



CfPA
The Center for Professional Advancement
Accredited Technical Training Worldwide

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

Course Catalog



January – March 2008 European Course Offerings

Course Topics in this Catalog Include:

- IQ/OQ/PQ
- Documentation Management
- ISO 13485
- Good Laboratory Practices
- Validation of Computer Systems
- Plant Start-up

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

January - March 2008

Training for the Pharmaceutical, Medical Device and Related Industries

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Welcome

For 40 years CfPA has been meeting the needs of professionals in the pharmaceutical, biotechnology, clinical and medical device industries with the most comprehensive selection of accredited technical training programs available anywhere. Our curriculum of over 450 courses in 19 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 courses, visit our website at:

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

Client-Site Training

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

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

Atomization, Sprays and Atomizers

ID: 1883 Offering #: 0803-106

6-7 March 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is for professionals in the chemical, biotechnology, agricultural sprays, food, pulp and paper, combustion and medical areas. Those involved with spray-dependent processes, including chemical reactors, coatings, spray drying, powder metallurgy, evaporative cooling, specialty chemicals, combustion and medical sprays will benefit including:

- Biotechnologists
- Food Technologists
- Agricultural Engineers
- Coating Engineers
- Combustion Engineers

Course Summary: Atomization is an important process used in many industries, including chemical, petrochemical, biochemical, medical, food, paper, combustion, fuels, and agriculture. This course provides an introduction to atomization for engineers, scientists and technologists who are interested in or need to know more about atomization, atomizer design, atomizer specifications and selection for various applications.

Key areas to be covered include the various atomization methods, atomizer design, factors affecting operation, flow in atomizers, drop size, spray angle and other spray characteristics, atomizer performance criteria, atomizer maintenance and drop size distributions. Proper atomizer selection will be emphasized. Worked problems on flow number for nozzles and the air-to-liquid ratio for two fluid atomizers will be presented in class. Calculations for spray dryers will also be reviewed.

The course will follow a lecture/discussion/video presentation format. Demonstrations of the use of the atomization equipment and maintenance procedures will be shown.

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Group Rate*) (Must register and pay by 10 January 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

CMC Submissions in CTD Format

ID: 1989 Offering #: 0803-403

26-27 March 2008 • Amsterdam, The Netherlands

Who Should Attend: This course is intended for all personnel in pharmaceutical companies especially those in:

- Regulatory Affairs
- Chemistry and Analytical Departments
- Pre-formulation
- Pharmaceutical Development
- QA/QC for the CMC section of the NDA/CTD

It is recommended that you have at least one year experience in either regulatory affairs, chemistry, analytical, QA/QC or pharmacy department or pharmaceutical development to fully benefit from this course.

Course Summary: This course will provide an in depth review of the chemistry, manufacturing and controls (CMC) requirements for development and ultimate submission to the FDA and European regulatory bodies in the new drug application (NDA). Emphasis will be placed on current FDA, European and ICH requirements for the filing of the quality section of the CTD for manufacturing, analytical, sterility and stability issues as they apply to the drug substance and drug product. In addition, details on supplemental applications for changes to an NDA will be presented focusing on SUPAC requirements.

Course Director:

Carolyn H. Kruse, MSc., M.TOPRA, Consultant to the Pharmaceutical Industry, Kruse Consulting Group

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Group Rate*)

(Must register and pay by 3 January 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 9 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.

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Conception, Design and Implementation of Plant Safety Systems

ID: 1672 Offering #: 0803-209

12–14 March 2008 • Amsterdam, The Netherlands

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

- Technologists
- Engineers
- Technicians
- Managers

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

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

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

Course Director:

Andrew C. Hiestler, P.E., Acetic Anhydride Department Senior Technical Associate, Eastman Chemical Company

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 16 January 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

Conducting Effective Quality Audits

ID: 1681 Offering #: 0803-204

11–14 March 2008 • Amsterdam, The Netherlands

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

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

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

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

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

Course Director:

Renée B. Galkin, Quality Management Consultant

Tuition:

Early Registration (SAVE \$200): U.S. \$2600 (\$2480 with Group Rate*) (Must register and pay by 15 January 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

Design Control & Product Validation for Medical Devices

ID: 1900 Offering #: 0802-508

26-27 February 2008 • Dublin, Ireland

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

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

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

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

Emphasis will be on understanding the requirements and providing tools to assist in management of the design control process. The course will discuss each phase of the design process and explain the terms: design input, design output, design review, verification, validation, and design history file. Particular emphasis will be given to understanding the difference between design verification vs. design validation, and describing activities relative to validating a product design. Also discussed will be FDA's inspection strategy and how to manage a successful audit for design controls.

You will return to the workplace with new tools to apply an effective project management approach to your design control process which will ultimately reduce time to get to market, reduce development cost, and ensure regulatory compliance.

Course Co-Directors:

Jan Miller & Michele Vovolka, Quality Systems Consultants, Vantage Consulting International, Ltd.

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Group Rate*) (Must register and pay by 1 January 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

Documentation Management and Control

ID: 1866 Offering #: 0803-304

17–18 March 2008 • Amsterdam, The Netherlands

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

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

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

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

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

Course Director:

Renée B. Galkin, Quality Management Consultant

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Group Rate*) (Must register and pay by 21 January 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

Effective Project Management in Today's World

ID: 129

Offering #: 0803-207

11–13 March 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
- Design
- Manufacturing
- Construction
- Information Systems

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, "L O O K O U T", © 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 15 January 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

Good Laboratory Practices (GLP)

ID: 545

Offering #: 0803-404

26–28 March 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*, Long & Associates International Consulting Ltd.

Tuition:

Early Registration (SAVE \$200): U.S. \$2345 (\$2235 with Group Rate*) (Must register and pay by 30 January 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

International Patent Law for Managers, Engineers & Scientists

ID: 2100

Offering #: 0803-108

6-7 March 2008 – Amsterdam, The Netherlands

Who Should Attend: This course would be profitable to those who are interested in the nature and extent of patent rights, how they are acquired, and how they may and may not be used. This includes, but is not limited to:

- Inventors
- Engineers
- Managers in industry, government and educational institutions
- Chemists
- Scientists

Course Summary: The U.S. Court of Appeals for the Federal Circuit is the focal point for the legal criteria by which US patents are enforced. The Court's rulings on recent multi-million dollar patent infringement awards illustrate how important it is for the business manager to understand how the patent system works.

With the great increase in the cost of technology development, and the rapidity of technical progress in global markets, protection of intellectual property on a worldwide basis is becoming of critical importance. This course will provide inventors, and those who manage inventors, with a working knowledge of the U.S. and international procedures for the protection of intellectual property by patents. Emphasis will be placed on understanding the extent and limits of protection afforded by the patent laws, the U.S. re-examination procedure, the ways in which inventors can assist in obtaining patent protection, and the use of patents as a company asset. The relationship between patents and trade secrets, copyrights and trademarks will also be discussed. Instruction will include an explanation of problem areas in obtaining and maintaining patent rights. Correcting common misconceptions about patent systems and pointing out recent changes in the patent laws will also be emphasized.

Course Directors:

Burton A. Amernick, *Partner*, Law Firm of Connolly, Bove, Lodge & Hutz
T. Gene Dillahunty, *Executive Vice President*, Earth Renew, Inc.

Tuition:

Early Registration (SAVE \$200): U.S. \$1640 (\$1560 with Group Rate*) (Must register and pay by 10 January 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

IQ/OQ/PQ

ID: 1808

Offering #: 0801-504

30–31 January 2008 • Dublin, Ireland

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

- Engineering
- 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 5 December 2007)

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

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

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

ID: 2092

Offering #: 0802-507

25–27 February 2008 • Dublin, Ireland

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

- Regulatory
- QA
- R&D
- Manufacturing

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

Course Director:

Bea Salis, *Consultant, QualASyst International*

Tuition:

Early Registration (SAVE \$200): U.S. \$2445 (\$2335 with Group Rate*)

(Must register and pay by 31 December 2007)

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

ACCREDITATIONS/CERTIFICATIONS



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

Packaging of Pharmaceuticals

ID: 42

Offering #: 0802-402

20–22 February 2008 • Dublin, Ireland

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

The program will be especially beneficial to those employed in:

- Development
- QA/QC
- Regulatory Affairs
- Purchasing
- Technology
- Auditing
- Production Processes
- Marketing
- The supply of packaging materials and packaging machinery

Course Summary: This intensive course provides the participants with the knowledge of how packaging for all types of pharmaceuticals (ethical, OTC, veterinary medicines) and other related products are developed, manufactured, tested, filled, transported, stored and used. Emphasis will be placed on the characteristics of all commonly used packaging materials which can influence the packed product: protection, compatibility, safety, compliance, design, performance on the filling and closing lines, as well as during distribution, marketing and use. The relevant physical and chemical properties of each type of material are identified and covered in detail. This course will also accentuate the importance of the influence of the processes used to manufacture, convert or prepare materials for use, on their specifications, performance and quality of the final packages. Future and present trends in health-care packaging will be reviewed. The increasing amount of information, that is needed on packaging, to satisfy both the company and 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. \$2,345 (\$2235 with Group Rate*) (Must register and pay by 26 December 2007)

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

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

Pilot Plant & Scale-Up Studies: Process Development & Scale-Up Methods

ID: 1882

Offering #: 0803-105

3–5 March, 2008 • Amsterdam, The Netherlands

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

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

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

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

Course Director:

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

Tuition:

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

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

ACCREDITATIONS/CERTIFICATIONS



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

Process Plant Start-Up

ID: 561

Offering #: 0802-509

25–28 February 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 31 December 2007)

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

ACCREDITATIONS/CERTIFICATIONS



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

3-5 March 2008 • Amsterdam, The Netherlands

Who Should Attend: This course will be of particular value to individuals responsible for:

- System Quality Control
- System Management and Development
- Computer System Validation

Course Summary: Recent problems associated with computer inaccuracies have led the FDA to pressure the pharmaceutical and blood processing industries into adoption of rigid standards of system validation and testing. The application of a testing methodology is of particular importance in design, operation and quality control of manufacturing systems, where computers are integrally used in product control and inventory tracking.

This course is designed to provide the necessary skills for mastering the principles and techniques of developing and implementing a system validation and testing plan for manufacturing-related computer systems. The course uses a combination of lecture/discussions, case studies, "role-play actors," and multimedia presentations to provide a living case of a computerized pharmaceutical system in need of a validation plan for cGMP information systems. The program will take participants step-by-step through the process of developing and implementing that plan, and will conclude with a session adapting the plan to each participant's unique environment and products.

Features of the Course Include:

- Specification of a methodology for meeting FDA and PMA guidelines for manufacturing systems involving computers
- Practical experience in applying that methodology to actual computerized manufacturing systems
- New update on 21 CFR Part 11

Course Director:

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

Tuition:

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

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

Customized Training Through Client Site Programs

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

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

What are the advantages to a Client Site Course?

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

How to arrange a Client Site Course:

If your company is interested in a **Client Site** training program, please contact our **Client Site** division at +1 732.238.1600 ext. 4549 or E-mail clientsite@cfpa.com.

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# 716-000-08-401-L04



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

Accreditations/Certifications

CfPA holds 13 Accreditations. The following are available for the selected courses in this catalog. For more information on all of our Accreditations/Certifications visit our website at www.cfpa.com.



The Center for Professional Advancement has been reviewed and approved as an Authorized Provider (#640) of continuing education and training programs by the International Association for Continuing Education and Training (IACET). Continuing Education Units (CEU) will be awarded for participation in this course at a rate of 0.1 CEU per contact hour. CEU will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation.



SME Certified Manufacturing Engineers (CMfgE) and Technologists (CMfgT) may earn recertification credits. (See specific course for details) Certification is valuable to everyone in industry. It is a recognized method of maintaining knowledge and skills in your field. For complete details on SME Certification, contact Diane Wrobel, Coordinator, SME, Manufacturing Engineering Certification Institute, One SME Drive, Dearborn, MI 48121, 313.271.1500, ext. 516.

The American Board of Industrial Hygiene® (ABIH)®

Certain courses have been approved for Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification. (See specific course for details)

ABIH Certification:

Certain courses have been approved for Certification Maintenance Points by



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)



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.



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

Locations

CfPA courses on pages 1-8 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

Mövenpick Hotel Amsterdam City Center:

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

Crowne Plaza Amsterdam City Centre:

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

Golden Tulip Apollo Amsterdam:

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

Renaissance Amsterdam Hotel:

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

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.