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

Course Catalog



April – July 2008 European Course Offerings

Course Topics in this Catalog Include:

- ICH Q9: Managing Risk in Pharmaceutical Manufacturing
- Critical Process Cleaning and Cleaning Validation
- Pathways to Skin Penetration
- ISO 13485, ISO 9001 and QSR Regulations for Medical Device Companies
- REACH: Registration, Evaluation and Authorization of Chemicals
- Technical Writing in the Pharmaceutical and Allied Industries

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



www.cfpa.com

April - July 2008

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

Welcome

For 40 years CfPA has been meeting the needs of professionals in the pharmaceutical, biotechnology, cosmetic and medical device 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:

www.cfpa.com/onlinetraining
or E-mail: onlinetraining@cfpa.com

Client Site Training

Take advantage of the benefits Client Site training offers: cost effective, convenient, customized one-on-one attention. Any course in this listing can be brought to your company and tailored to your specific needs. For further information, please contact Client Site Programs:

732.238.1600 ext. 4549
or E-mail: clientsite@cfpa.com

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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.

Analytical Methods Validation for FDA Compliance

ID: 1887 Offering #: 0804-402

21–23 April 2008 • 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 analysis 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 25 February 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

Active Pharmaceutical Ingredients

ID: 840 Offering #: 0806-105

2–4 June 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is for individuals working in all phases of human and veterinary Active Pharmaceutical Ingredients (API) production and control including:

- Pilot and commercial production
- QA/QC
- Regulatory affairs
- Process development
- Engineering
- Management

The course models a GMP compliant API operation, everyone’s role in achieving compliance, and penalties for noncompliance. Government investigators who inspect API operations are encouraged to attend.

Course Summary: This course prepares attendees to meet the challenges they face in this heavily regulated industry. It is vital for API producers to ensure that GMP principles are applied to API production and control, and to demonstrate knowledge of FDA, ICH and other governmental and industry guidance documents.

This course will provide guidance in the design, construction, and validation of GMP pilot and production facilities. Examples of facilities will be discussed. The selection, qualification, and cleaning of equipment will be included with specific examples. Process validation is of singular importance and validation principles and their application will be demonstrated with examples. Process development and technical transfer reports will be described. The function of the quality unit to establish and manage the systems required to maintain compliance will be discussed. Throughout the program there will be interactive class exercises. On the last day of the course participants will receive instruction on managing an FDA inspection followed by a workshop in which participants prepare written responses to simulated FDA-483s (List of Inspectional Observations) based on actual FDA observations. The exercise will result in a valuable exchange of information and approaches with your colleagues.

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 7 April 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

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.

Auditing for cGMP Compliance

ID: 1881 Offering #: 0806-302

18–19 June 2008 • Amsterdam, The Netherlands

Who Should Attend: Newly assigned auditors or those who expect to be involved in auditing in the near future, will find the course beneficial. Those individuals who expect their departments, groups or functions to be audited, will also find the program of great interest. Thus the course can be of interest to professionals in a variety of functions such as:

- Quality Assurance • Quality Control • Regulatory Compliance • Packaging • Pre-formulation
- R&D • Laboratory • Production • Engineering • Purchasing • Vendors

Course Summary: This practical, introductory course was designed to provide a mechanism for European auditors to understand the basic requirements for auditing in compliance with United States Current Manufacturing Practice for Drugs and Finished Pharmaceuticals and with Quality Systems regulations. The course presents an introduction to the evolutionary process of the regulations and provides a road map for auditors in setting up an audit trail from beginning to end. Specific cGMP compliance aspects in the laboratory and manufacturing operations will be covered. Specific concerns regarding suppliers and vendors will be presented as well. Related topics of validation and computer systems validation are presented as they pertain to the auditing process.

A hands-on workshop will present an opportunity for participants to apply to real life situations the information presented as well as the methodology and techniques learned, by designing and setting up a company cGMP audit program.

The course will consist of lectures, interactive discussions and a hands-on workshop.

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 23 April 2008)

Regular Registration: U.S. \$1,840 (\$1760 with Group Rate*)

Attend this course and its companion course **Surviving an FDA Inspection -- FDA Inspections of Non-U.S. Sites** (ID# 1880) and save \$300[†]. See page 19 for course description. [†]Discount applies only to combined regular tuition.

Complaint Procedures for Medical Devices

ID: 1834 Offering #: 0806-304

16–18 June 2008 • Amsterdam, The Netherlands

Who Should Attend: This practical program will be of benefit to all medical device personnel involved with their company's Complaint Systems including:

- Implementation
- Management
- Product Performance Monitoring
- Training
- Auditing
- Regulatory Compliance

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 will give you tools for survival. It will provide a step-by-step guide to the setting-up, operation, management and auditing of a complaint 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:

Michael Barile, *Managing Partner*, Barile & Associates, Consulting for the Medical Device, Pharmaceutical, Human Tissue, and Biotechnology Industries

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 21 April 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

Cosmetic Product Formulation

ID: 1350 Offering #: 0804-404

21–23 April 2008 • Amsterdam, The Netherlands

Who Should Attend: Individuals in the cosmetic/toiletries industry who seek to broaden their knowledge of development, evaluation, and performance of a variety of products will find this course very beneficial.

Technical personnel in service and allied functions in the cosmetic/toiletries field who are not directly involved in product development but require a better understanding of the development process will also find this course of value. These would include:

- Analytical chemists
- Process engineers/chemists
- Safety and regulatory specialists
- Microbiologists

Marketing personnel with sufficient technical background should also find this course helpful in their interactions with research and development.

Course Summary: This course will review the methodologies used to develop the major types of cosmetic and toiletries products. Idea generation, formulation development, manufacturing considerations, and stability testing will be discussed for each product type. The basis in the development of stable emulsions will also be discussed. Among the product types to be reviewed will be: creams, lotions, hair products (including shampoos, conditioners, waving products, and grooming products), makeup products, shaving products, soaps and related washing products.

Particular attention will be given to critical problem areas which can affect the development process as well as the effects of specific ingredients on product performance, stability, and product scale-up.

Course Co-Directors:

John Carson, *Principal*, Carson Product Development, Inc.

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 25 February 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 21 for full description of each Accreditation)

Critical Process Cleaning and Cleaning Validation

ID: 1867 Offering #: 0805-505

28–30 May 2008 • Amsterdam, The Netherlands

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

- Process Engineering
- Production
- Quality Assurance
- Validation
- 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 April 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

4–6 June 2008 • Amsterdam, The Netherlands

Who Should Attend: The course is intended for engineers, chemists and technicians involved with the design, analysis or operation of organic or inorganic crystallization processes at the bench-scale, pilot plant or commercial-scale level including:

- Design Technologists
- Process Development Technologists
- Vendor Testing
- Pilot Plant Technologists
- Plant Operation Technologists

Their supervisors and others working with them can profit from a detailed practical knowledge of crystallization technology.

Course Summary: This course provides a practical treatment of crystallization technology, presented in light of the many recent advances in the understanding of crystallization processes. Emphasis will be given to the practical problems of crystallizer operation, and a logical way of understanding the potential and limitations of crystallizer performance will be presented. Both organic and inorganic systems will be treated in batch and continuous mode. Elementary topics in the analytical description of particle-size distributions will be presented. The treatment will not emphasize the mathematics of particle distributions, but rather the basic principles involved and the results that can be applied.

Practical problems to be considered are Crystal Size Distribution (CSD) and its interaction with crystal habit, purity, and fouling; secondary nucleation; crystallizer configuration, e.g., seeding, classification, fines removal, scale-up considerations, the impact of mixing, polymorphism, crystallizer transients and stability, and online measurement of crystallization parameters. Efficient techniques for scanning crystal growth, nucleation and habit modifiers will be discussed. These problems will be considered from both analytical and operational points of view.

Course Director:

Dr. Wayne J. Genck, *President*, Genck International

Tuition:

Early Registration (SAVE \$200): U.S. \$2545 (\$2435 with Group Rate*) (Must register and pay by 9 April 2008)

Regular Registration: U.S. \$2745 (\$2635 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 9 for full description of each Accreditation)

Design Control and Product Validation for Medical Devices

ID: 1900

Offering #: 0806-307

19–20 June 2008 • Amsterdam, The Netherlands

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 24 April 2008)

Regular Registration: U.S. \$1840 (\$1760 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

Drug Product Stability and Shelf-Life

ID: 599

Offering #: 0805-304

14–16 May 2008 • 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 19 March 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

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(Please refer to page 21 for full description of each Accreditation)

Effective Project Management in Today's World

ID: 129

Offering #: 0807-201

8–10 July 2008 • Amsterdam, The Netherlands

Who Should Attend: This **basic** course is designed for those leading or managing a project and for those who must work with the project manager within:

- R&D
 - Construction
 - Design
 - Information Systems
 - Manufacturing
- Personnel within the Pharmaceutical, Medical Device, Chemical, Electronic and Food industries will benefit. Experienced project managers will find this course helpful as a refresher.

Course Summary: In today's corporate environment of limited available resources and multiple projects being performed simultaneously and competing for the necessary resources, project management and the requisite project planning is increasingly important. The effective management of projects is the first line of control in the overall management of an organization. This basic course covers the essential knowledge and skills required to organize, plan and control projects of all sizes and types. It serves as an introduction to the leadership or the management of any type of project including those with reliance on outsourcing of key elements. Emphasis is placed on practical approaches and techniques that will work within the existing organizational environment of any company.

Interactive discussion through examples and casework is encouraged during the program to involve all participants and to personalize the learning experience. A "hands-on" case, "LOOKOUT", © A.L.L. Associates, is included to enhance the learning process.

Course Director:

Bruce H. Frank, President, A.L.L. Associates

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 13 May 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 21 for full description of each Accreditation)

Elements of Applied Process Engineering

ID: 1512 Offering #: 0804-301

15–18 April 2008 • 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 19 February 2008)

Regular Registration: U.S. \$2915 (\$2795 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 21 for full description of each Accreditation)

Emulsion-Suspension Technology

ID: 274 Offering #: 0805-401

19–21 May 2008 • Amsterdam, The Netherlands

Who Should Attend: This program will benefit personnel in the pharmaceutical, cosmetic, personal care, household products and food industries including:

- Scientists
- Technologists
- Engineers
- Product planning
- Development personnel
- Quality control
- Regulatory affairs specialists
- Pilot plant
- Production research

Course Summary: This course emphasizes the application of emulsion and suspension principles to the solution of practical, technological problems in the preparation and evaluation of pharmaceutical, cosmetic and related personal care products. Throughout the course, the interrelationship of the many specialty areas involved in emulsion and suspension products will be stressed. Newer technologies such as microemulsions and liposomes will be discussed. A blend of scientific principles and practical technology will be presented with special attention to the conceptual model of the oil-water interface as the basis for emulsion design. Techniques for studying the solid-liquid interface will be presented and applied to physicochemical problems which arise in the development of suspensions. Processing problems, with particular emphasis on scale-up, will be discussed.

Course Co-Directors:

Dr. Stanley L. Hem, Professor of Physical Pharmacy, Purdue University

Dr. Norman D. Weiner, Professor of Pharmaceutics, University of Michigan

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 24 March 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

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(Please refer to page 21 for full description of each Accreditation)

Environmental Control and Monitoring

ID: 1937 Offering #: 0806-107

2-3 June 2008 • Amsterdam, The Netherlands

Who Should Attend: Technical and managerial professionals involved with sterile products, clinical materials, drug development, cosmetics, aseptics, food and beverage, medical research and QC testing will all benefit from the rigorous and practical discussions of this intensive course. It will be especially beneficial to

- Microbiologists
- Processing Engineers
- Manufacturing Personnel
- Quality Assurance Professionals
- Validation and Compliance Staff Members

Course Summary: Although one of the most basic and long standing areas of pharmaceutical and FDA regulated manufacturing, "cleaning," "sanitation," or "environmental control" programs remain an essential part of cGMP compliance with numerous issues and potential problems such as effectiveness and safety of chemical agents, sterility or cleanliness requirements for supplies and cleaning tools, and methods selection and proper techniques for sampling and measuring viables and nonviables.

It is an ironic but accepted problem in this field that one of the major sources of contamination is the frequent sampling and measurement of contamination required by cGMPs. It is felt that, because the cleaning methods are predominantly manual, they can not be fully "validated." In addition to a rigorous environmental monitoring program, worker technique and training are critical factors in process reliability.

This course will shed light on these important issues and offer pragmatic help to overcome obstacles that often stand in the way of consistent, cost effective, biodecontamination programs. Just as important, the course will provide valuable guidance on conforming to qualification and validation requirements including disinfectants, facility conformance, gowning and pass-through, environmental sampling plans, data collection and reporting and response/action plans

Course Director:

Steven A. Weitzel, *Technical Director*, Critical Process Cleaning, Inc.

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Group Rate*) (Must register and pay by 7 April 2008)

Regular Registration: U.S. \$1840 (\$1760 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 21 for full description of each Accreditation)

Excipient GMPs

ID: 2050 Offering #: 0805-504

28-30 May, 2008 • Den Haag, The Netherlands

Who Should Attend: This course is intended for chemical manufacturers who want to learn about supplying excipients to the industry and for those manufacturers already supplying excipients that need to learn about excipient GMP compliance. It is also intended for pharmaceutical manufacturers that must assess the compliance of their excipient suppliers to appropriate GMP requirements.

Personnel in the following areas have found this course beneficial:

- Quality Assurance
- Regulatory Affairs
- New Business Development
- Quality Control
- Quality Audit

Course Summary: This course will cover the regulatory, quality, and manufacturing issues involved in providing chemicals for use as excipients (inactive ingredients) in the manufacture of drug products. You will learn about the regulation of chemicals sold for use as excipients by the FDA, the expectations of the pharmaceutical industry, and excipient quality system requirements (GMP). There will also be topical information on current issues facing the industry.

Course Director:

Irwin Silverstein, Ph.D., *President*, IBS Consulting in Quality LLC., and *Chief Operating Officer*, International Pharmaceutical Excipients Auditing Inc.

Tuition:

Early Registration (SAVE \$200): U.S. \$2405 (\$2295 with Group Rate*) (Must register and pay by 2 April 2008)

Regular Registration: U.S. \$2605 (\$2495 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

GMP for Dietary Supplements

ID: 2094 Offering #: 0804-403

21–22 April 2008 • Amsterdam, The Netherlands

Who Should Attend: This course will benefit consultants and others involved in the dietary supplement industry including, but not limited to, those involved in:

- Supplying and distribution of dietary supplements
- Auditing of in-house and contract laboratories
- Regulatory Affairs
- Manufacturing
- Labeling
- Scientists
- Quality Control/Assurance
- Laboratory Operations

Course Summary: This two-day course will cover regulatory and legal aspects of GMP's for dietary supplements. It will provide a comprehensive introduction and a "how to" program for implementation. Participants will understand issues involved in manufacturing and testing of dietary supplements. They will become familiar with FDA expectations when performing audits of dietary supplement companies. A rational approach to setting up manufacturing and improving a GMP compliant operation will be presented.

FDA Final Rule; No Longer Voluntary

Course Director:

Joy Joseph, *Consultant to the Pharmaceutical, Dietary Supplement and Cosmetic Industries*

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Group Rate*)
(Must register and pay by 25 February 2008)

Regular Registration: U.S. \$1840 (\$1760 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

Granulation, Tableting & Capsule Technology

ID: 541 Offering #: 0805-503

26–29 May 2008 • Den Haag, 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
- Validation
- R&D
- Manufacturing/Production
- Marketing
- Purchasing
- Regulatory Affairs
- Engineering Support

Course Summary: The main aim of this course is to review the science relating to tableted 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 31 March 2008)

Regular Registration: U.S. \$2800 (\$2680 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

24–25 April 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for beginner formulators or marketing personnel and those with some experience who have the desire to quickly widen their level of knowledge and become familiar with the marketing, technical and claim substantiation issues related to hair product development such as:

- Analytical chemists
- Scientists
- Microbiologists
- Technicians

Personnel in research and development, sales, marketing, and labeling will find this course very valuable.

Course Summary: This course provides a review of the main marketing trends in hair care, followed by an analysis of the fundamental properties of human hair as related to cosmetic treatments. A thorough review of the foremost raw materials presently used in the industry will be discussed so that the formulators and marketing professionals will quickly become familiar with the products, properties and raw material supplied to the hair care area of the cosmetic industry. In addition, the main technologies and challenges relevant to product development in the areas of shampoos, conditioners, styling products, hair colorants, relaxers, etc., will be explained. A critical analysis of the methodology used for claim substantiation in hair care will also be addressed. An all-participants interactive session has been developed that is dedicated to the design of typical hair care products from the knowledge gained within the course.

Course Director:

Manuel Gamez-Garcia, Ph.D., Sr. Research Scientist, Ciba Specialty Chemicals

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Group Rate*) (Must register and pay by 28 February 2008)

Regular Registration: U.S. \$1840 (\$1760 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 21 for full description of each Accreditation)

ICH Q9: Managing Risk in Pharmaceutical Manufacturing



ID: 2158

Offering #: 0805-403

20–21 May 2008 • Amsterdam, The Netherlands

Who Should Attend: This comprehensive quality system workshop will benefit professionals who are involved in managing and operating in the ICH Q8, Q9 and Q10 areas, as well as those who interact with PAT and QbD programs, including:

- PAT and QbD Team Leaders and Members
- Quality and Efficiency Personnel
- Manufacturing Operations Personnel
- Product Development Teams
- Technology Transfer Personnel
- In-process and Finished Goods Analysts
- Analytical Instrument and Manufacturing Equipment Suppliers
- Managers tasked with improving pharmaceutical operating efficiency

Course Summary: ICH Q9 is one of the three “cornerstone” guidances proposed by the International Conference on Harmonization and undergoing adoption in The European Union, Japan and the USA. These policies, called Q8, Q9 and Q10, form an international platform that will dramatically improve efficiency and safety within the entire pharmaceutical life cycle. ICH Q8 and Q10 cover drug manufacturing and drug development by treating their individual operating steps as entities that are subject to variance. The platforms aim to reduce stepwise variance so that the likelihood of failure or rejection at the conclusion of the process is minimal. Both use risk-management techniques to accomplish their goals.

Risk management involves assessment of pharmaceutical unit operations for critical-to-quality attributes, evaluation of tolerable variance, measurement and control of those parameters and eventually, high release rates with minimal likelihood of recall or patient risk. Putting risk management into practice involves multivariate analysis of all development and production factors.

This course provides both principles and practices for successful ICH Q9 implementation.

Course Director:

John E. Carroll, C.Ph.C., Managing Partner, Cadrai Technology Group, President, Carroll Ventures, Inc.

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Group Rate*) (Must register and pay by 25 March 2008)

Regular Registration: U.S. \$1840 (\$1760 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)



In Vitro Testing Methodologies for Safety Assessment of Cosmetic Ingredients

ID: 2161

Offering #: 0805-402

19–21 May 2008 • Amsterdam, The Netherlands

Who Should Attend: Professionals in the cosmetic and personal care or related industries that work and specialize in the following disciplines, as well as groups or companies that provide services in these areas:

- Research and Development
- Regulatory Affairs
- Safety Assessment
- Product Development
- Formulations Development

Course Summary: This comprehensive course attempts to provide the spectrum of the reasons, rationale, tools and approaches to address safety assessment of cosmetic ingredients.

In this current environment of establishing regulations and environmental issues awareness, an effort is put together to offer guidance to individuals in the industry who are concerned with present approaches and future implications.

With the unique position of the cosmetic and personal care industry of animal testing ban and emergence of REACH, this course is designed to bring together records on key parties involved, market leads and sources for information.

The core of the course is focused on the understanding of current available methodologies to test for safety, their scope and limitations.

Course Director:

Nava Dayan, Ph.D., Skin Care Research Expert

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 24 March 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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

ISO 13485, ISO 9001 and QSR Regulations for Medical Device Companies

ID: 2092

Offering #: 0806-207

11–13 June 2008 • Amsterdam, The Netherlands

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 16 April 2008)

Regular Registration: U.S. \$2645 (\$2535 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 9 for full description of each Accreditation)

16–18 June, 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is designed for personnel in the pharmaceutical, diagnostic, biomedical engineering and biotechnology industries responsible for the specification, development and production of lyophilized products, including:

- Biochemists
- Chemists
- Chemical Engineers
- Microbiologists
- Pharmacists
- R & D Personnel
- Pilot Plant Operations
- Production Supervisors
- Managers
- QA/QC

Those new to the industry and as well as those with previous experience will find the course beneficial.

Course Summary: This course is designed to provide participants with an up-to-date understanding of the theory and practice of lyophilization. Freeze-drying (lyophilization) will be presented and explained in physical, physicochemical, biochemical and engineering terms. Theory and practice will be interrelated and biotechnological and pharmaceutical applications will be emphasized. Participants should acquire a comprehension that transcends common disciplinary boundaries.

Topics covered will include vacuum physics, properties of water and ice, supercooling and supersaturation, phase behavior during freezing, differential thermal analysis, electrical resistance, glassy state behavior, collapse phenomena, desorption phenomena, product formulation, heat and mass transfer, development of freeze-drying cycles, end point determination, residual moisture, product stability, process scale-up, process control and optimization, Current Good Manufacturing Practice (cGMP), and validation. Fault finding and problem solving will be presented using case studies.

Course Director:

Dr. J. Jeff Schwegman, *Co-Founder/Chief Scientific Officer*, BioConvergence LLC

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 21 April 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

Microbiological Control and Validation

ID: 902 Offering #: 0805-303

14–16 May 2008 • Amsterdam, The Netherlands

Who Should Attend: The course is designed for professionals in the medical device, biotechnology and pharmaceutical industries including:

- Those needing a basic knowledge of microbiology as it affects their function
- Microbiology personnel who wish to get updated on new, more reliable rapid testing, monitoring and identification methods
- Audit personnel needing more background in the microbiological aspects to be considered when auditing
- Personnel with little background in microbiology, such as manufacturing, validation, and facilities staff that need to gain a better understanding of how to better deal with microbiological issues

Course Summary: This course will present information on microbiological control in manufacturing, laboratory auditing and sterilization. The course will also cover ISO, EP, BP, USP, AAMI and U.S. FDA documents and guidelines. Validation of sterilization processing will be discussed and case studies will be presented. Environmental monitoring programs will be discussed in depth. Design and testing of product packages for sterility assurance will be covered via case studies. All aspects of microbiological control will be covered. Microbiological testing schemes will be presented and the key aspects of GLP/cGMP will be reviewed.

Course Director:

William Marshall, *President*, William G. Marshall and Associates

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*)

(Must register and pay by 19 March 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

Microencapsulation and Particle Coating

ID: 774 Offering #: 0804-406

22–24 April 2008 • Amsterdam, The Netherlands

Who Should Attend: The course should be of value to those working in microencapsulation, as well as to 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 26 February 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 21 for full description of each Accreditation)

Non-Clinical Drug Safety Evaluation & Drug Development

ID: 1153 Offering #: 0804-207

7–9 April 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is designed for a broad range of pre-clinical, clinical, management, investment, and regulatory personnel in both established and emerging pharmaceutical companies. It will be of special value to:

- Scientists who wish to gain an understanding of pharmaceutical toxicity studies
- Managerial personnel
- Project management staff
- Investors
- Regulatory Scientist involved in preclinical development

Course Summary: This course provides a comprehensive explanation of the non-clinical development of drugs and biologics, emphasizing the principles of pharmaceutical toxicology and the assessment of product safety. In addition to the different types of toxicity studies in modern pharmaceutical development, it also describes the relationship between pharmacology, clinical trial design, regulatory strategy and project management.

Emphasis will be placed on how toxicity studies are integrated into the multidisciplinary development plans of new drugs and biologics, and how they affect development decisions. Regulatory affairs will be covered, and descriptions given of the European and the U.S. FDA requirements, the new drug review process, and common regulatory errors.

The goal of this course is to give a working knowledge of pharmaceutical toxicology and drug development to enable you to develop new drugs faster and more efficiently.

Course Director:

Dr. Shayne C. Gad, Principal, Gad Consulting Services

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*)

(Must register and pay by 11 February 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

Pathways to Skin Penetration

ID: 2149 Offering #: 0804-204

10–11 April 2008 • 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
- Formulation chemistry
- Toxicology and regulatory affairs
- Technical sales and marketing
- Design and development of topically applied formulations

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 14 February 2008)

Regular Registration: U.S. \$1840 (\$1760 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

Pharmaceutical Process Development

ID: 1358 Offering #: 0804-302

14–16 April 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for personnel in process development, technical service and pilot plant groups within the pharmaceutical industry. This includes personnel responsible for manufacturing of dosage forms for clinical studies. It will also be of value to personnel in

- Research & Development
- Regulatory Affairs
- Quality Assurance
- Product Development
- Analytical Services
- CMC Projects
- Production
- Manufacturing

The course is not designed to provide an in-depth review of science and technology of any specific process technology. Other courses offered by the Center should be considered for that purpose.

Course Summary: This three-day course is designed to provide a basic understanding of the significant process development effort involved in taking an R&D laboratory formulation to commercial production.

This course will focus on two main areas:

1. How to develop a pilot process suitable for scale-up to commercial production.
2. Factors to consider during scale-up and technology transfer to take a product from formulation development to the production floor.

The course will review topics such as process flow and equipment selection. Regulatory considerations, such as documentation and a need for pilot scale products to be representative of commercial production, will be discussed.

Various technologies available for manufacturing dosage forms will be reviewed in the context of scale-up parameters. These will include processing methods for mixing, granulation, compression and coating of solid dosage forms, as well as processing methods for solutions, emulsions, suspensions and sterile parenteral products.

Course Director:

Mukund (Mike) Yelvigi, *Director, CMC Development Planning, Wyeth Research Laboratories*

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 18 February 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

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.

Pharmaceutical Use of Near Infrared Spectroscopy

ID: 1583

Offering #: 0805-203

7-9 May 2008 • Amsterdam, The Netherlands

Who Should Attend: The course is intended for NIR professionals who have a direct or even casual interest in the field including:

- Analysts
- Spectroscopists
- Chemists
- Process Engineers

Since it is designed to be practical and down-to-earth, the program is aimed to provide a full understanding of NIR and its applications to the pharmaceutical industry including identity check of incoming raw materials.

Course Summary: This course is designed to provide an overview of modern near infrared spectroscopy for those who are inexperienced in the field. In addition, it should reinforce the lessons learned in instrument manufacturers' training courses or from instruction manuals from specified manufacturers, and will add new perspectives and practical information for the more experienced user. This course will include fundamental information on the optical, spectroscopic, and mathematical principles on which this technique is based. Examples of some of the many applications of NIR to a variety of pharmaceutical problems will be used to describe the technique's utility. Updates on current instrument and data treatment technologies will be included.

Course Director:

Emil W. Ciurczak, NIR Consultant to the Pharmaceutical Industry

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 12 March 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

Powder Mixing Technology

ID: 777

Offering #: 0806-206

9-12 June 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is designed for professionals who are concerned with blended powder R&D and production technology in managerial, operational and supervisory positions involved in such industrial applications as powder metallurgy, food, pigments, cosmetics, pharmaceuticals, chemicals, propellants, ceramics, plastics and fertilizers. This includes:

- Chemical Engineers
- Quality Assurance Specialists
- Pharmacists
- Physicists
- Mechanical Engineers
- Statisticians
- Industrial Engineers
- Chemists
- Scientists

Course Summary: The course presents the principles and techniques of mixing free-flowing or cohesive powders. Selection of suitable industrial equipment for particular mixing duties will be discussed analyzing mixer performance in terms of process advantages, mixture quality and the flexibility of the mixer for multi-product manufacture.

Other topics to be covered include powder sampling techniques, a practical discussion of the statistics of mixing, the significance of statistics in powder formulation, the aggregation of mixtures, and the use of lubricants and flow aids for powders.

There will be special emphasis on the mixing of cohesive powders and the opportunities this can present to produce superior quality mixtures. The handling, packaging and marketing of powder products will also be discussed. Throughout the course, the faculty will relate principles to specific industrial problems.

The practical industrial application of powder mixing, powder aggregation and handling principles can be extended with an optional day visit to Hosokawa Micron and Gemco.

Course Director:

Professor Norman Harnby, School of Engineering, University of Bradford, England

Tuition:

Early Registration (SAVE \$200):

(Must register and pay by 7 April 2008)

Regular Registration:

Days 1-3

U.S. \$2420 (\$2310 with Group Rate*)

U.S. \$2620 (\$2510 with Group Rate*)

Days 1-4

\$2675 (\$2555 with Group Rate*)

\$2875 (\$2755 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 21 for full description of each Accreditation)

Preparation, Packaging and Labeling of Clinical Trial Materials

ID: 858

Offering #: 0807-203

7-9 July 2008 • Amsterdam, The Netherlands

Who Should Attend: This introductory survey course will emphasize the procedures and techniques needed to prepare compliant clinical trial supplies. The course is intended for personnel who are new to the clinical supply process and well as for those who have experience in CTM preparation but want to update or refresh their knowledge. This includes, but is not limited to those involved in:

- Packaging
- Labeling
- Regulatory Affairs
- Clinical Manufacturing
- Quality Assurance/Control
- Research & Development
- Contract Packaging

Course Summary: The aim of this comprehensive survey course is to provide an introduction to the many details that must be considered in the design, preparation, packaging, labeling and distribution of clinical trial materials in support of adequate and well-controlled clinical studies. Emphasis will be given to practical examples of procedures, components, and regulatory requirements needed to provide acceptable investigational materials. Comparison of the requirements of the United States and Europe and consideration of the harmonization of international clinical studies will be given.

The interrelationships of the industrial pharmacist, clinical research associate, medical monitor, regulatory officer, clinical pharmacist, clinical supplies and quality assurance/control personnel will be discussed. In addition, cGMP will be reviewed to ensure compliance during the preparation, use and return of the trial materials.

The course provides participants the opportunity to share experiences with faculty and colleagues about effective methods to design, produce, package, and label clinical trial materials. The concepts presented during the course are integrated by means of case studies that consider real-world clinical trial supply problems and solutions.

Course Director:

Dr. Efreem Zaret, *President*, EZ Associates, Inc.

Tuition:

Early Registration (SAVE \$200): U.S. \$2375 (\$2265 with Group Rate*) (Must register and pay by 12 May 2008)

Regular Registration: U.S. \$2575 (\$2465 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

REACH: Registration, Evaluation and Authorization of Chemicals

ID: 2145

Offering #: 0805-506

26-28 May 2008 • Hoofddorp, The Netherlands

Who Should Attend: This course offers a comprehensive review of the most recent European harmonized chemical policy. It is designed for professionals involved in all aspects of chemical applications for a wide range of product development, including:

- Research & Development
- Technology, Formulation & Product Development
- Marketing & Technical Sales
- Business Decision Makers
- QA & QC Professionals
- Regulatory Affairs

This course would also benefit producers, manufacturers, processors and users within the chemical and cosmetic industry.

Course Summary: This course will provide an in depth overview of the REACH chemical program for professionals involved in chemical applications for all aspects of product development with business interests in the European Union. It will also provide a side by side comparison and contrast of REACH and its various international chemical regulation counterparts in other major world markets. Particular attention will be given to the basic regulatory components of REACH, regulatory authorities, the implementation infrastructure and initial schedules for compliance. Finally, small group discussion/workshops will be conducted throughout the course to familiarize the participants with the impact of REACH concerning the chemical industry (manufacturers and users alike) in terms of the potential enforcement outcomes, the socio-economic cost, and the possible evolution of the best industrial practice for compliance.

Course Director:

Wen Schroeder, *President*, SEKI Cosmetics, LLC

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 31 March 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 21 for full description of each Accreditation)

Risk Analysis and Human Factors Engineering

ID: 2106

Offering #: 0806-306

16–17 June 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is designed for those who work in the medical device industry and who currently are or wish to design and sell their products in US, Europe and other parts of the world. This includes, but is not limited to those in the following functions:

- R&D and Quality Engineering
- QA or Regulatory
- Engineering and Manufacturing

All participants will gain tools to incorporate risk analysis throughout the quality system in compliance with global regulations and to ensure safe devices.

Course Summary: This course will review the current regulations and expectations for the use of risk management processes and methods in the life cycle of medical devices. We will discuss the use of the ISO 14971:2000 standard and FDA's guidance documents on Human Factors Engineering to provide a clear understanding of what techniques to use and when they should be implemented. Practical workshop activities will provide guidance on how customer use and potential misuse information can be acquired and used, as well as actual performance of various risk analysis techniques. The course will also provide guidance on what type of risk analysis should be performed at each phase of the medical device history, from early design concepts through use in the field.

Course Director:

Bea Salis, *Consultant, QualASyst International*

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by 21 April 2008)

Regular Registration: U.S. \$1940 (\$1860 with Group Rate*)

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 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# 716-000-05-504-L04



(Please refer to page 21 for full description of each Accreditation)

Root Cause Investigation for CAPA

ID: 2089

Offering #: 0804-205

8–9 April 2008 • Amsterdam, The Netherlands

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 12 February 2008)

Regular Registration: U.S. \$1840 (\$1760 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 21 for full description of each Accreditation)

Skin Product Development

ID: 1050 Offering #: 0804-203

7–9 April 2008 • Amsterdam, The Netherlands

Who Should Attend: The course is designed for individuals who are engaged in the personal care, cosmetic and pharmaceutical industries. It is intended for individuals who work both in the development of raw materials, delivery systems and finished formulations, including:

- Research and Development
- Technical Sales
- Formulations Development
- Marketing

Course Summary:

The design of topically applied formulation combines scientific knowledge in physics, chemistry, engineering and biochemistry and requires imagination and artistic skills.

Throughout the design, one must become familiar with the fundamentals of skin structure, its pharmacology and possible delivery approaches. The understanding of formulation's physical properties, ways of measuring these properties are additional essential aspects to learn.

Becoming familiar with both, one can extrapolate the possible interactions between a topically applied formulation and the skin as a viable organ. This can allow for optimization of development.

Over the past decade, both the pharmaceutical and cosmetic industries have gone through major changes that are mainly driven by consumer demand, aggressive market claims, regulatory issues and scientific breakthrough discoveries.

This course will provide participants with understanding the diversity of the above and will channel and focus their development approaches. It will also provide knowledge in related terminology to create sales tools and marketing claims.

Course Director:

Nava Dayan, Ph.D., *Skin Care Research Expert*

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 11 February 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

Sterile Products: Formulation, Manufacture and Quality Assurance

ID: 435

Offering #: 0806-103

2–4 June 2008 • Amsterdam, The Netherlands

Who Should Attend: This **overview** course is intended for those having specific responsibilities in the areas of sterile drug product science and technology. It will be of particular value to those in:

- Research
- Production
- Development
- Quality Assurance and Control

Those who wish to broaden their appreciation of these technologies and review the latest developments, as well as managers who have responsibility for a broader base of activities will find the course of interest.

Course Summary: This comprehensive course provides an appreciation and general understanding of the overall contemporary state of science and technology associated with the design, development and manufacturing of sterile drug dosage forms. Emphasis will be oriented toward formulation development and product manufacture of quality sterile dosage forms that meet or exceed expected good manufacturing practice requirements.

Course Director:

Dr. Michael J. Akers, *Senior Director of Pharmaceutical R&D, Baxter BioPharma Solutions*

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 7 April 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 21 for full description of each Accreditation)

Sterilization in the Pharmaceutical Industry

ID: 2075 Offering #: 0805-205

8–9 May 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is designed for pharmaceutical and related industry personnel who participate in acquiring and preparing data related to the sterilization technology section of regulatory filings to the FDA. It is best suited for supervisors, managers, and directors in many disciplines including:

- Quality Assurance
- Production
- Microbiology
- Engineering
- Regulatory Affairs

This course may also be useful to management personnel that wish to understand the requirements of sterilization process validation documentation essential to regulatory agencies.

Course Summary: This course will include discussion on topics such as container/closure integrity testing, product stability studies, engineering heat penetration and distribution studies, container thermal mapping, and environment control programs. In addition to an overview of moist heat sterilization, and FDA requirements, the attendees will participate in the resolution of proposed case studies, and perform data calculations and graphing exercises to assure a practical understanding of the sterilization principles and procedures that will be discussed. Discussions on how moist heat sterilization is employed during aseptic processing, and the requirements for moist heat sterilization of aseptic processing equipment and product components will also be presented. Emerging regulatory positions in the USA, and Europe regarding moist heat sterilization will be summarized. On the final day, the course allows for interactive time to clarify issues, topics, or offer suggestions regarding actual situations that the attendees may be encountering.

Course Director:

Jeanne Moldenhauer, *Pharmaceutical Consultant*, Vectech Pharmaceutical Consultants, Inc.

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Rate*) (Must register and pay by 13 March 2008)

Regular Registration: U.S. \$1840 (\$1760 with Group Rate*)

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 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# 716-000-08-620-L04



(Please refer to page 21 for full description of each Accreditation)

Sunscreen Technology and Product Development



ID: 2017 Offering #: 0805-404

21–23 May 2008 • Hoofddorp, The Netherlands

Who Should Attend: This course is designed for professionals in the personal care, cosmetic and pharmaceutical industries engaged in sunscreen product development, including:

- Research & Development
- Marketing & Technical Sales
- Business Decision Makers
- Technology, Formulation & Product Development
- Regulatory Affairs
- QA & QC Professionals

Course Summary: To formulate a successful sunscreen product for topical application requires a multidisciplinary approach. Factors need to be taken into consideration include the current market trends & demands, regulatory framework & compliance requirements, scientific learning on skin structure and function, UV-interacting chemistry & science, and appropriate delivery systems for optimal effectiveness and safety. This course will provide an overview of sunscreen regulations and technologies that enable the participants to design proper strategies for successful product development and marketing. In addition, small group discussion / workshops on real-life case studies will be conducted throughout the course to familiarize the participants with the complex regulatory framework and product labeling & advertising guidelines.

Course Director:

Wen Schroeder, *President*, SEKI Cosmetics, LLC

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 26 March 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 21 for full description of each Accreditation)

9–12 June, 2008 • Amsterdam, The Netherlands

Who Should Attend: This **intensive** training course is designed for professionals in various industrial fields including: detergents, cosmetics, agrochemicals, pharmaceuticals, biotechnology, paints, paper coatings, inks, ceramics. It would be most beneficial for:

- Research and Development Scientists
- Formulation Chemists
- Material scientists and biologists

The course can also be valuable to postgraduate research staff.

Course Summary: This course is designed to bring you up-to-date on the basic principles involved in colloid and interface science, as well as surfactants, and to demonstrate their relevance for solving practical problems. Such problems are encountered in various engineering aspects of formation of dispersions, their long-term physical stability, and the preparation of various systems of paints, inks, agrochemicals, pharmaceuticals, ceramics, detergents and many household products. The course provides the fundamental principles of colloid and interface science, with particular emphasis on surfactants and their applications. Theories are adequately described, but more emphasis is given toward commercial application of the fundamental concepts. Application of these fundamental principles follows in a logical way. Practical examples of formulation solving are included and you are encouraged to bring your problems and needs for public or private discussion with the faculty.

Course Co-Directors:

Dr. Gregory D. Botsaris, *Professor of Chemical Engineering, Tufts University*

Dr. Tharwat F. Tadros, *Independent Consultant*

Tuition:

Early Registration (SAVE \$200): U.S. \$2600 (\$2480 with Group Rate*) (Must register and pay by 14 April 2008)

Regular Registration: U.S. \$2800 (\$2680 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 21 for full description of each Accreditation)

Surviving an FDA Inspection—FDA Inspections of Non-U.S. Sites

ID: 1880 Offering #: 0806-301

16–17 June 2008 • Amsterdam, The Netherlands

Who Should Attend: This **overview** course is intended for individuals whose functions have direct or indirect involvement with FDA inspections. These functions include among others:

- Regulatory Affairs
- Plant Management
- Engineering
- Quality Systems Management
- Quality Assurance/Control
- Auditing
- Research & Development
- Documentation Management

The course will focus on various types of inspections in the pharmaceutical and related industries and will look at policies, procedures and experiences relevant to those inspections.

Course Summary: This course provides an **overview** of the FDA inspection process in general and of particulars applicable to “foreign inspections”. It provides a background and understanding of the role played by the Agency, its administrative and enforcement powers. The course provides a step by step description of the inspectional process with specific examples regarding cGMP compliance inspections and pre-approval inspections.

The latest FDA initiatives regarding inspections, like risk based approach and system based approach, will be discussed in detail. This will enable participants to better understand how to prepare their companies for FDA inspections.

The course consists of lectures, discussions, case studies analysis, and a hands-on workshop in setting up a company policy/procedure for handling inspections.

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 21 April 2008)

Regular Registration: U.S. \$1840 (\$1760 with Group Rate*)

Attend this course and its companion course **Auditing for cGMP Compliance** (ID# 1881) and save \$300[†].

See page 2 for course description. [†]Discount applies only to combined regular tuition.

ACCREDITATIONS/CERTIFICATIONS



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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# 716-000-07-803-L04*



(Please refer to page 21 for full description of each Accreditation)

9–11 June 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for professionals in the pharmaceutical and allied industries who must write or revise documents that are integral to product development and production. It is ideal for those in

- Research & Development
- Quality Control
- Regulatory/Compliance
- Validation

This includes, but is not limited to:

- Engineers
- Scientists
- Chemists
- Technicians

This course is also intended for those who wish to gain better writing skills and learn more effective ways to deliver technical information.

Course Summary: This practical course will teach you the basic steps in preparing those written documents most frequently required in the pharmaceutical and related industries. Through lectures, discussions, and workshops, you will learn to work your way through the writing process to express complex ideas clearly and to organize your writing into standard forms such as memos, letters, proposals, and reports. You will also learn strategies for revising, editing, and documenting your work.

Course Director:

Patricia Wagner, Professor of English, Victor Valley College

Tuition:

Early Registration (SAVE \$200): U.S. \$2385 (\$2275 with Group Rate*) (Must register and pay by 14 April 2008)

Regular Registration: U.S. \$2585 (\$2475 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 21 for full description of each Accreditation)

Vendor and Contract Supplier Qualification

4–6 June 2008 • 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*) (Must register and pay by 9 April 2008)

Regular Registration: U.S. \$2545 (\$2435 with Group Rate*)

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 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# 716-000-07-170-L04



(Please refer to page 21 for full description of each Accreditation)

General Information

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 reviewed and approved as an Authorized Provider (#640) of continuing education and training programs by the International Association for Continuing Education and Training (IACET). Continuing

Education Units (CEU) will be awarded for participation in this course at a rate of 0.1 CEU per contact hour. 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.



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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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.

Locations CfPA courses on pages 1-20 are held in the following hotels. Please refer to individual course on our website for appropriate location.

Amsterdam, The Netherlands

NH Amsterdam Centre Hotel:

Stadhouderskade 7
1054 ES Amsterdam, The Netherlands
Phone: +31/20/685.13.51 • Fax: +31/20/685.16.11

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

Amsterdam Marriott Hotel:

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

Mövenpick Hotel Amsterdam City Center:

Piet Heinkade 11-19
1019 BR Amsterdam, The Netherlands
Phone: +31.20.519.1200 • Fax: +31.20.519.1239

Crowne Plaza Amsterdam City Centre:

Nieuwezijds Voorburgwal 5
1012 RC Amsterdam, The Netherlands
Phone: +31/20/620.05.00 • Fax: +31/20/620.11.73

Golden Tulip Apollo Amsterdam:

Apollolaan 2
1077 BA Amsterdam, The Netherlands
Phone: +31/20/673.5922 • Fax: +31/20/570.5744
Tele: 14084

Renaissance Amsterdam Hotel:

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

Amsterdam American Hotel:

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

Dublin, Ireland

Radisson SAS St. Helen's:

Stillorgan Road, Dublin 4, Ireland
Phone: +353/1/218.6000 • Fax: +353/1/218.6010

Den Haag, The Netherlands

NH Den Haag:

Prinses Margriet Plantsoen 100
2595 BR The Hague
Tel.: +31.70.3812345
Fax: +31.70.3812323

Hoofddorp, The Netherlands

Courtyard by Marriott-Amsterdam Airport:

Kruisweg 1401
2131 MD Hoofddorp, NL
Phone: +31/23/556.9000
Fax: +31/23/556.9009

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

Tuition payable in US funds net of all charges includes luncheon, breaks and course notes.

Payment is due prior to course start date. If payment has not been received two weeks before the course, a credit card will be required to guarantee admittance.

Discounts/Rates: Early registration discount requires payment at time of registration and before expiration or regular tuition will apply.

***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: 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.

Confirmation Letters: Before each course begins, all registrants will receive written confirmation including detailed information regarding course location. If confirmation is not received two weeks prior to the course please contact us.

For those requiring visas, confirmation letters will not be sent until payment is received.

Please note: **English** will be used in all lectures and course notes.

For our full terms and conditions, visit www.cfpa.com.

For course information, go to www.cfpa.com

ID: 2148 - Offering: 0712-802 - BID: C7-376

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



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April – July 2008 European Course Offerings

Course Topics in this Catalog Include:

ICH Q9: Managing Risk in Pharmaceutical Manufacturing, Critical Process Cleaning and Cleaning Validation, Pathways to Skin Penetration, ISO 13485, ISO 9001 and QSR Regulations for Medical Device Companies, REACH: Registration, Evaluation and Authorization of Chemicals, Technical Writing in Pharmaceutical and Allied Industries



www.cfpa.com

Registration

ONLINE: www.cfpa.com
 (Please Use Priority Code Below)

FAX: +31.20.620.21.36

MAIL: The Center for Professional Advancement (CfPA)
 Oudezijds Voorburgwal 316A • 1012 GM Amsterdam, The Netherlands

Name		Title	
Company			
Address			
Postal Code	City		Country
Phone	Fax	E-mail	

Instructions:

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

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

Course Title: 1)	Course ID#	Tuition
2)		
3)		
		Total \$

Payment

- Send Invoice** (POs must be received in advance of course) **Check:** Payable in US funds to: **The Center for Professional Advancement**
- Bank Transfer** (Pay by Bank Transfer to Account No. 62.62.46.628 at ABN-AMRO Bank N.V., Postbus 407, 1000 AK Amsterdam, The Netherlands. The course offering number and participant's name must be included on bank transfer.)
- Credit Card:** ___ Visa ___ Mastercard ___ American Express **Card #:** _____ **Exp. Date:** _____
- Cardholder Name:** _____ **Signature:** _____



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