those hazards
- Proper implementation of a plant safety system that performs as designed over the life of the plant.

Emphasis will be placed on guiding principles relating to these aspects of plant safety systems. Discussions will center on issues that need to be addressed in order to make informed and logical decisions.

Course Director:
Andrew C. Hiester, P.E., Acetic Anhydride Department Senior Technical Associate, Eastman Chemical Company

Tuition:
Early Registration (SAVE $200): U.S. $2345 ($2235 with Group Rate*) (Must register and pay by 9 February 2009)
Regular Registration: U.S. $2545 ($2435 with Group Rate*)
Conducting Effective Quality Audits

24–27 March 2009 • Amsterdam, The Netherlands

Who Should Attend: This overview course is designed for those who have recently been involved or expect to be involved in external or internal audits.

The program will benefit individuals in the pharmaceutical and related industries such as cosmetics, food, medical devices, diagnostics, biotechnology as well as vendors, suppliers and contract organizations. The course can be of interest to professionals in a variety of functions such as:

• QA/QC
• R&D
• Materials Management
• Laboratory
• Production
• Regulatory
• Toxicology
• Clinical Research
• Packaging
• Purchasing

Course Summary: Government regulations have both explicit and implicit requirements for an internal audit function in the pharmaceutical and related industries. Auditing is a powerful management tool in establishing how effectively a company controls the quality of its products and ensures compliance. The course will deal primarily with auditing techniques which are applicable to any industry or function. Specific examples will cover auditing of certain aspects of operations for compliance with GMP, GCP and GLP. An FDA viewpoint primarily with auditing techniques which are applicable to any industry or function. Specific examples will cover auditing of certain aspects of operations for compliance with GMP, GCP and GLP. An FDA viewpoint on auditing/inspecting will be presented. The course will consist of lectures, discussions, exercises, workshops and a role-playing session involving a simulated compliance audit.

The course is not designed for in-depth presentation of regulatory issues, which are covered by other courses offered by CFPA.

Course Director:
Renée B. Galkin, Quality Management Consultant

Tuition:
Early Registration (SAVE $200): U.S. $2600 ($2480 with Group Rate*) (Must register and pay by 27 January 2009)
Regular Registration: U.S. $2800 ($2680 with Group Rate*)

Critical Process Cleaning and Cleaning Validation

27–29 April 2009 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for professionals in:

• Process Engineering
• Quality Assurance
• Technical and management positions

You should have some familiarity and experience with the basic subject as it applies to research and manufacturing of pharmaceuticals, personal care products, nutritional materials and fine chemicals.

Course Summary: This course will provide a solid overview of the principles and practices of residue removal and residue measurement on product contact surfaces. It will address the latest issues, industry practices and compliance strategies regarding choice of cleaning techniques, cleaning agents, analytical methods, residue challenges, grouping strategies and validation protocols. Examples and case histories will be presented. Recent regulatory expectations and guidance from US and Europe will be discussed in depth.

For participants experienced on this subject, this practical course will help to better audit, evaluate and develop their own or third party cleaning programs to balance production objectives against QA/validation objectives. The idea is to first achieve an effective, reliable cleaning process defined parametrically, then generate sufficient data without going overboard on the number of samples, the number of analytical tests and the number of qualification studies that have become an excessive burden to many firms.

Participants are encouraged to bring a cleaning problem to the course for evaluation by participant teams or for inclusion in “Participant Problem Clinic” on the second day.

Course Director:
Steven A. Weitzel, Technical Director, Critical Process Cleaning, Inc.

Tuition:
Early Registration (SAVE $200): U.S. $2345 ($2235 with Group Rate*) (Must register and pay by 2 March 2009)
Regular Registration: U.S. $2545 ($2435 with Group Rate*)

For course information, go to www.cfpa.com

Please note course topics, dates, and locations subject to change. Please refer to our website for the most current information.
Corrosion Control in Industry and Plants

20–23 April 2009 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for engineers and scientists, from a wide variety of industries, who seek a basic understanding of corrosion engineering and familiarity with the methods used in corrosion control and its prevention. In view of its comprehensive nature and the effective integration of corrosion engineering, the course should benefit:

• Project and Process Engineers
• Plant Designers
• Maintenance and plant engineers
• Those in management who must make the decisions concerning the reduction of corrosion problems

While the course should also be of interest to material engineers and researchers who require a familiarity with corrosion science and corrosion engineering that is outside the area of their present activities, as well as representatives of government agencies concerned with utilization and performance of materials in various applications. Those personnel involved with risk analysis for insurance purposes will obtain familiarity in corrosion engineering and associated corrosion risks analysis.

Course Summary: Corrosion resistance of materials is frequently a decisive factor in the development of advanced technology as encountered in power generation, energy conversion, environmental protection techniques, and numerous industrial processes operating under severe corrosive environments. The general aim of this course is to provide a basic understanding of corrosion mechanisms and the methods used in corrosion control and prevention. To convey this in a proper perspective the entire course offers a unified treatment of corrosion fundamentals with the practice of corrosion engineering.

There will be in-depth coverage of electrochemical principles of metallic corrosion, discussion of various corrosion mechanisms, methods of corrosion control, high temperature corrosion, degradation of polymers and ceramics, and the selection of metallic, organic and ceramic materials. Each section of the course includes industrial applications of the subject material using case studies of practical engineering problems. Discussion of engineering problems, along with corrosion science principles, results in an integrated approach to providing solutions to corrosion engineering problems from a wide variety of industries.

Course Director:
Colin F. Britton, Independent Corrosion Consultant

Tuition:
Early Registration (SAVE $200): U.S. $2775 ($2655 with Group Rate*) (Must register and pay by 23 February 2009)
Regular Registration: U.S. $2975 ($2855 with Group Rate*)

Design Control and Product Validation For Medical Devices

23–24 February 2009 • Dublin, Ireland

Who Should Attend: This course is intended for personnel who are responsible for medical device design and development such as:

• Engineers
• Senior technicians
• Scientists
• Department heads
• Project leaders
• Technical managers

Quality assurance, compliance and regulatory personnel will also benefit because of their responsibility for implementation, validation and evaluation of design controls as part of the overall quality system. Sales and marketing personnel will learn their vital roles in providing input to the design process and requirements for design changes.

Course Summary: The course describes how to establish and implement a system for design controls for various classes of medical devices for both the U.S and Europe. It also provides guidance to assist manufacturers in knowing when controls are required. The underlying concepts will be explained in practical terms and exercises will be used to promote understanding. Sample procedures and forms will be provided in both hard copy and computer disc format.

Emphasis will be on understanding the requirements and providing tools to assist in management of the design control process. The course will discuss each phase of the design process and explain the terms: design input, design output, design review, verification, validation, and design history file. Particular emphasis will be given to understanding the difference between design verification vs. design validation, and describing activities relative to validating a product design. Also discussed will be FDA’s inspection strategy and how to manage a successful audit for design controls. You will return to the workplace with new tools to apply an effective project management approach to your design control process which will ultimately reduce time to get to market, reduce development cost, and ensure regulatory compliance.

Course Co-Directors:
Jan Miller & Michele Vovolka, Quality Systems Consultants, Vantage Consulting International, Ltd.

Tuition:
Early Registration (SAVE $200): U.S. $1640 ($1560 with Group Rate*) (Must register and pay by 29 December 2008)
Regular Registration: U.S. $1840 ($1760 with Group Rate*)

Please note course topics, dates, and locations subject to change. Please refer to our website for the most current information.
**Documentation Management and Control**

30–31 March 2009 • Amsterdam, The Netherlands

**Who Should Attend:** This basic introductory course is designed for individuals responsible for documentation writing and management in the pharmaceutical and related industries. The course will benefit individuals in a variety of functions such as:

- Quality Assurance
- Regulatory
- R&D
- Clinical Research
- Product Development
- CRO’s
- Quality Control
- Toxicology
- Vendors/Suppliers
- Production

**Course Summary:** FDA regulations such as Good Manufacturing Practice (GMP) for drugs and medical devices, Good Laboratory Practice (GLP), Good Clinical Practice (GCP), as well as quality system standards like ISO 9000, require that documentation, such as standard operating procedures, plans and various types of records, be in place. These regulations, however, do not provide any guidelines to the industry on how to set up and manage documentation systems. It is, therefore, left to companies to design and set up their own internal documentation systems.

This course provides hands-on methodology and techniques on how to identify what systems require documentation coverage; how to flowchart operations to identify what type of documentation is required; and how to set up, implement and manage the maintenance of such documentation systems to ensure continuous compliance. Types of documentation addressed include: quality manuals, policy manuals, standard operating procedures, work instructions, forms, records, logs, protocols, etc. The course also covers areas related to computer validation documentation, such as validation protocols and 21 CFR Part 11—Electronic Records and Signatures. Emphasis is placed on controls that need to be in place to ensure proper manipulation of documentary systems.

The course consists of lectures, discussions and interactive workshops with classroom presentations.

**Course Director:**
Renée B. Galkin, Quality Management Consultant

**Tuition:**
- Early Registration (SAVE $200): U.S. $1640 ($1560 with Group Rate*) (Must register and pay by 3 February 2009)
- Regular Registration: U.S. $1840 ($1760 with Group Rate*)

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**Drug Product Stability and Shelf-Life**

25-27 May 2009 • Dublin, Ireland

**Who Should Attend:** This course contains in-depth coverage of the science and practice of drug stability and shelf-life, and is designed to benefit the following personnel:

- QC/QA Managers/Supervisors
- Product Stability Managers
- Manufacturing Personnel
- Research & Product Development Scientists and Managers
- Regulatory Personnel
- Pharmaceutical Consultants

**Course Summary:** This course focuses on the science and principles concerning stability of pharmaceutical, biotechnology and cosmetic products. Kinetic approaches to chemical stability will be covered and the advantages and limitations of accelerated stability testing will be discussed. Degradation by chemical, physical and microbiological factors will be covered. Data analysis and practical aspects of stability such as the role of packaging in stability will be included. Considerable attention will be given to analytical methodology, data analysis and data management. Current FDA Stability guidelines and ICH Guidelines on stability will be discussed. The course includes a workshop for hands-on experience of data and statistical analysis.

**Course Director:**
Dr. Pardeep K. Gupta, Associate Professor of Pharmaceutics, Philadelphia College of Pharmacy, University of The Sciences in Philadelphia (USP)

**Tuition:**
- Early Registration (SAVE $200): U.S. $2345 ($2235 with Group Rate*) (Must register and pay by 30 March 2009)
- Regular Registration: U.S. $2545 ($2435 with Group Rate*)

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**ACCREDITATIONS/CERTIFICATIONS**

**Documentation Management and Control**

- The Center for Professional Advancement (CPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; certificate will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program # 716-000-08-156-L04

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**Drug Product Stability and Shelf-Life**

- The Center for Professional Advancement (CPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; certificate will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program # 716-000-07-119-L04

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For course information, go to [www.cfpa.com](http://www.cfpa.com)

Please note course topics, dates, and locations subject to change. Please refer to our website for the most current information.
Elements of Applied Process Engineering

ID: 1512   Offering #: 0904-401

20–23 April  2009 • Amsterdam, The Netherlands

Who Should Attend: The course is mainly directed to those just entering the Process Engineering field including engineers, chemists and technicians in the areas of:
- Plant Operation
- Process Development
- Process Scale-Up
- Process Start-Up

Experienced process engineers, however, can profit from the concise reviews and exposure to the innovative concepts, including short-cut methods. The course will also benefit those who supervise process engineers but who have had no formal training in the field.

Course Summary: This course fills the void between the curriculum of a theoretical education and the practical demands of applied process engineering or process-mechanical engineering. It is structured to follow the major responsibilities of a process engineer as a project progresses. Therefore, the course reviews such topics as: in-depth explanation of necessary process documentation emphasizing engineering diagrams, frictional and pressure drop calculations for incompressible, compressible and complex fluid flows, heat transfer calculations methods and the sizing and economic selection of pumps, fans, blowers, compressors, material selection for piping and equipment, process and storage tanks, mixing equipment, heat transfer equipment, electrical equipment. Emphasis is placed on simplifying methods, shortcut techniques, and mnemonic devices throughout, making the applications of process engineering as practical as possible.

There is also a brief introduction to motor controls, and instrumentation and control.

Course Director:
Edward T. Luckiewicz, Adjunct Professor of Chemical Engineering, Coordinator of P.E. Review Program, Drexel University

Tuition:
Early Registration (SAVE $200): U.S. $2715  ($2595 with Group Rate*) (Must register and pay by 23 February 2009)
Regular Registration: U.S. $2915  ($2795 with Group Rate*)

Good Laboratory Practices (GLP)

ID: 545   Offering #: 0904-202

6–8 April 2009 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for all management within industry, government, academia and/or contract biological testing facilities especially:
- Scientists
- Regulatory/Compliance Personnel
- Those newly assigned GLP responsibilities
- Quality Assurance Staff
- More experienced personnel needing to update their knowledge

Course Summary: The main intent of this course is to review the requirements imposed by Good Laboratory Practice (GLP) regulations for facilities engaged in, toxicology and product safety testing, primarily in animals and biological test systems. The responsibilities and functions of management, the Study Director, Principal Investigator and the Quality Assurance Unit (QAU) will be covered. Various procedures for meeting the requirements of the regulations will be presented.

The lectures will be supplemented by a question and answer session conducted by the Faculty and by workshops involving problem-solving exercises.

The course will concentrate on OECD and FDA Good Laboratory Practice and their application. This will include recent developments regarding multi-site studies and their practical interpretation. Additionally there will be sessions relating to computer validation, particularly as required by FDA in their 21 CFR Part 11 documents.

Emphasis will be placed on practical implementation of GLP and discussion including consideration of problems that the participants bring to the course. Practical hints and recommendations for steps in the implementation of GLP will be included.

Course Presenters:
David Long and Phil Withers, Consultants
With special participation from Theo Helder, Head of Dutch GLP Monitoring Inspections

Tuition:
Early Registration (SAVE $200): U.S. $2345  ($2235 with Group Rate*) (Must register and pay by 9 February 2009)
Regular Registration: U.S. $2545  ($2435 with Group Rate*)

For course information, go to www.cfpa.com

Please note course topics, dates, and locations subject to change. Please refer to our website for the most current information.
Granulation, Tableting & Capsule Technology
11–14 May 2009 • Amsterdam, The Netherlands

Who Should Attend: This broadly based course is intended for all scientists and technologists concerned with the development and processing of tablets, capsules and similar products, and with related drug 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:

• Quality Assurance  • R&D  • Marketing  • Regulatory Affairs
• Validation  • Manufacturing/Production  • Purchasing  • Engineering Support

Course Summary: The main aim of this course is to review the science relating to tabletted and encapsulated pharmaceutical products. The course begins with a consideration of raw material testing and the basic aspects of powder and granulation technology, progresses through formulation of solid dosage forms to manufacturing processes and equipment including scale-up and technology transfer. The program concludes with key aspects of the evaluation of finished products and the regulatory constraints that must be considered at each stage. Formal sessions of the course are supplemented with informal discussion periods between lecturers and course participants and problem-solving sessions are held on both an open and private basis.

Course Director:
Dr. Cecil W. Propst, Director of R&D, SPI Pharma Group, Grand Haven

Tuition:
Early Registration (SAVE $200): U.S. $2600  ($2480 with Group Rate)* (Must register and pay by 16 March 2009)
Regular Registration: U.S. $2800  ($2680 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS
The Center for Professional Advancement (CfPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; certificate will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program# 716-000-07-139-L04

(Please refer to page 17 for full description of each Accreditation)

IQ/OQ/PQ
18–19 February 2009 • Dublin, Ireland

Who Should Attend: This introductory course is designed for individuals who need a basic, but thorough, understanding of the Validation Process for equipment and processes used in the manufacturing of pharmaceutical sterile and oral solid finished dosage forms, and bulk active ingredients through the use of IQ/OQ/PQ Protocols. The course will benefit individuals in:

• Engineering  • Technical Services/Validation  • Production  • Regulatory Affairs
• Quality Control/Assurance  • R&D  • Regulatory Affairs
• University and allied health care professionals

Course Summary: The installation/operational/performance qualification of equipment, systems, facilities, and processes for pharmaceutical sterile, oral solid dosage, finished and bulk manufacturing operations are an essential part of the validation process. Equipment must be installed, operated, and maintained within design specifications, while processes must be shown to be reliable, all of which to assure the consistent quality and integrity of the product. This course provides a basic and thorough understanding to preparing, executing, reviewing, and approving protocols. A Risk Based approach to impact and critical component assessment is also provided along with an overview of the current on-going activities to provide International Consensus Standards being considered by the Industry and Regulatory authorities to define future Qualification requirements. Protocol examples/workshops will be utilized to enhance the learning, however this course will not provide a library of completed protocols.

Course Director:
Steven J. Wisniewski, Senior Associate and Director of Compliance, Integrated Project Services (IPS)

Tuition:
Early Registration (SAVE $200): U.S. $1640  ($1560 with Group Rate*) (Must register and pay by 24 December 2008)
Regular Registration: U.S. $1840  ($1760 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS
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(Please refer to page 17 for full description of each Accreditation)

Please note course topics, dates, and locations subject to change. Please refer to our website for the most current information.
ISO 13485, ISO 9001 and QSR Regulations for Medical Device Companies

11–13 March 2009 • Dublin, Ireland

Who Should Attend: Participants who work in the medical device industry and who currently are or wish to sell their product in the US, Europe and other parts of the world will profit by attending this course. This includes professionals responsible for understanding and interpreting global regulations within their companies, in areas such as:

• Regulatory
• QA
• R&D
• Manufacturing

Course Summary: This course provides a detailed description of the current European and US regulations for medical devices. With the continued growth in the development and acceptance of global standards, all device companies must stay up to date on the various regulations to ensure marketability of their products globally. With 25 European countries now using the ISO 13485 standard, it is critical to companies to understand how the similarities and differences in these standards can be implemented into their own quality system to enhance their marketability. The primary focus of this course is on the development of one quality system which complies with the ISO 13485:2003 standard, ISO 9001:2000 standard and the FDA Quality System Regulations. Participant interaction, problem solving and open discussion will be strongly encouraged.

Course Director: Bea Salis, Consultant, QualASyst International

Tuition:
Early Registration (SAVE $200): U.S. $2445 ($2335 with Group Rate*) (Must register and pay by 14 January 2009)
Regular Registration: U.S. $2645 ($2535 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS

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(Please refer to page 17 for full description of each Accreditation)

Microencapsulation and Particle Coating

20–22 April 2009 • Amsterdam, The Netherlands

Who Should Attend: The course should be of value to those working in microencapsulation, as well as those in industry and research laboratories who would profit from a thorough presentation and discussion of the many techniques and the characteristics of the microcapsules formed from them. It should be of particular interest to personnel in the following industries:

• Pharmaceutical • Cosmetic • Bioengineering
• Food • Chemical • Agricultural

Course Summary: This program will provide an up-to-date assessment of available encapsulation techniques. Each lecturer will present the basic chemical and physical principles of their processes, as well as a discussion of specific techniques and applications. The aim of the program is to provide an understanding of the unique advantages and difficulties of each major microencapsulation technique. Emphasis will be placed on proven techniques, results and actual applications in various industries. The instructors, all of whom are recognized experts in their areas, will present the latest available information regarding the processes in which they specialize. The lectures are structured to encourage open discussions between lecturers and participants.

Course Director: Dr. James D. Oxley, Senior Research Scientist, Department of Microencapsulation, Nanomaterials, and Process Engineering, Southwest Research Institute

Tuition:
Early Registration (SAVE $200): U.S. $2345 ($2235 with Group Rate*) (Must register and pay by 23 February 2009)
Regular Registration: U.S. $2545 ($2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS

(Please refer to page 17 for full description of each Accreditation)
Mixing of Liquids & Complex Materials

24–27 March 2009 • Hoofddorp, The Netherlands

**Who Should Attend:** This course is for individuals in process industries such as pharmaceutical, chemical, cosmetic, mineral, environmental, polymer, biological, food and paper where mixing or formulation (often of complex materials) is undertaken in stirred vessels or other mixing equipment. These professionals include but are not limited to:

- Chemists
- Engineers
- Pharmacists
- Biologists
- Material scientists

The course will benefit those concerned with scale-up, design, development, research or production. A basic knowledge of some fluid mechanics would be helpful, but is not essential.

**Course Summary:** This popular course presents the fundamentals of mixing and shows how they can be applied to a selection of commercial operations, taking into account the most recent developments in research and practice. The lectures will cover the basics of turbulence, rheology and interfacial phenomena. Building on these basic concepts, mixing processes will be analyzed for single phase systems of low and high viscosity and complex rheology. Solid/liquid, gas/liquid and liquid/liquid systems (including interfacial phenomena) will be analyzed. Design and performance relationships for mixing equipment will be developed and scale-up issues addressed.

Examples will be presented involving mixing and scale-up of precipitation, crystallization, fermentation, food processing, chemical and polymer reactions. Sessions will be supplemented by videos, case studies and discussion of problems presented by participants.

The course faculty has extensive experience all having consulted, taught, undertaken research and written extensively for many years while remaining at the forefront of developments. All will be present throughout, giving participants the opportunity to hear several views on a particular topic and participants are encouraged to discuss their own interests, experiences and problems during the course.

**Course Director:**
Dr. Alvin W. Nienow, Professor of Biochemical Engineering, University of Birmingham, U.K.

**Tuition:**
- Early Registration (SAVE $200): U.S. $2675 ($2555 with Group Rate*) (Must register and pay by 27 January 2009)
- Regular Registration: U.S. $2875 ($2755 with Group Rate*)

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Packaging of Pharmaceuticals

11–13 May 2009 • Dublin, Ireland

**Who Should Attend:** This training is designed for personnel involved in packaging in the following industries: pharmaceuticals; medical devices; personal care products; cosmetics & toiletries; nutritional products and veterinary medicines.

The program will be especially beneficial to those employed in:

- Development
- Technology
- University and allied health care professionals
- The supply of packaging materials and packaging machinery

**Course Summary:** This intensive course provides the participants with the knowledge of how packaging for all types of pharmaceuticals (ethical, OTC, veterinary medicines) and other related products are developed, manufactured, tested, filled, transported, stored and used. Emphasis will be placed on the characteristics of all commonly used packaging materials which can influence the packed product; protection, compatibility, safety, compliance, design, performance on the filling and closing lines, as well as during distribution, marketing and use. The relevant physical and chemical properties of each type of material are identified and covered in detail. This course will also accentuate the importance of the influence of the processes used to manufacture, convert or prepare materials for use, on their specifications, performance and quality of the final packages. Future and present trends in health-care packaging will be reviewed.

The increasing amount of information, that is needed on packaging, to satisfy both the company and quality of the final packages. Future and present trends in health-care packaging will be reviewed.

**Course Director:**
Mervyn J. Frederick, Former Head of the Packaging Development Group, N.V. Organon, AKZO-Nobel

**Tuition:**
- Early Registration (SAVE $200): U.S. $2345 ($2235 with Group Rate*) (Must register and pay by 16 March, 2009)
- Regular Registration: U.S. $2545 ($2435 with Group Rate*)

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For course information, go to www.cfpa.com

Please note course topics, dates, and locations subject to change. Please refer to our website for the most current information.
Pathways to Skin Penetration

ID: 2149   Offering #: 0904-405

23–24 April 2009 • Amsterdam, The Netherlands

Who Should Attend: This overview is intended for individuals who are interested in expanding their knowledge and understanding in recent findings about the skin as a barrier, possible ways of interaction between the skin and applied compounds and patterns and pathways for penetration into and through the skin. Attendees may hold a function in the following areas:

- Skin Research and Development
- Toxicology and Regulatory Affairs
- Design and Development of Topically Applied Formulations
- Formulation Chemistry
- Technical Sales and Marketing

Course Summary: This two-day course is tailored for individuals who want to gain better understanding in the detailed structure of the skin and the correlation between structure and penetration. Participants will be introduced to the biochemistry of the upper layer of the skin, the stratum corneum, and the different theories about pathways of penetration through it.

The course will provide tools for understanding the limitations in penetration and will suggest possible ways to overcome the skin barrier. It will discuss testing models as well as considerations to be taken such as skin age and condition.

Course Director:
Nava Dayan, Ph.D., Skin Care Research Expert

Tuition:
Early Registration (SAVE $200): U.S. $1640 ($1560 with Group Rate*) (Must register and pay by 26 February 2009)
Regular Registration: U.S. $1840 ($1760 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS

The Center for Professional Advancement (CfPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program # 716-000-07-713-L04

Pharmaceutical Technology Transfer

ID: 2095   Offering #: 0904-206

8–9 April 2009 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for individuals from

- Formulation Development
- Process Development
- Regulatory Affairs
- Quality Control
- Quality Assurance
- Package Engineering
- Analytical Development
- Manufacturing
- Process Development
- Regulatory Affairs
- Quality Control
- Quality Assurance
- Analytical Development
- Manufacturing

Participants will benefit by gaining a better understanding of the complexities of technology transfer in the pharmaceutical industry.

Course Summary: This course will provide a basic understanding of the technology transfer of analytical methods, quality control standards, packaging components/operations and various pharmaceutical dosage forms from R&D to manufacturing. It is designed to provide an understanding of the issues affecting the transfer within and outside a company. Topics will include transfer of technology to/from international sites as well as to/from third parties. Regulatory requirements and recommended approaches will be discussed. Speakers will use practical examples to highlight issues critical to successful technology transfer. Best practices from several pharmaceutical companies and contract manufacturers will be presented and contrasted.

Course Director:
Walter G. Chambliss, Professor of Pharmaceutics, University of Mississippi

Tuition:
Early Registration (SAVE $200): U.S. $1640 ($1560 with Group Rate*)
(Must register and pay by 11 February 2009)
Regular Registration: U.S. $1840 ($1760 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS

The Center for Professional Advancement (CfPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program # 716-000-08-707-L04

For course information, go to www.cfpa.com

Please note course topics, dates, and locations subject to change. Please refer to our website for the most current information.
**Pilot Plant & Scale-Up Studies**

**ID: 1882  Offering #: 0905-302**

12–14 May 2009 • Amsterdam, The Netherlands

**Who Should Attend:** Engineers and scientists who are involved with process development, process translation, scale-up and pilot plant studies will benefit from this course. This includes those in:

- Pilot plant operations
- Food processing
- Waste processing
- Process and project design
- Biotechnology and fermentation
- Specialty chemical production
- Chemical reactor design
- Pharmaceutical production
- Composite material manufacturing

**Course Summary:** This course will provide concepts, methods and advice on how to scale-up or translate a process or model to larger sizes. Emphasis throughout the course will be on proper designs, modeling and processing. The importance of the process geometry will be emphasized.

The course will cover the different scale-up methods and how to establish viable process objectives. A general scale-up method is presented and a number of examples are worked as illustrations. Scale-up traps and pitfalls are reviewed as well as ways to avoid these. The importance of process objectives will be emphasized. Basic concepts of importance are reviewed using different areas as examples. Power analysis will be presented as a useful tool in scale-up. Examples will show how to use the power analysis in applications and to establish the controlling mechanisms. Detailed suggestions for pilot studies will be given. Scale-up in the mixing and contacting area is reviewed. Equipment, operating conditions, optimum designs and processing conditions will be discussed. Methods to perform process translation in mixing will be developed and examined as to their practicality. Correlations and data use will be reviewed for process accuracy and use in pilot studies. Pitfalls and the use of analogies in solving processing problems will be discussed.

**Course Director:**
Dr. Gary B. Tatterson, Professor, Chemical Engineering, North Carolina A&T State University

**Tuition:**

- Early Registration (SAVE $200): U.S. $2345 ($2235 with Group Rate*) (Must register and pay by 17 March 2009)
- Regular Registration: U.S. $2545 ($2435 with Group Rate*)

**ACCREDITATIONS/CERTIFICATIONS**

(Please refer to page 17 for full description of each Accreditation)

**Process Plant Start-Up**

**ID: 561  Offering #: 0903-504**

30 March – 2 April 2009 • Amsterdam, The Netherlands

**Who Should Attend:** This course is designed for Senior and mid-level technical people involved in project execution and preparation for plant start-up in any process industry. While the actual start-ups may differ by industry, the commonalities in preparation provide valuable lessons for people such as the following:

- Project Managers
- Contractors
- Plant Managers
- Plant Supervisors
- Start-up manager, Commissioning Manager
- Process experts, Equipment specialists
- Construction Managers/Foremen
- Maintenance Manager

The greatest benefit arises from the application of these start-up oriented ideas throughout a project, beginning at the conceptual phase. The practical techniques, illustrated by example and discussion, provide useful insights that are valuable at any stage of the project execution and preparation for start-up.

**Course Summary:** The initial start-up of any plant, irrespective of size, type, technology or industry, is a unique experience that poses some special problems. Lack of experience in dealing with these problems has frequently resulted in prolonged and costly start-ups, caused by inadequate preparation for the events of start-up. This course provides guidance for the necessary preparation required to achieve a successful plant start-up. Start-up oriented thinking at all stages of the project from engineering to commissioning is the first step in proper preparation.

The course includes estimating start-up costs, people requirements and resources. It defines and illustrates the vital role of project management and plant personnel. Unanticipated events during start-up, along with inherently hazardous conditions require extra preparation effort to avoid safety incidents. Troubleshooting performed during the start-up can be very expensive and must be done as effectively as possible. The goal of troubleshooting is to minimize the time and cost of going from initial start-up to full production. The fourth day will provide a review of techniques and discussion of numerous examples to develop troubleshooting skills.

**Course Co-Directors:**
John Butler, Manager Process Engineering, Process and Energy Group, URS Corporation
Chris Wallsgrove, Start-up Consultant

**Tuition:**

- Early Registration (SAVE $200): U.S. $2600 ($2480 with Group Rate*) (Must register and pay by 2 February 2009)
- Regular Registration: U.S. $2800 ($2680 with Group Rate*)

**ACCREDITATIONS/CERTIFICATIONS**

(Please refer to page 17 for full description of each Accreditation)
Root Cause Investigation for CAPA

ID: 2089  Offering #: 0901-403

20–21 January 2009 • Dublin, Ireland

Who Should Attend: This is a highly practical and workshop-oriented course for those in the pharmaceutical or medical device industry who conduct Corrective and Preventive Action (CAPA) investigations, especially those in the following areas:
• Regulatory Affairs  • Quality Assurance  • Manufacturing  • Product/Process Development
• R&D  • Maintenance

Course Summary: Most organizations have procedures for implementing corrective and preventive actions, but many do not have an effective methodology to actually investigate to find the root cause. As a result the investigation is often careless, unsuccessful, and costly. Root Cause Investigation for CAPA is a proven methodology to investigate and identify the root cause when there has been a shift in the performance of a product, machine, equipment, work process, or system.

The methodology identifies the change (or changes) that has occurred so that the change can be eliminated and the performance can return to its previous level. It is ideal for investigating an increase in:
• Product or service defect levels
• Customer complaints
• Negative patient reactions with the product
• Manufacturing scrap or rework
• Equipment or process aberrations
• Any performance change where a CAPA investigation is required

This workshop, intensive course is designed to develop the skills necessary so that you can conduct an effective investigation immediately upon returning to your job.

Course Director:
Tom Weaver, Quality and Operations Improvement Consultant

Tuition:
Early Registration (SAVE $200): U.S. $1640  ($1560 with Group Rate*) (Must register and pay by 25 November 2008)
Regular Registration: U.S. $1840  ($1760 with Group Rate*)

Scale-Up and Post Approval Changes Guidelines (SUPAC & API Changes)

ID: 1948  Offering #: 0904-05

6–8 April 2009 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for personnel in the pharmaceutical industry involved in the development of drug dosage forms including:
• Process Development  • Production  • Quality Assurance
• Pilot Plant  • Technical Service  • Research & Development
• Regulatory Affairs

Course Summary: This course will provide a basic understanding of the FDA Scaleup and Post Approval Guidelines & the recent 2004 guideline on Changes to approved NDA or ANDA. This also addresses the impact of withdrawal of the FDA BACPAC I guideline on changes in API synthesis. The issues affecting batch size scaleup/scale-down, various post approval formulation component or composition changes, site of manufacturing changes, manufacturing process changes, and/or equipment changes will be addressed along with the issues affecting analytical methodology, packaging and labeling changes.

The course will focus on:
1. The criteria that determines the level or degree of change.
2. The type of study data or information that must be generated to support changes at each level.
3. The FDA recommended chemistry manufacturing & control tests to support each level or degree of change.
4. The type of in-vivo or in-vitro testing required to support the various levels of degrees of change.

Case examples will be employed to allow the students to determine the type of data that are required to support the level of changes proposed.

Course Director:
Mukund “Mike” Yelvigi, Director and Head of CMC Therapeutic Area Management Chemical and Pharmaceutical Development Division, Wyeth Research Laboratories

Tuition:
Early Registration (SAVE $200): U.S. $2545  ($2435 with Group Rate*) (Must register and pay by 9 February 2009)
Regular Registration: U.S. $2345  ($2235 with Group Rate*)
2–3 March 2009 • Amsterdam, The Netherlands

**Who Should Attend:** This program will benefit:

- Scientists
- Technicians
- Engineers
- Managers

Who work in the following areas:

- Research and Development
- Regulatory Affairs/Quality Control
- Technology Transfer Managers

**Course Summary:** This course is designed to provide a set of theoretical and practical tools for those interested in working with dispersed phases and predicting and understanding their sometimes complex behavior. The participant will learn to use the materials and processes needed to create dispersed-phase products, and to effectively solve problems arising during development. Troubleshooting existing commercial product problems will be emphasized as well. The theoretical underpinnings of emulsion and suspension behavior will be described to provide a backdrop for discussions of specific emulsifying and suspending systems. Current methods to analyze the behavior of dispersed phases will be described, as will methods to measure and predict stability of the products. Processing and scale-up issues specific to the type of equipment needed to create dispersed phases will also be discussed.

**Course Co-Directors:**

- Larry D. Ford, Ph.D., Research Principal, Kraft Foods Global Inc.
- Edgar N. Jaynes, Jr., Ph.D., CQE, Technical Transfer Liaison, Banner Pharmacaps Inc.

**Tuition:**

- Early Registration (SAVE $200): U.S. $1640 ($1560 with Group Rate*)
- Regular Registration: U.S. $1840 ($1760 with Group Rate*)

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### Vendor and Contract Supplier Qualification

23–25 February 2009 • Amsterdam, The Netherlands

**Who Should Attend:** This course has been designed for those who need to understand and improve their customer/supplier relationships. It is of particular interest to appropriate persons in

- Corporate and Plant Management
- Materials Management
- Manufacturing
- Engineering
- Regulatory Affairs
- Purchasing
- Scheduling
- Packaging
- Distribution
- QA/QC

While the examples discussed are drawn mainly from the pharmaceutical industry, the material has applicability to other industries including the biological, device, diagnostics, and cosmetics industries.

**Course Summary:** From both a regulatory and business perspective, firms should partner with their suppliers (both vendors and contract suppliers) to assure that they receive materials and services according to predetermined specifications for quality, quantity, and delivery. Some firms limit this activity to some degree of “qualification” while others extend it to “certification” or to some type of “strategic alliance.”

This course reviews the regulatory, legal and operational aspects including the role of the quality and operations functions. It includes a review of the techniques by which customers and suppliers can monitor one another via such techniques as statistical analysis and auditing. The FDA perspective, including the role and effect of FDA inspections, is reviewed and particular attention is given to the problems involved in contract work (i.e., outsourcing) with an emphasis on the need for carefully defining the respective responsibilities of the customer and supplier. The course includes a hands-on workshop in which mini-teams analyze case studies and present their findings.

**Course Director:**

Dr. Alan J. Smith, Pharmaceutical Quality and Technology Consultant

**Tuition:**

- Early Registration (SAVE $200): U.S. $2345 ($2235 with Group Rate*)
- Regular Registration: U.S. $2545 ($2435 with Group Rate*)

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**ACCREDITATIONS/CERTIFICATIONS**

The Center for Professional Advancement (CPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; certificate will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program# 716-000-09-208-L04

1.8 credits

(Please refer to page 17 for full description of each Accreditation)
Introducing

Online Training

A new way to experience CfPA’s Accredited Technical Training!

CfPA’s Online Training is a perfect complement to our public and client site programs. Experience the ability to supplement your training needs or expand on your knowledge in areas critical to your job function. Available live and on-demand.

Advantages of CfPA’s Online Training:

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- **Interactive** – Actively participate with instructor and participants in a virtual classroom through the use of polls, Q&A and other online tools
- **Topics** – All courses taught by leading industry experts, topic areas are similar to our public courses and include basic concepts to the latest advances
- **Accredited** – Training programs are accredited and/or certified
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- **Cost Effective** – Save on travel costs and time out of the office
- **On-Demand** – Previously held courses are available for viewing when it is convenient for you

For more information on our Online Training:
Go to [www.cfpa.com/onlinetraining](http://www.cfpa.com/onlinetraining) or E-mail onlinetraining@cfpa.com

Customized Training Through

Client Site Programs

Whatever your on-site needs may be, we can meet them.

Offered at your location and at your convenience, CfPA will bring any course to your team for customized training, or we can work with you to develop a program to address the specific issues most critical to you.

What are the advantages to a Client Site Course?

- You can have up to thirty-five of your engineers, scientists and technical managers participating simultaneously in a course.
- You have the opportunity to tailor the standard program to your company’s specific problems and interests.
- You have one-to-one access with a top teaching team specializing in your industry, and comprehensive course material, for an all-inclusive fee.
- You save on costly hotel and travel expenses.

How to arrange a Client Site Course:
If your company is interested in a Client Site training program, please contact our Client Site division at 732.238.1600 ext. 4549 or E-mail clientsite@cfpa.com.
Online Training — A new way to experience CfPA’s Accredited Technical Training!

CfPA’s Online Training is a perfect complement to our public and client site programs. Experience the ability to supplement your training needs or expand on your knowledge in areas critical to your job function. Available live and on-demand.

Upcoming Live Online Training:

Nov 6 & 11, 2008  | Clinical Testing Plan & Submissions (2 part course) | ID# 2242
Nov 13, 2008  | Lyophilization: Optimized Pre-Formulation, Formulation, and Cycle Development Techniques | ID# 2241
Nov 20, 2008  | Silicon to Siloxanes: Chemistry and Properties | ID# 2247
Dec 2, 2009  | Nutritional Supplement Formulation Basics | ID# 2246
Dec 4, 2008  | Natural Ingredients in Formulating Skin Care Products | ID# 2239
Dec 11, 2008  | Introduction to Pharmaceutical cGMP | ID# 2244
Jan 8, 2009  | Pharmaceutical cGMP – The Quality System | ID# 2245
Jan 13, 2009  | FDA Quarterly Briefing–January 2009 | ID# 2232
April 7, 2009  | FDA Quarterly Briefing–April 2009 | ID# 2233

On-Demand Online Training available anytime:

Assuring Your Supply Chain through Supplier Qualification | ID# 2227
Best Practices in SAS Statistical Programming: Understanding and Applying the QC Plan to Validate Summary Tables (First in a Two-Part Series) | ID# 2213
Biocidal and Plant Protection Products in the EU: Borderlines and Overlaps | ID# 2218
Bringing Nanotechnology to Your Market | ID# 2157
CAPA – The Heart of Your Quality System | ID# 2124
cGTP in a Nutshell | ID# 2179
Choosing Sensors, Monitors and Instruments for PAT Programs | ID# 2128
Complaint Systems - The Essential Requirements | ID# 2132
Computerized Systems Used in Clinical Investigations: the New FDA Guidance | ID# 2184
Conducting Compliant Endotoxin Testing | ID# 2185
Cost Effective Quality-by-Design and Critical-to-Quality Tools for PAT | ID# 2127
Control of Microbial Contamination in Manufacture of Sterile and Non-Sterile Products | ID# 2215
CSOs: Are They Right for You? | ID# 2240
DQ: A Guide to Protecting Your Interests When Procuring Sensors | ID# 2220
Encapsulation: Basic Techniques and Applications | ID# 2196
Endotoxin Testing: Resolving Interference and Test Validation | ID# 2204
Equipment Qualification in a Nutshell | ID# 2135
Evolution of the Pharmaceutical Industry through 2020 | ID# 2198
Getting a Share of the BioDefense Grant Billions | ID# 2205
Guidelines to In Vitro Skin Absorption Studies | ID# 2202
Introduction to Skin Aging | ID# 2125
Investigation of Microbial Contamination in Sterile and Non-Sterile Products | ID# 2216
Lyophilization 101: Principles, Physical Properties and Characterization Techniques | ID# 2236
Pharmaceutical Water: Chemistry, System Design and Validation | ID# 2211
Practical Steps to Understanding ICH Q9 | ID# 2160
Preservatives and Biocides in Consumer Products | ID# 2221
Risk Hazard Assessment for Validation - ISO 14971 | ID# 2147
Skin Inflammation – Reasons, Prevention, Treatment and Testing | ID# 2217
Understanding Pharma: Business Growth and Drivers | ID# 2199

For Complete Listing of CfPA’s Live and On-Demand Online Training Courses, Visit www.cfpa.com/online-training

Please note course topics, dates, and locations subject to change. Please refer to our website for the most current information.
About CfPA

The Center for Professional Advancement (CfPA) is the most recognized accredited technical training organization in the world, offering a comprehensive curriculum of over 350 public, Client Site and Online courses in 18 industries including: Pharmaceutical, discovery through production; Chemical; Food and Medical Device.

Since 1967 CfPA has trained over 500,000 professionals therefore earning high recognition by thousands of leading industrial and life sciences companies who consider CfPA to be an integral part of their training programs. In addition, CfPA has received “authorized provider” status from 14 scientific and engineering associations and societies to award accreditation to professionals who meet recognized standards of excellence through participation in approved courses.

In 2007 The Company launched Online Training, an initiative to confirm CfPA’s commitment to bringing industry professionals accredited training through the most state-of-the-art, cutting-edge technology available.

Headquartered in East Brunswick, New Jersey, CfPA has offices in Amsterdam, The Netherlands and São Paulo, Brazil. Public courses are offered throughout the U.S., Puerto Rico, Europe and Latin America. For additional information about CfPA, please visit www.cfpa.com.

Upcoming June and July 2009 Public Courses – Visit www.cfpa.com for more information.

Powder Mixing Technology
8 – 10 June 2009 | Amsterdam, The Netherlands | ID# 777

Crystallization Technology
9 – 11 June 2009 | Amsterdam, The Netherlands | ID# 149

Surviving an FDA Inspection -- FDA Inspections of Non-U.S. Sites
16 – 17 June 2009 | Amsterdam, The Netherlands | ID# 1880

cGMP Auditing
18 – 19 June 2009 | Amsterdam, The Netherlands | ID# 1881

ISO 13485, ISO 9001 and QSR Regulations for Medical Device Companies
24 – 25 June 2009 | Amsterdam, The Netherlands | ID# 2092

Starch: Chemistry, Properties and Applications
25 – 26 June 2009 | Amsterdam, The Netherlands | ID# 542

Effective Project Management
30 – 32 June 2009 | Amsterdam, The Netherlands | ID# 129

Risk Analysis and Human Factors Engineering
29 – 30 June 2009 | Amsterdam, The Netherlands | ID# 2106

Preparation, Packaging and Labeling of Clinical Trial Materials
8 – 10 July 2009 | Amsterdam, The Netherlands | ID# 858

Intellectual Property, Antitrust, Ethics and Licensing Laws
14 – 15 July 2009 | Amsterdam, The Netherlands | ID# 2059

Design Control and Product Validation
13 – 14 July 2009 | Amsterdam, The Netherlands | ID# 1900
Accreditations/Certifications

CfPA holds 14 Accreditations. The following are available for the selected courses in this catalog. For more information on all of our Accreditations/Certifications visit our website at www.cfpa.com.

The Center for Professional Advancement has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102. In obtaining this approval, The Center for Professional Advancement has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. As a result of their Authorized Provider membership status, The Center for Professional Advancement is authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards.

This course has been approved for recertification credits by the AACE International Certification Board toward meeting the continuing education requirements for recertification as a Certified Cost Engineer, Certified Cost Consultant, Planning and Scheduling Professional and Earned Value Professional.

ASQ Certification: ASQ Certified Quality Engineers, Reliability Engineers and Quality Auditors may earn recertification credits for attending this program, providing it is covered under one area of the body of knowledge in which they are seeking recertification or is job enhancement.

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Locations

CfPA courses on pages 1-13 are held in the following hotels. Please refer to individual course on our website for appropriate location.

Amsterdam, The Netherlands

Amsterdam American Hotel:
Leidsegracht 97
1017 PN Amsterdam, The Netherlands
Phone: +31/20/556.3100 • Fax: +31/20/556.3001

Amsterdam Marriott Hotel:
Stadhouderskade 12
1054 ES Amsterdam, The Netherlands
Phone: +31/20/607.55.08 • Fax: +31/20/607.55.12

Holiday Inn Amsterdam:
DeBoelelaan 2
1083 HJ Amsterdam, The Netherlands
Phone: +31/20/64.62.300 • Fax: +31/20/64.64.790

Park Plaza Victoria Amsterdam Hotel:
Damrak 1-5
1012 LG Amsterdam, The Netherlands
Phone: +31/20/62.34.255 • Fax: +31/20/62.52.997

Renaissance Amsterdam Hotel:
Kattengat 1 • 1012 SZ Amsterdam, The Netherlands
Phone: +31/20/621.2223 • Fax: +31/20/627.5245
www.renaissancehotels.com

Hoofddorp, The Netherlands

Courtyard by Marriott–Amsterdam Airport:
Kruisweg 1401
2131 MD Hoofddorp, NL
Phone: +31/23/556.9000 • Fax: +31/23/556.9009

Dublin, Ireland

Gresham Hotel
23 Upper O’Connell Street
Dublin – 1, Ireland
Phone: +353/1/874.6881 • Fax: +353/1/878.7175

Radisson SAS Royal Hotel
Golden and Chancery Lanes,
Dublin 8, Ireland
Phone: +353/1/898.2900 • Fax: +353/1/898.2901

Radisson SAS St. Helen’s:
Stillsorgan Road, Dublin 4, Ireland
Phone: +353/1/218.6000 • Fax: +353/1/218.6010

A limited block of rooms in the hotel will be held for our registrants until four weeks before the course. Participants must, however, make their own reservations; the cost of hotel accommodation is not included in the course fee. To receive CfPA’s rate and room block, be sure to mention that you will be attending one of our courses.

Terms and Conditions

Payment: Tuition payable in US funds net of all charges. Payment is due BEFORE course start date. 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 Registration Discount, payment is required at time of registration and/or BEFORE early registration discount expires or the regular tuition rate will apply. If choosing invoice/check/wire transfer, payment must be received prior to expiration of early registration discount or the regular tuition rate will apply. All tuition prices are per person rate. To qualify for the Group Rate tuition, registration must be for two or more enrollments registering at the same time, from the same company, for the same course. Multiple discounts not applicable.

*Group Rate is for two or more enrollments registering at the same time, from the same company, for the same course. Multiple discounts not applicable.

Cancellations/Substitutions/FEES: All cancellations are subject to a $150.00 processing fee. Applicants may cancel up to two weeks prior to the course start date for a refund. If less than two weeks, a credit will be issued that can be used towards a future course up to one year from the date of issuance. No refunds or credit will be issued for those who do not attend the scheduled course and/or cancel less than two working days before the start date. Substitutions are permitted at any time. 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.

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