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Accredited Technical Training for the Pharmaceutical, Biopharmaceutical and Related Industries

Course Catalog




September – December 2008 European Course Offerings

Course Topics in this Catalog Include:

- Advanced Tablet Press Operation **NEW!**
- Critical Process Cleaning and Cleaning Validation
- Endotoxin Testing: Drugs, Medical Devices and Biopharmaceuticals
- Fundamentals of Biotechnology **NEW!**
- Role of PAT and QbD in Biologic Drug Production **NEW!**
- Packaging of Pharmaceuticals

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

September - December 2008 Accredited Technical Training for the Pharmaceutical, Biopharmaceutical and Related Industries

Welcome

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:








www.cfpa.com/online-training
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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.

Advanced Tablet Press Operation

ID: 2206 Offering #: 0812-203

8-9 December 2008 • Hoofddorp, The Netherlands

Who Should Attend: This course is intended for personnel needing a comprehensive understanding of tablet press operation. Those who have gained valuable information from this course include:

- Fully trained process operators
- First line supervisors and managers
- QA personnel competent in tablet press understanding
- Regulatory Affairs Personnel competent in tablet press understanding

This course is intended for individuals competent in tablet press operation and wishing to acquire advanced knowledge of the tablet press, its operation and troubleshooting complex problems. This course is NOT intended for untrained operators, newly hired technical and senior managerial personnel, for whom other related courses are available.

Course Summary: This course is an advanced course for process operators and first-line supervisors. The course begins with a basic review of the tablet compressing cycle, then continues with a comprehensive discussion of all aspects of tablet press set up, start up, computer adjustment and problem solving. The application of cGMP, as applied to tablet press operation, will also be presented.

The course includes video presentation, two workshops and discussion periods between faculty and course participants. Problem-solving sessions are held on both an open and private basis.

Course Director:

Fred A. Rowley, Director, Watson Pharmaceuticals

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by 13 October 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

Analytical Methods Validation for FDA Compliance

ID: 1887 Offering #: 0810-508

27-29 October 2008 • Dublin, Ireland

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 1 September 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 and Inspecting Preclinical Research for GLP Compliance ID: 1774 Offering #: 0812-102

1–3 December 2008 • Amsterdam, The Netherlands

Who Should Attend: This advanced course is designed for Quality Assurance personnel, or managers wishing to know more about how best to implement and audit GLP in their facilities. As the course explores issues innovative to the GLP arena, it provides an opportunity for experienced personnel to update their competencies. Participants may come from:

- Industry
- Academia
- Government
- Contract Testing Facilities

Course Summary: This course will explore the activities of a Quality Assurance department when auditing studies for GLP compliance. All aspects of QA work will be discussed including; the preparation of planning documents, review of protocols and SOPs, inspection of facilities and processes, performance of inspections of in-life phases and the audit of final reports. The presenters will consider how an effective rationale can be developed to provide a solid basis for the implementation of a QA audit & inspection program. Consideration will be given to the auditing of suppliers and subcontractors and the role of QA vis-à-vis computer systems. The reference materials will be the FDA and OECD Good Laboratory Practice Regulations and the series of monographs of the OECD relating to the interpretation of the GLP text. Time will also be given to the setting up of quantitative techniques for the measurement of Quality, enabling participants to follow the compliance level within laboratories. Lectures will be supplemented with many interactive case studies, problem solving experiences and workshops. Emphasis will be on the options available for meeting regulatory requirements.

Course Director:

David Long, Consultant

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 6 October 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)

Biopharmaceutical Process Systems: Design, Engineering & Validation ID: 1116 Offering #: 0810-205

6–8 October 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for operating and engineering personnel involved in specifying, designing, installing, commissioning and validating biopharmaceutical production equipment. The course will cover the entire project lifecycle, with particular focus on key decision points, design parameters and drivers for success.

Course Summary: All biopharmaceutical products are manufactured in a regulated environment to ensure the quality and safety of these substances. Biopharmaceutical facilities are licensed to manufacture a specific product and are inspected by regulatory agencies such as: FDA, European Agency for the Evaluation of Medicinal Products (EMA), and Medicines Control Agency (MCA) in the UK. These agencies provide a framework for process equipment GMP requirements. Process equipment suppliers also offer specific design features to optimize operation, cleaning and maintenance of integral production modules.

Design specifications for biological process equipment including process requirements and functional requirements to define material selection, instrumentation and controls, and for interfacing with facility utility systems will be discussed. Process and facility validation requirements for the process modules will be related to their ultimate use. Finally, the process unit modules must be able to operate and perform as an integrated production train. Practical solutions to real issues will be emphasized.

Course Director:

Charles A. Clerucuzio, P.E., Vice President, Biopharmaceuticals AMEC, Inc.

Tuition:

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

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

ACCREDITATIONS/CERTIFICATIONS



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

Calibration in the FDA Regulated Industry

ID: 2026 Offering #: 0810-504

30–31 October, 2008 • Amsterdam, The Netherlands

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
- Quality Engineering
- Technical Support
- Research and Development
- Facilities and Equipment Maintenance

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 4 September 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)

cGMP for Pharmaceutical Production Supervisors

ID: 604 Offering #: 0810-304

14–16 October, 2008 • Amsterdam, The Netherlands

Who Should Attend: This practical course is intended for professionals in the pharmaceutical, cosmetic and related industries, including:

- First-line production
- Foremen
- Quality control supervisors
- Group leaders of incoming inspection

It is most beneficial to manufacturing personnel involved in:

- Packaging
- Materials handling
- In-process inspecting
- Final inspecting
- Maintenance and warehousing
- Processing

Higher level technical and managerial personnel will find the course a worthwhile refresher of the basics and interpretive aspects of the regulations.

Course Summary: This course will provide an orientation and understanding of the Current Good Manufacturing Practice segment of the U.S. Food, Drug, and Cosmetic Act. The course will cover supervisory techniques and practices for complying with the U.S. FDA regulations in packaging, assembly, production and manufacturing. It will provide a practical application of the cGMP on the operating level. Actual experiences and case studies will be included. Ample time will be given to the specific problems of participants. This course will prepare first-line supervisors and other plant manufacturing personnel to successfully discharge their responsibility for implementing a company's cGMP program.

Course Director:

Dr. Mary Foster, VP Regulatory Compliance, Catalent Pharma Solutions (formerly Cardinal Health, PTS)

Tuition:

Early Registration (SAVE \$200): U.S. \$2645 (\$2535 with Group Rate*) (Must register and pay by 19 August 2008)

Regular Registration: U.S. \$2845 (\$2735 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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

Clean Room Technology

ID: 23 Offering #: 0810-204

9–10 October 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for all personnel involved with the following areas of pharmaceutical and medical device sterile facilities:

- Design
- Construction
- Validation
- Operation
- Monitoring

Other personnel who will find this course of interest:

- Design Engineers
- Contractors
- Equipment Manufacturers
- Regulatory Affairs
- Production
- QA/QC
- Maintenance

Course Summary: This course reviews the current state of the technology associated with pharmaceutical, medical device, active pharmaceutical ingredient, medical component, R&D, and microbiological clean rooms. Regulations and guidelines for the U.S. and E.U. will be covered.

The course is conducted in an environment that encourages discussion, questions, input, and debate by the attendees. Case studies of actual rooms are presented. Attendees are invited to bring their own projects for discussion and review.

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Group Rate*) (Must register and pay by 14 August 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)

Commissioning, Qualification & Validation

ID: 1954 Offering #: 0812-205

8–10 December 2008 • Amsterdam, The Netherlands

Who Should Attend: This advanced course is designed for individuals responsible for validation, commissioning, construction, or design who need a thorough understanding of the Validation and Commissioning Process for approved pharmaceutical/biopharmaceutical manufacturing facilities. The course will benefit individuals in:

- Engineering
- Quality Control/Assurance
- Regulatory Affairs
- Technical Services/Validation
- Production

Pharmaceutical Industry Service Providers will also find this course beneficial.

Course Summary: Because validation is the critical factor in achieving FDA approval of new and renovated facilities, it is essential that validated systems and equipment be commissioned using GEP in a manner to facilitate the validation process.

This course will cover what has become the traditional approach to conduct Qualification and Validation, and will also show how that approach supports the new Regulatory Science and Risk Based Approach for the 21st Century. Current industry application of the impact assessment process for utility systems and equipment will be covered, and assessment results on Master Plans will be explained. The course demonstrates the importance of applying Good Engineering Practice in the preparation of design specifications, conducting design qualification, and correctly establishing contractor responsibilities for adherence to these specifications during construction and installation.

The course will show the relationship of all the steps in commissioning to the project life cycle. Necessary elements will be explored in detail to assure a successful integrated commissioning/qualification effort. Examples will be used to provide guidance for development of sound commissioning and validation programs resulting in reduction of cost and time of 10%-20%.

Course Director:

Steven Wisniewski, *Senior Associate and Director of Compliance*, Integrated Project Services (IPS)

Tuition:

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

Critical Process Cleaning and Cleaning Validation

ID: 1867 Offering #: 0812-101

3–5 December 2008 • Dublin, Ireland

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

- Process Engineering
- Quality Assurance
- Technical and management positions
- Production
- Validation

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 8 September 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)

Developing Specifications for Drug Substances (APIs) and Drug Products

REVISED!

ID: 1918 Offering #: 0810-307

13–16 October, 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for personnel from both Generic and Research-based pharmaceutical industries including:

- Pharmacists
- Regulatory Affairs Personnel
- Pre-clinical scientists will benefit from the course by gaining a better understanding of the complexities of the drug development process and of the importance of setting specifications
- Analytical and Synthetic Chemists from R&D
- Staff from production departments and from QA and QC

Course Summary: The course will present a review of the activities that will occur in the process of setting specifications for APIs made by synthesis or conventional fermentation. Critical specification issues for drug substances and drug products will be reviewed, specifically focusing on the interactions and dialogue necessary between analytical and pharmaceutical/chemical groups during the development of specifications. Using practical examples, the importance of understanding "real-life" constraints and regulatory requirements will be highlighted across a wide variety of drug product formulations. Strategies for Out-Of-Specification (OOS) findings will be discussed. The course will review the latest activities of ICH with respect to specifications for drug substances and drug products. You will benefit in your job by applying facts learned in this course. Increases in productivity will result. An open and interactive environment is encouraged throughout the course.

The optional fourth day includes topics on ICH Q7, and GMPs for the production of APIs.

Course Director:

Goetz E. Hardtmann, Ph.D., *Senior Partner*, H&H Consultants

Tuition:

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

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

Days 1-3

U.S. \$2345 (\$2235 with Group Rate*)

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

Days 1-4

\$2600 (\$2480 with Group Rate*) (Must register and pay by 18 August 2008)

\$2800 (\$2680 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 #: 0812-301

15-17 December 2008 • Amsterdam, The Netherlands

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 20 October 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)

Endotoxin Testing: Drugs, Medical Devices and Biopharmaceuticals

ID: 526 Offering #: 0811-109

3-5 November 2008 • Amsterdam, The Netherlands

Who Should Attend: The course will benefit those involved in testing pharmaceutical, medical device and biotechnology products, especially:

- QA/QC Personnel
- Laboratory managers
- Analysts
- Senior technicians

It will be of particular value to those involved in the establishment of new programs and to those who have recently started work and management in this area. The course will also benefit those concerned about endotoxin contamination of tissue culture media.

Course Summary: The aim of this course is to give you a full understanding of the bacterial endotoxins test, including principles, practice, limitations and regulatory considerations. Endotoxins are recognized as being by far the most significant pyrogen, but they are often poorly understood. LAL testing for the presence of endotoxins is an established procedure in the manufacture of products that enter the blood stream. The course covers the nature of endotoxins and the implications of their biochemical properties for the LAL test and cell cultures. The principles of the various LAL methodologies are given and the advantages/disadvantages of each are considered. Strategies for overcoming and avoiding problems are explained. The course examines the FDA Guideline on LAL Testing and the USP Bacterial Endotoxins Test with a view to writing SOPs for LAL testing. The value of in-process testing is stressed.

Course Director:

Dr. Michael E. Dawson, Director of Regulatory Affairs, Associates of Cape Cod, Inc.

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 8 September 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 #: 0811-207

13-15 November 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, "LOOK OUT", © 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 18 September 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

Fired Process Heaters

ID: 259

Offering #: 0811-110

3-6 November 2008 • Amsterdam, The Netherlands

Who Should Attend: The course is intended for professionals working with fired process heaters in the petroleum, petrochemical, chemical and allied industries and would be especially valuable to:

- Process Designers
- Maintenance Personnel
- Process Engineers
- Operators
- Those involved in design, retrofitting and specification

Course Summary: This course will provide an insight into the **basics** of thermal and mechanical design of furnaces, and the safe and efficient operation of this equipment. Emphasis will be on common design methods, consideration of fuel type, combustion chemistry and heat release, and combustion air supply and control. Mechanical factors will include burners, refractories, instrumentation, tube design, and corrosion and fouling mitigation. Techniques to improve efficiency, operate safely and meet emission guidelines will be reviewed.

Course Director:

Eugene Barrington, Senior Staff Engineer, Retired, Shell Oil Company

Tuition:

Early Registration (SAVE \$200): U.S. \$2900 (\$2780 with Group Rate*) (Must register and pay by 8 September 2008)

Regular Registration: U.S. \$3100 (\$2980 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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

Fluid Flow and Line Sizing



ID: 2162 Offering #: 0809-409

25–26 September 2008 • Amsterdam, The Netherlands

Who Should Attend: The course is directed primarily toward entry level personnel responsible for the design, construction and maintenance of piping and fittings. The material would be of value to the staff of facilities where the flow of fluids is essential. It will apply to many industries such as

- Process
- Power systems
- Pharmaceutical
- Refinery systems

The information found in this course would be useful for many phases of plant operations including process piping development, start-up, operation, scale-up, troubleshooting and maintenance.

Experienced process and mechanical engineers, as well as management and quality assurance personnel responsible for piping systems oversight, will find the course material useful.

Course Summary: This course is intended to bridge the gap between fluid mechanics theory and the practical demands of industrial pipe sizing, systems design and troubleshooting. It provides systemic methods and shortcuts for analyzing flow and pressure drops in piping systems, beginning with relatively simple techniques for incompressible fluids, to the more complex analysis of two-phase flow in piping systems.

The course includes:

- Examination of the effect of fluid properties on fluid flow through piping systems
- How to estimate or extrapolate these properties logically
- An introduction to the pipe, tubing and fittings, and their impact on fluid flow and pressure drop
- Special attention to control valves and safety pressure relief devices
- Simple incompressible fluids, such as liquids; compressible fluids, such as gases and vapors, with the more complex two-phase flow systems
- Vacuum piping, its similarities and differences to gas flow; sizing and selection of vacuum equipment
- Sizing and selection of fluid movers, such as pumps, fans, blowers and compressors; identifying and solving the various problems such as cavitation and surge
- Shortcut methods which can increase efficiency in pipe sizing and troubleshooting

Course Director:

Edward T. Luckiewicz, Adjunct Professor Emeritus of Chemical Engineering, Drexel University

Tuition:

Early Registration (SAVE \$200): U.S. \$1690 (\$1610 with Group Rate*) (Must register and pay by 31 July 2008)

Regular Registration: U.S. \$1890 (\$1810 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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

Fundamentals of Biotechnology



ID: 2197 Offering #: 0812-207

8–11 December 2008 • Amsterdam, The Netherlands

Who Should Attend: This introductory-level course is for the non-specialist interested in learning the basics of biotechnology. It presents essential information for personnel involved in, or contemplating participation in, biochemically-related and biotechnological research, supervision, scale-up or manufacture. It is most useful for:

- Non-specialist Scientific Personnel
- Engineers
- Chemists
- Technical Operations Personnel
- Lawyers

This course is not intended for those with extensive background in the field.

Course Summary: With the rapid developments in genetic engineering, it has become increasingly important to have a firm background in the basics pertaining to this area of research and technology. This course is designed to provide these fundamentals. The course will present the properties and manipulation of genetic material and will examine the primary gene product—the protein. Details of current approaches for making recombinant DNA and its use will be emphasized. Participants will be introduced to the fundamentals of genetic engineering through a study of molecular biology pertaining to the biochemistry of DNA and RNA, their structure and synthesis. Transfer of genetic information and its expression into product will provide the necessary background for the study of genetic engineering techniques. The course will focus on the basics of cutting and splicing DNA (gene cloning) and of introducing recombinant DNA into cells for expression into product. The state-of-the-art techniques for manufacturing and purifying a product will also be presented.

Course Director:

Ronald A. Pepin, Ph.D., Senior Vice President, Business Development, Medarex, Inc.

Tuition:

Early Registration (SAVE \$200): U.S. \$2600 (\$2480 with Group Rate*) (Must register and pay by 13 October 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)

Good Laboratory Practices (GLP)

ID: 545 Offering #: 0809-501

29 September – 1 October 2008 • 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
- Quality Assurance Staff
- Those newly assigned GLP responsibilities
- 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 Director:

David Long, Consultant

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 4 August 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)

Hydrogenation Technology

ID: 150 Offering #: 0810-409

20–22 October 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is designed for technical professionals who are, or will be, involved with hydrogenation processes in R&D or manufacturing situations for the specialty chemical, pharmaceutical, and petrochemical industries.

It would be of particular benefit to:

- Chemists
- Laboratory Personnel
- Production Personnel
- Engineers
- Pilot Plant Personnel
- Process Development Personnel

Course Summary: This is a survey course intended to provide participants with a practical understanding of hydrogenation. The role of catalysts will be covered, including specific industrial catalysts and the reactions and processes where used. Emphasis will be placed on the design and layout of the hydrogenation laboratory, pilot plant and commercial plant and on hydrogenation operations in laboratory, pilot plant and plant equipment. The design of batch and continuous reactors, hydrogen handling and overall operation safety will also be discussed.

Course Director:

Dr. A.K.S. Murthy, Technology Fellow, The Linde Group

Tuition:

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

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

ACCREDITATIONS/CERTIFICATIONS



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

ICH-Q7: Harmonized GMPs for API Production and Control

ID: 2091

Offering #: 0812-104

3–5 December 2008 • Amsterdam, The Netherlands

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

- QA/QC
- Auditing
- Validation
- Regulatory Affairs
- Pilot and Commercial Production
- Engineering
- Technical Services
- Process Development

Corporate managers benefit from opportunities the course offers for individual and group discussion of compliance issues. Regulatory Agency Investigators are encouraged to attend.

Course Summary: This course will prepare you to meet the varied challenges now facing the global active pharmaceutical ingredient industry. It is important that API production facilities operating under different national and international regulatory authorities not be required to meet diverse standards. For this reason an Expert Working Group in ICH developed the ICH-Q7 document as a single standard that all suppliers must apply to production of APIs used in human drug products manufactured in any of the ICH signatory regions.

This course will provide historical insight into the development of the Q7 document and specific interpretation of requirements in the document. The Q7 document addresses all aspects of API production in 19 sections, and each of these sections will be examined in detail during the course. Throughout the formal presentations participation by the registrants is welcome. There are interactive exercises periodically spaced through the first two days that allow registrants to analyze real life situations that occur in typical operations. These afford an opportunity to exchange information and approaches with colleagues. The final activity is a workshop in which registrants are asked to apply what they have learned to resolve issues in test cases.

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$2355 (\$2245 with Group Rate*) (Must register and pay by 8 October 2008)

Regular Registration: U.S. \$2555 (\$2445 with Group Rate*)

ICH Q10: Pharmaceutical Quality System

ID: 2131

Offering #: 0811-103

6–7 November 2008 • Amsterdam, The Netherlands

Who Should Attend: This course has been designed to benefit those in the Pharmaceutical industry with responsibilities related to the design, operation or management of the overall Quality System or any individual quality system used by the industry. The course is particularly suitable for personnel working in:

- Site & Corporate Management
- Production
- Pre-Market Departments
- Regulatory Affairs
- Quality Units (including QA, QC & Quality Audit)

The course is applicable to personnel in API, commodity and outsource suppliers to the industry in addition to those in primary manufacturers of drug products.

Course Summary: The draft of ICH Q10 is the latest document that aims to define the requirements for a quality system for pharmaceutical operations. It discusses how the function of the system should evolve during pre-market operations, what its function is when a drug is marketed and how opportunities for product improvement should be identified and implemented throughout the product life cycle. The main element discussed in Q10 is what management, especially senior management, should be responsible for in assuring an effective Quality System. Other important elements receiving an emphasis in Q10 are the Quality System components such as change control, deviation control, CAPA, root cause determination, input/process/output monitoring, product reviews and documentation.

This course analyzes the content of Q10 and compares it with previous standards including the FDA Guidance on Quality Systems and ISO 9000. It analyzes its relationship with Q8 (Product Development) and Q9 (Risk Management) and the FDA Guidance on their Six-Systems Inspection Program and discusses the quality systems to which Q10 refers with particular reference as to how such systems can be effectively managed & integrated in accordance with Q10.

Course Director:

Alan J. Smith, Ph.D, *Pharmaceutical Quality & Technology Consultant*

With Presentations by: John G. (Jerry) Lanese, Ph.D, *President, The Lanese Group, Inc.*

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Group Rate*) (Must register and pay by 11 September 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)

ACCREDITATIONS/CERTIFICATIONS



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

INDs/NDAs/CTDs

REVISED!

ID: 448

Offering #: 0810-411

20–22 October 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is directed to personnel involved in new pharmaceutical product development, pre-clinical and clinical research, regulatory affairs and quality assurance.

Participants should have an understanding of the steps in new product development and/or the responsibilities of regulatory affairs in submitting new product applications worldwide.

Course Summary: The content of this course is to present detailed components of INDs/NDAs, BLAs, ANDAs, SNDAs, IMPDs and CTDs (Modules 1–5). These regulatory submissions will be based on the requirements of the US code of Federal Regulations, EU Directives and ICH guidelines. Each of these regulatory documents will be presented as they are related to safety, quality and efficacy necessary for global submissions. Details of non and pre-clinical data, clinical data, and CMC data necessary to achieve new product approvals globally will be presented and discussed. Recommendations for expediting new product approvals will be correlated with the regulatory procedures. Other topics presented that will help participants understand the structure and bureaucratic demands will include :

- FDAs internal structure, policies and procedures
- Regulation requirements for new product submissions including SNDAs, CTDs and DMFs globally
- Acceptance of international data for use in new product approvals
- Similarities between EU directives and FDAs Code of Federal Regulations

Course Director:

Dr. Richard A. Guarino, *President, Oxford Pharmaceutical Resources, Inc.*

Tuition:

Early Registration (SAVE \$200): U.S. \$2545 (\$2435 with Group Rate*)

(Must register and pay by 25 August 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

Industrial Drying of Heat Sensitive Materials

ID: 767

Offering #: 0811-306

18–20 November 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is designed for personnel involved in developing, designing, selecting, operating and/or upgrading industrial drying systems handling heat sensitive materials. It is most beneficial for:

- Engineers
- Scientists
- Supervisory Personnel

In the following industries:

- Chemical
- Dairy
- Food
- Polymer
- Pharmaceutical/ Biochemical
- Cosmetic

Course Summary: This course describes the aspects of achieving successful drying operations involving heat sensitive materials, especially where dryer feedstocks are available as a liquid formulation or as a moist solid particulate. Another major focus is the drying of such difficult-to-dry materials as foams and extremely dense large particulates. Reference will be made to the relevant drying theory, and the importance to the total drying process of media conditions (temperature, humidity, flow) and material properties (morphology, temperature, drying characteristics) in meeting dried product quality specifications. The ease of materials handling to achieve a successful drying operation will be also emphasized.

Attention will be given to the design and operating features of four dryer types that are widely applied in industry. These are: fluid bed dryers, freeze dryers, microwave/dielectric dryers and spray dryers. The latest developments, operational parameters, economic factors and operational limits will be thoroughly discussed by a faculty member familiar with the design, performance and application issues of each type.

As each faculty member is currently active and highly experienced in his area of dryer specialization, participants will have a unique opportunity to discuss subjects of particular interest, either individually or in a forum enabling a problem solving, recommendation for consideration or a constructive exchange of views.

Course Directors:

Dr. Keith Masters, *President, SprayDryConsult, Denmark*

Robert F. Schiffmann, *President, R.F. Schiffmann Associates, Inc., USA*

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 23 September 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

22–23 September 2008 • Amsterdam, The Netherlands

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

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 28 July 2008)
Regular Registration: U.S. \$1840 (\$1760 with Group Rate*)

Laboratory Analysis in Clinical Trials

2–3 October 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is for professionals involved in analytical activities as part of clinical trials. The course is designed for:

- Persons working in laboratories performing analysis of biological samples from clinical trials
- Monitors or investigators involved in clinical trials
- Persons involved in assessing or selecting clinical laboratory facilities to perform analysis
- Quality Assurance personnel

Participants may come from the pharmaceutical industry, government institutions, hospitals, academic organizations or contract facilities.

Course Summary: Good Clinical Practices (GCP) does not provide detailed requirements regarding the conduct of laboratory activities in clinical trials. Therefore, laboratories have applied their own standards to such work drawing from relevant guidance in other publications, for example ICH in relation to method validation, GLP relating to preclinical studies and other quality systems such as ISO standards. At the core of this course is a collection of basic scientific and management principles that, if applied, will ensure the credibility of laboratory data.


This course draws together information to provide a set of principles for laboratories dealing with blood chemistry, haematology or analysis of test drugs in biological matrices, which will ensure that the data stands up to scrutiny.

Practical applications of principles are given maximum priority in this course through the high level of interactive, dynamic, problem solving workshops. These mirror situations that the participants are actually involved in. Solutions to the workshops require the application of good practices in areas of regulatory science where guidelines have been unspecified or unaddressed. The presenters recognize that many courses can provide information, but information can only be turned into knowledge through the depth of understanding that comes from sharing experience and exchanging ideas. This is why a workshop approach is so valuable.

Directed by:
David Long, Consultant

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

Laboratory Control System

3–5 November 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is designed for those who are responsible for performing laboratory work or managing a laboratory in conformance to current good manufacturing practice (cGMP) for pharmaceutical products. It will be of special interest to:

- QC Chemists
- Managers
- Developmental Chemists
- QA Record Reviewers and QA Auditors
- Microbiologists
- Laboratory Supervisors


Course Summary: Laboratory Control has been the largest identifiable area of cGMP observations of non-compliance during FDA inspections for the past decade. In 2001 the FDA changed its inspectional technique to focus on systems. More recently, the FDA and the ICH have published guidance documents that encourage the industry to establish Quality Systems. The emphasis of this seminar will be the Laboratory Control System identified in the FDA Systems Inspection Program and the relationship of the Laboratory Control System components to the cGMPs (21CFR210 and 211), ISO 17025 and FDA and ICH guidance documents. Discussions include examples of investigational observations. Discussions, workshops and course notes include assessment checklists.

Course Director:
Dr. John G. (Jerry) Lanese, President, The Lanese Group, Inc.
With Presentations by: Dr. Alan J. Smith, Pharmaceutical and Technology Consultant

Tuition:
Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 8 September 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)

Packaging of Pharmaceuticals

24–26 November 2008 • Amsterdam, The Netherlands

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
 - QA/QC
 - Auditing
 - Regulatory Affairs
 - Production Processes
 - Purchasing
 - Marketing

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 regulatory authorities will be examined from a worldwide perspective. Through exercises in small groups and discussions, participants will be given practice at developing solutions to, and prevent, problems that can occur in practice, in product stability and material-machinery interfaces. Examples and samples of various packs and packaging systems will be used.

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 29 September 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)

PAT Online Process Analysis

ID: 2030 Offering #: 0812-206

8–10 December 2008 • Amsterdam, The Netherlands

Who Should Attend: This comprehensive course is intended for professionals in the pharmaceutical, chemical, petroleum, and instrumentation industries, including:

- Process and Analytical Chemists
- Process Control Specialists
- Chemical Engineers
- Manufacturing and Quality Improvement Managers
- Sales or Service Engineers
- Instrumentation Engineers

Course Summary: Online chemical process analysis is a rapidly evolving technology offering large potential savings in energy costs, reduction of offgrade production, efficient facilities employment, improved safety, and better quality. In addition, an in-situ analyzer in a pilot facility can help to tune processes and speed scaleup. On the other hand, the wrong analyzer or a problematic installation can cost hundreds of thousands of dollars with no gain. It is important that informed decisions be made on the purchase and installation of these instruments. This three-day course will provide an overview of some of the most important of the currently available technologies, how they compare, where they might be employed, example applications, and what is needed to achieve a successful installation. Calibration issues, spectral interpretations, and comparison with laboratory values, will be covered and examples given. Many other types of analyzers, such as pH, moisture, physical property, inferential, acoustic, density and others will also be reviewed, but in less detail than chemical composition analyzers.

A Team Presentation by:

Christian Hassell, *Science and Technology Group Leader*, AMTI
James F. Tatera, *Sr. Process Analysis Consultant*, Tatera & Associates
Lois G. Weyer, *Analytical Chemist* with Alliant Techsystems (ATK) and *Consultant* with Tres-Ark, Inc.

Tuition:

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

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

ACCREDITATIONS/CERTIFICATIONS



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

Pharmaceutical Quality Assurance and Control

ID: 224 Offering #: 0811-203

10–14 November 2008 • Amsterdam, The Netherlands

Who Should Attend: This course will benefit those who need to know how quality can be assured and controlled in the production of pharmaceuticals and related products. The material is particularly suitable for chemists, pharmacists, engineers and administrators working in the following areas:

- R&D
- Purchasing
- Engineering
- QC
- Maintenance
- Regulatory Affairs
- Corporate/Plant Management
- Plant Operations
- QA

The course will also benefit personnel in Regulatory Agencies and Suppliers to the Industry.

Course Summary: This course provides an understanding of the principles and practice of pharmaceutical quality assurance and control and of specific topics which have become important because of regulatory interest or recent technological achievements. Throughout the course an emphasis is placed upon quality as viewed on a cost/benefit basis as well as a cGMP basis.

The first day provides an understanding of the basic principles and practice of the QA and QC functions, covering their role during product design, production and revision, with the role in production being dealt with in particular detail. The second, third and fourth days consist of reviews, first of broad current quality issues including FDA activities, and then the QA/QC aspects of a number of specific issues including: handling of laboratory controls, validation (equipment, processes, computers, cleaning and test methods), label and labeling, water systems, change control, electronic records and signatures, deviations and discrepancies, (including OOSs), FDA inspections, internal and supplier audits, vendor and contract supplier qualification, annual product reviews, and training. A general question and answer session is also provided. The fifth day is devoted to the QA/QC aspects of stability program operation and also to documentation. The course includes hands-on workshops as well as lectures.

Course Director:


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

Tuition:

Early Registration (SAVE \$200): U.S. \$2790 (\$2665 with Group Rate*) (Must register and pay by 15 September 2008)

Regular Registration: U.S. \$2990 (\$2865 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS

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

Pharmaceutical Technology Transfer

ID: 2095 Offering #: 0810-507

27–28 October 2008 • Dublin Ireland

Who Should Attend: This course is intended for individuals from

- Formulation Development
- Regulatory Affairs
- Quality Assurance
- Analytical Development
- Process Development
- Quality Control
- Package Engineering
- 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 1 September 2008)

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*



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

Piping Design, Analysis and Fabrication

ID: 496 Offering #: 0811-305

17–19 November 2008 • Amsterdam, The Netherlands

Who Should Attend: This course provides an overview of all significant aspects and considerations of piping for those who are involved in the design, analysis, fabrication, installation, maintenance or ownership of piping systems. Personnel who work in the chemical, petroleum, utility, plastic processing, paper, manufacturing, environmental, heat and air conditioning fields will find this course valuable, including those in

- Engineering
- Quality Assurance
- Maintenance
- Manufacturing

Those who must comply with Code requirements will benefit from the practical approach presented in this course in obtaining satisfactory and economical piping systems.

Course Summary: The course will review the basic requirements of the various sections of the ASME B31 Code for Pressure Piping with emphasis on B31.1, Power Piping and B31.3, Process Piping. General topics in the course include: pressure design, flow and sizing considerations, flexibility analysis, dead loads, equipment loads, dynamic loads, and supports and restraints. Applications of these concepts, including simple hand analysis methods and computer-based analysis methods, will be demonstrated. Examples of the required analysis and sources of further information will be provided. The practical aspects of material selection and fabrication will be considered, including materials for high and low temperature service, cutting, bending, welding processes, heat treatment requirements and nondestructive examination. Code requirements and the practical limitations of each operation will be discussed, as well as the economics of material selection and alternate fabrication processes.

Each session will be conducted in a lecture/discussion format designed to provide intensive instruction and guidance on understanding Code requirements, and also on developing an awareness of other considerations in the design, analysis, fabrication and installation of piping which is not covered by the Codes. There will also be a demonstration of computer software that can be used to assist in piping analysis. The faculty will be available following each day's session to provide participants with further opportunity for discussion and consideration of specific problems.

Course Co-Directors:

Larry A. Loziuk, P.E., *President*, Piping Technology Consultants, Inc.
Walter J. Sperko, P.E., *President*, Sperko Engineering Services, Inc.

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 22 September 2008)

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

Powders: Their Properties and Processing

ID: 117 Offering #: 0810-308

13–16 October 2008 • Amsterdam, The Netherlands

Who Should Attend: The course is designed primarily for those concerned with products developed or manufactured from powdered solids in the pharmaceutical, cosmetic, and related industries. Most of the material, however, will be general enough to prove valuable to a much wider range of interests including but not limited to:

- Scientists
- Suppliers
- Technologists

Course Summary: The primary purpose of this course is to review the various properties of powdered solids pertinent to the development and manufacture of the products of the pharmaceutical, cosmetic and allied industries. In particular, the latest experimental techniques and equipment for evaluating important properties of powders will be discussed and related to both the underlying principles and common industrial problems. The different powder processing operations will be discussed and the range of equipment and machinery for each will be critically reviewed. Each topic will be briefly introduced at a fairly fundamental level, but will then be extended to cover more sophisticated and innovative techniques, emphasizing the practical usefulness whenever relevant. The formal sessions will be supplemented by informal discussion periods. You will be encouraged to raise specific problems.

Course Director:

Dr. Cecil W. Propst, *Director R&D*, SPI Pharma Group (Grand Haven)

Tuition:

Early Registration (SAVE \$200): U.S. \$2600 (\$2480 with Group Rate*) (Must register and pay by 18 August 2008)

Regular Registration: U.S. \$2800 (\$2680 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; 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# 716-000-08-087-L04



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

Process Plant Start-Up

ID: 561 Offering #: 0811-210

10–13 November 2008 • 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 15 September 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

Radiation Curing: Ultraviolet Light and Electron Beam Technology

ID: 592 Offering #: 0810-306

13–15 October 2008 • Amsterdam, The Netherlands

Who Should Attend: This course covers a broad spectrum of general, practical and scientific knowledge and is designed for professionals in the following industries: automotive/transportation, building/ construction, cosmetics, electronics, electrical insulation, graphic arts, packaging, flooring, adhesives, industrial coatings, ink, bottle and can manufacturing, dental and medical, metallizing, packaging, converting of paper/film/foil, textiles, communications media, plastic decoration and wood finishing.

It is best suited for those involved in efficiently producing quality finished products and in new process/product developments including:

- Production/Manufacturing Managers
- Production Engineers
- Product Specialists/Managers
- Formulators
- Design Engineers
- Material Scientists
- Chemists/Scientists
- R&D
- Marketing and Sales
- Technical Service Specialists

Course Summary: Radiation curing (ultraviolet light and electron beam technology), a new high-growth innovative technology, is a chemical manufacturing process for products and product finishing including adhesives, coatings, inks, photopolymers, photoresists and other systems which use radiant (ultraviolet-UV and electron beam-EB) energy for polymerization, crosslinking or degradation of a formulated chemical product or material. This comprehensive course will cover both basic concepts and new developments in this technology.

Radiation curing provides the following advantages: 100% reactive, one-component formulations; pollution abatement and compliance with governmental regulations; low substrate heating; increased productivity; reasonable capital investment; improved product quality; and unique product performance capabilities. Detailed presentations will provide information on applications and markets, chemistry/photoinitiation technology, additives, equipment, formulations, synthesis methods, manufacturing, application techniques, evaluation and testing, health and safety, government regulations and new developments/markets.

Particular emphasis is placed on encouraging individual interaction with the faculty throughout the course. Specific participants' interests are also addressed in the popular open forum panel discussion.

Course Director:

Dr. David Armbruster, *President*, Armbruster Associates, Inc.

Tuition:

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

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

ACCREDITATIONS/CERTIFICATIONS



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

Refractories for Industrial Applications

ID: 551 Offering #: 0810-410

20–22 October 2008 • Den Haag, The Netherlands

Who Should Attend: This practical course on new materials and installation methods has proven beneficial to:

- Maintenance and operating personnel
- Supervisors responsible for plant and unit operations
- Managers responsible for decisions on refractory problems
- Refractory installers
- Third party inspectors
- Contract maintenance personnel

An engineering or technical background is not required although technical professionals will certainly benefit from the broad base of both theoretical and practical information presented in the course.

Course Summary: This course will emphasize the practical aspects of refractory selection, installation, and repair techniques in a number of industrial applications. No engineering training will be assumed and the extensively revised course notes will allow the attendee to easily follow the lectures. Many refractory materials and placement methods have changed significantly with the development of new materials based on nano-technology. New methods to place materials have been developed to utilize the unique properties of many monolithic refractories. Vibratable and pumpable castables with excellent properties, along with improved bricks, plastic refractories and refractory ceramic fiber make optimum refractory selection even more critical. Bricks, plastic refractories, and refractory ceramic fiber applications will be covered for a variety of industrial uses. The included field trip provides a hands-on demonstration of various installation methods. The faculty will be available to privately discuss particular problems.

Course Director:

Dr. Michael S. Crowley, P.E., *Engineering Consultant*

Tuition:

Early Registration (SAVE \$200): U.S. \$2395 (\$2285 with Group Rate*) (Must register and pay by 27 August 2008)

Regular Registration: U.S. \$2595 (\$2485 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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

Role of PAT and QbD in Biologic Drug Production

ID: 2163

Offering #: 0810-201

9–10 October 2008 • Amsterdam, The Netherlands

Who Should Attend: This comprehensive quality system workshop will benefit professionals who are involved in the entire biologic drug chain, from development through unit operations to product fill, storage and release to market, 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
- Biologic Excipient Suppliers
- Analytical Instrument and Manufacturing Equipment Suppliers
- Managers tasked with biologic product development and evolution

Course Summary: PAT – Process-Analytical Technology – is a risk management approach for ensuring consistent production of prescription drugs within a well-defined quality envelope. QbD – Quality by Design – encompasses PAT and uses its concepts across a much wider front; from drug discovery and development to the patient. Both PAT and QbD are mainstays of 21st century good manufacturing practice.

This course establishes an operating baseline for biologic PAT programs, using the outcomes of successful small-molecule PAT efforts. Course modules include an analysis of biologic business drivers and timelines, PAT and QbD principles and their relationship to the ICH – International Conference on Harmonization.

The course includes sections on biologic unit operations, in-process testing and supra-process testing – including the use of dynamic test technologies to support mainstream production methods.

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 7 August 2008)

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

Root Cause Investigation for CAPA

ID: 2089

Offering #: 0811-204

11–12 November 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 16 September 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)

ACCREDITATIONS/CERTIFICATIONS



1.2 credits

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

System Validation, GAMP Harmonization and P.A.T.

ID: 2203

Offering #: 0812-302

15–17 December 2008 • Amsterdam, The Netherlands

Who Should Attend: This three-day, practical course will be of interest to professionals in the Pharmaceutical, Biopharmaceutical and other FDA regulated industries. This includes but isn't limited to:

- Automation Managers/ Directors
- Validation Engineers
- QA/QC Personnel
- Systems Administrators
- User Support Staff

Course Summary: This course is intended to be an overview of the latest emergent issues of FDA compliance, including: Process Analytical Technology (PAT); computer system validation; risk assessment; 21 CFR Part 11; and harmonization with GAMP4. Now that computers have replaced many of the manual operations associated with the acquisition and management of information, it is important to ensure that appropriate testing and control procedures are applied to the new systems. This course will cover the available techniques for verifying that computer systems function as they are intended to. In addition, the role of procedures and documentation will be presented.

The computer industry has, for some time, been developing validation procedures for systems; however, many of these techniques have not been presented in the context of international regulations. This course will address the emerging trends based on industry experience, including results from recent findings in FDA computer system audits. There are specific times set aside to discuss establishing such a validation program in participants' respective organizations.

Course Director:

Dr. Sandy Weinberg, *Vice President, Regulatory Affairs Tikvah Therapeutics*

Tuition:

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

(Must register and pay by 20 October 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)

The GLP Study Director

ID: 2136

Offering #: 0812-103

4–5 December 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is designed for those who already have some experience in managing GLP studies; those who wish to extend their role to study direction and their competence in study management, particularly in the complex multi-site environment. The course will benefit the following individuals:

- Existing Study Directors who wish to upgrade their competence in a multi-site situation
- The newly appointed Study Director
- Study supervisors who wish to become Study Directors
- Study Monitors
- Principal Investigators in the field of preclinical regulatory R&D
- Coordinators of multi-site projects

Course Summary: The current regulatory environment imposes far reaching responsibilities on Study Directors and Principal Investigators in preclinical regulatory R&D. This course takes as reference the GLP regulations of the FDA and OECD and the associated OECD interpretive monographs particularly on study direction, sponsor responsibilities and multi-site studies.

Dealing with the increased range of duties and responsibilities of study managers is the core issue of this course.

The course goes further than presenting the theoretical roles of study managers in the difficult arena of multi-site studies. The workshop based activities address the practical aspects of study direction and investigate possible solutions to ensure full compliance.

A strong feature of this course is the high level of interactive, dynamic problem solving situations that the participants are asked to resolve appropriately and speedily. The strategies available for managing compliant studies are given topmost priority.

The presenters recognize that many courses can provide information, but information can only be turned into knowledge through the depth of understanding that comes from sharing experience and exchanging ideas. This is why a workshop approach is so valuable.

Course Director:

David Long, *Consultant*

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Group Rate*) (Must register and pay by 9 October 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)

U.S. FDA Drug Development and Compliance

ID: 587

Offering #: 0809-403

22–24 September 2008 • Amsterdam, The Netherlands

Who Should Attend: Because of its comprehensive content, this course should prove most valuable to:

- Regulatory Affairs Professionals
- QA/QC
- Scientists/Laboratory Staff
- Supervisors
- Engineers
- Management
- Manufacturing Personnel
- Legal Staff

Those who are new to the industry or to their current position and do not have an in-depth knowledge of the FDA and its workings will benefit from this course. The program provides an opportunity for more experienced personnel, including middle and upper management, to update and broaden their knowledge.

Course Summary: This continually updated course covers current FDA drug development issues and compliance with respect to marketing human drugs and biologics, including the FD&C Act, case law, and the FDA's authority to promulgate and enforce regulations. Among the topics to be discussed will be: FDA's regulatory policies, how they develop and where they are documented; the regulatory process, including regulatory and pre-approval inspections, recalls, warning letters, injunctions, seizures and criminal prosecutions; cGMP; compliance programs, how they develop and are administered; compliance policy guides; the Regulatory Procedures Manual and the Inspection Operations Manual. Laboratory and process validation, NDAs, ANDAs, and other pre-approval documents, stability, the Establishment Inspection, the FD-483 and interactions with FDA's inspectors (investigators) will also be discussed. The course will have applications to drugs and biotechnology-derived products.

Course Co-Directors:

Mary L. Richardson, *Vice President Regulatory Affairs*, Mission Pharmacal Company

Gary L. Yingling, Esq., *Partner*, K&L Gates

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 28 July 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)

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 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.



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. (See specific course for program #'s)

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

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

Amsterdam American Hotel:

Leidsekade 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

Renaissance Amsterdam Hotel:

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

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

Dublin, Ireland

Radisson SAS St. Helen's:

Stillorgan 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

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.

Waste Incineration and the Combustion Process

ID: 71

Offering #: 0810-505

27–30 October 2008 • Amsterdam, The Netherlands

Who Should Attend: This intensive course is intended for those professionals involved in any aspect of incinerating waste material in an incinerator, boiler, fired heater, furnace, or kiln. It would be most beneficial to, but not limited to:

- Engineers
- Analysts
- Plant Personnel
- Technologists
- Environmental Scientists
- Managers

Those seeking pragmatic information on combustion chemistry and pollutant formation mechanisms (such as dioxin, NOX and salts) and the latest proven equipment technologies available to achieve successful incineration of hazardous or non-hazardous waste should also attend.

Course Summary: This course presents a practical approach to the incineration of hazardous and non-hazardous waste in various types of combustion systems. You will be guided through the details of equipment selection based on principles of chemistry, fluid mechanics, thermodynamics, and pollution formation mechanisms.

Applications will be made to the incineration of all species of waste including municipal wastes. Many types of equipment will be discussed including rotary kilns, modular units, fluidized bed, multiple hearth, boiler firebox, furnaces and fired heaters. Air pollution control, stack monitoring, safety interlocks and instrumentation will be discussed.

Combustion mechanisms, heat/material balances and the selection of principle organic constituents will be presented in the context of various European and U.S. environmental regulations including the IPPC act.

Includes field trip to a municipal waste to energy plant.

Course Director:

Mark E. Illian, *President*, Synergy Services Corporation

Tuition:

Early Registration (SAVE \$200): U.S. \$2855 (\$2735 with Group Rate*) (Must register and pay by 1 September 2008)

Regular Registration: U.S. \$3055 (\$2935 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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



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Accredited Technical Training for the Pharmaceutical, Biopharmaceutical and Related Industries

September – December 2008 European Course Offerings

Course Topics in this Catalog Include:

Advanced Tablet Press Operation, Critical Process Cleaning and Cleaning Validation, Endotoxin Testing: Drugs, Medical Devices and Biopharmaceuticals, Fundamentals of Biotechnology, Role of PAT and QbD in Biologic Drug Production, Packaging of Pharmaceuticals



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:		Instructions: Please complete Registrant Information, Course Information and Payment Sections. Submit one form per individual registrant. <input type="checkbox"/> Check here if group rate applies (two or more enrollments for the same course, from the same company).
Company:				
Address:				
Postal Code:	City:	Country:		
Phone:	Fax:	E-mail:		
Course Title:		Course ID#		Tuition:
Payment				
<input type="checkbox"/> Send Invoice (POs must be received in advance of course) <input type="checkbox"/> Check: Payable in US funds to: The Center for Professional Advancement				
<input type="checkbox"/> Bank Transfer (Pay by Bank Transfer to Account No. 62.62.46.628 (US\$) at ABN-AMRO Bank N.V., Postbus 2078, 1000 CB Amsterdam, The Netherlands. The Course Offering # and participant's name must be included on bank transfer.)				
<input type="checkbox"/> Credit Card: ___ Visa ___ Mastercard ___ American Express Card #: _____ Exp. Date: _____				
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