



CfPA

The Center for Professional Advancement
Accredited Technical Training Worldwide

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

Course Catalog



October – December 2008 U.S. Course Offerings

Course Topics in this Catalog Include:

- Advanced Tablet Press Operation **NEW!**
- Drug Product Stability and Shelf Life
- Granulation, Tableting & Capsule Technology
- Medical Device Regulatory Compliance
- Pathways to Skin Penetration
- The GLP Study Director **REVISED!**
- Vendor and Contract Supplier Qualification

CfPA Courses Offer:

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



www.cfpa.com

October–December 2008 U.S. Courses

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
or E-mail: onlinetraining@cfpa.com

For Upcoming Courses See Page 16

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 #: 0811-105

November 3–4, 2008 • New Brunswick, NJ

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. \$1375 (\$1315 with Group Rate*) (Must register and pay by September 8, 2008)

Regular Registration: U.S. \$1575 (\$1515 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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

Auditing & Inspecting Preclinical Research for GLP Compliance

ID: 1774 Offering #: 0811-201

November 10–12, 2008 • New Brunswick, NJ

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, Long & Associates International Consulting Ltd.

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by September 15, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

Clean Room Technology

ID:23 Offering #: 0810-101

October 1–2, 2008 • New Brunswick, NJ

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
- QA/QC
- Regulatory Affairs
- Production
- 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. \$1275 (\$1215 with Group Rate*)

(Must register and pay by August 6, 2008)

Regular Registration: U.S. \$1475 (\$1415 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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This course (#08-666) has been approved for 3.0 Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification.

This course meets Board of Certified Safety Professionals (BCSP) criteria for points toward the Continuance of Certification requirements.



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

Complaint Handling and MDR Reporting

ID: 1834 Offering #: 0811-108

November 3–5, 2008 • New Brunswick, NJ

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

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

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

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

Course Director:

Jim Colyn, *President*, Jim Colyn & Associates Quality Consulting

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by September 8, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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

Conducting Effective Quality Audits

ID: 1681 Offering #: 0810-501

October 27–30, 2008 • New Brunswick, NJ

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
- Laboratory
- R&D
- 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. \$2155 (\$1955 with Group Rate*) (Must register and pay by September 1, 2008)

Regular Registration: U.S. \$2355 (\$2155 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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

Critical Process Cleaning and Cleaning Validation **REVISED!**

ID: 1867 Offering #: 0810-102

October 1–3, 2008 • New Brunswick, NJ

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

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

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

Course Summary: This course will provide a solid **overview** of the principles and technology 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 of current industry cleaning validation practices and case histories will be presented. Recent FDA inspection history and regulatory comment regarding these issues will be discussed in depth.

This practical course will help participants familiar with this topic to better evaluate and develop their own FDA regulated cleaning programs that balance production objectives against QA/validation objectives. The idea is to first achieve an effective reliable cleaning process, then generate sufficient data and justification 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 inclusion in the "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. \$1740 (\$1660 with Group Rate*) (Must register and pay by August 6, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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The American Board of Industrial Hygiene® (ABIH)® This course (#07-1811) has been approved for 3.0 Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification.

BCSP – This course meets Board of Certified Safety Professionals (BCSP) criteria for points toward the Continuation of Certification requirements



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

Design Control and Product Validation

ID: 1900 Offering #: 0810-206

October 6–7, 2008 • New Brunswick, NJ

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

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

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

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

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.

Course Co-Directors:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1240 (\$1180 with Group Rate*)

(Must register and pay by August 11, 2008)

Regular Registration: U.S. \$1440 (\$1380 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#716-000-06-005-L04



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

Drug Product Stability and Shelf Life

ID: 599 Offering #: 0812-204

December 10–12, 2008 • Burlingame, CA

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
- Research & Product Development Scientists and Managers
- Product Stability Managers
- Regulatory Personnel
- Manufacturing 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. \$1740 (\$1660 with Group Rate*)

(Must register and pay by October 15, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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The American Institute of Chemists (AIC) offers many courses which have a chemical component. Such courses may earn up to 20 Certification Units toward certification by The National Certification Commission in Chemistry and Chemical Engineering, sponsored by The American Institute of Chemists.



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

Early Stage Clinical Studies for Drugs and Devices

ID: 2118 Offering #: 0810-405

October 23–24, 2008 • New Brunswick, NJ

Who Should Attend: This course will benefit those in the pharmaceutical, medical device and biologics industries especially:

- Personnel in development and clinical evaluation
- Scientists who have specialized in other areas and wish to master the basics of the regulatory and technical requirements and challenges involved in clinical development
- Regulatory and managerial personnel involved with planning project management and creation of development and regulatory strategies
- Personnel with limited development experience
- Newly hired employees of established companies whose responsibilities include new products evaluated in humans

Course Summary: This two-day course will give a comprehensive overview of the regulatory requirements, design, conduct and analysis of FIM (first in man) studies of new drugs, biologics and medical devices in human beings. The participant will come away knowing what must be done and what cannot be done for, and in, such studies and how these fit into the development process.

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1275 (\$1215 with Group Rate*)

(Must register and pay by August 28, 2008)

Regular Registration: U.S. \$1475 (\$1415 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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The American Board of Industrial Hygiene® (ABIH)®
Board of Industrial Hygiene (ABIH)
for recertification.

This course (#08-669) has been approved for 2.0 Certification Maintenance Points by The American



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

Elements of Applied Process Engineering

ID: 1512 Offering #: 0811-303

November 17–20, 2008 • New Brunswick, NJ

Who Should Attend: The course is mainly directed to those just entering the Process Engineering field including engineers, chemists and technicians in the areas of:

- Plant Operation • Process Scale-Up
- Process Development • Process Start-Up

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$2295 (\$2195 with Group Rate*) (Must register and pay by September 22, 2008)

Regular Registration: U.S. \$2495 (\$2395 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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

GMP for Dietary Supplements

ID: 2094 Offering #: 0810-502

October 27–28, 2008 • Burlingame, CA

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

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

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

FDA Final Rule; No Longer Voluntary

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1275 (\$1215 with Group Rate*)
(Must register and pay by September 1, 2008)

Regular Registration: U.S. \$1475 (\$1415 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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The American Board of Industrial Hygiene® (ABIH)® has been approved for 2.0 Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification.



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

Good Laboratory Practices (GLP)

ID: 545 Offering #: 0810-403

October 20–22, 2008 • New Brunswick, NJ

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. \$1740 (\$1660 with Group Rate*)
(Must register and pay by August 25, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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This course meets Board of Certified Safety Professionals (BCSP) criteria for points toward the Continuation of Certification requirements.



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

Granulation, Tableting & Capsule Technology

ID: 541

Offering #: 0812-201

December 8–11, 2008 • New Brunswick, NJ

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

The material will be presented in such a way as to be of value to a varying level of expertise. This course will especially benefit those in:

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$2155 (\$2055 with Group Rate*)
(Must register and pay by October 13, 2008)

Regular Registration: U.S. \$2355 (\$2255 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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IQ/OQ/PQ

ID: 1808

Offering #: 0811-205

November 11–12, 2008 • Burlingame, CA

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. \$1275 (\$1215 with Group Rate*)
(Must register and pay by September 16, 2008)

Regular Registration: U.S. \$1475 (\$1415 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



The Center for Professional Advancement (CfPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program# 716-000-07-137-L04

The American Board of Industrial Hygiene® (ABIH) has been approved for 2.0 Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification.



(Please refer to page 17 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.

October 20–22, 2008 • Burlingame, CA

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

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

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

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

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*)

(Must register and pay by August 25, 2008)

Regular Registration: U.S. \$1940 (\$1860 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# 716-000-08-714-L04

The American Board of Industrial Hygiene® (ABIH)® This course (#08-962) has been approved for 1.0 Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification.

The American Institute of Chemists (AIC) The Center for Professional Advancement (CFPA) offers many courses which have a chemical component. Such courses may earn up to 20 Certification Units toward certification by The National Certification Commission in Chemistry and Chemical Engineering, sponsored by The American Institute of Chemists.

This course meets Board of Certified Safety Professionals (BCSP) criteria for points toward the Continuation of Certification requirements.



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

Laboratory Analysis in Clinical Trials

October 13–14, 2008 • East Brunswick, NJ

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
- Persons involved in assessing or selecting clinical laboratory facilities to perform analysis
- Monitors or investigators involved in clinical trials
- 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 pre-clinical 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.

Course Director:

David Long, *Consultant*, Long & Associates International Consulting Ltd.

Tuition:

Early Registration (SAVE \$200): U.S. \$1275 (\$1215 with Group Rate*) (Must register and pay by August 18, 2008)

Regular Registration: U.S. \$1475 (\$1415 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



The Center for Professional Advancement (CFPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program# 716-000-07-506-L04

The American Board of Industrial Hygiene® (ABIH)® This course (#08-671) has been approved for 2.0 Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification.



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

Lyophilization Technology

ID: 279

Offering #: 0810-301

October 15–17, 2008 • New Brunswick, NJ

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

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

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

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

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

Course Director:

Dr. J. Jeff Schwegman, *Scientist*

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by August 20, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



The Center for Professional Advancement (CFPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program# 716-000-07-163-L04



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

Machinery Failure Analysis and Prevention

ID: 1054

Offering #: 0811-302

November 17–19, 2008 • Boca Raton, FL

Who Should Attend: This highly practical course is recommend for those involved in machinery operation and troubleshooting including:

- Maintenance Engineers
- Machinery Engineers
- Supervisors
- Technicians

Personnel from the refining, pharmaceutical, food, chemical, utilities, mining, fertilizer, and petrochemical industries will benefit.

Course Summary: This course presents a systematic approach to fault and failure prevention in a broad range of machinery. The key routes to maintenance avoidance are demonstrated through both overview and the study of examples in metallurgical failure analysis, vibration analysis, and a sequential approach to machinery troubleshooting and problem-solving.

Equipment failure events will be reviewed and you are encouraged to bring relevant assembly drawings or such components as failed bearings, gears, mechanical seals and similar machine elements for failure analysis discussion.

The course explores a systematic approach to successful failure analysis and troubleshooting programs. Through case studies, it will be shown that such a program can lead to significant failure reductions. A matrix approach to machinery troubleshooting uses illustrative examples in pumps, centrifugal compressors, blowers and fans, reciprocating compressors, engines and gas turbines.

A systematic approach to generalized machinery problem-solving is described in terms of situation and cause analysis, action generation, decision making and planning for change. Finally, a highly effective shortcut root cause analysis method is explained in detail.

Course Director:

Heinz P. Bloch, *Registered Consulting Engineer*

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by September 22, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



ISPE's professional development committee approved CFPA's courses which meet standards for professional development.

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

Medical Device Regulatory Compliance

ID: 1992 Offering #: 0811-104

November 3–5, 2008 • New Brunswick, NJ

Who Should Attend: Because of its comprehensive overview, this course will be most valuable to medical device industry professionals in:

- Management
- Compliance
- Quality Assurance
- Clinical Research
- Regulatory Affairs
- Research and Development
- Quality Control

The course will also be helpful for 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 as well as for more experienced personnel, including middle and upper management, to update and broaden their knowledge of FDA requirements.

Course Summary: This continually updated course covers current FDA regulatory compliance issues with respect to developing, manufacturing, and marketing medical devices. It includes an overview of the FD&C Act, case law, and pertinent FDA regulations. Among the many topics to be discussed will be: FDA's regulatory policies, how they develop and where they are documented; potential FDA enforcement for noncompliance including warning letters, injunctions, seizures, civil penalties, and criminal prosecutions; device classification and reclassification; premarket submissions requirements for 510(k)s, IDEs, PMAs, and PMA Supplements; device promotion and advertising; post market requirements including establishment registration, device listing, and adverse event reporting; inspections; recalls; and the QSR, including design controls and process validation. The course will focus on the application of the law, regulations, and policies to medical devices.

Course Director:

Suzan Onel, Esq., Partner, K&L Gates LLP

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*)

(Must register and pay by September 8, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



The Center for Professional Advancement (CFPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program# 716-000-07-181-L04



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

Microbiological Control and Validation

ID: 902 Offering #: 0811-101

November 5–7, 2008 • Boca Raton, FL

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

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

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

Course Director:

William Marshall, President, William G. Marshall and Associates

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*)

(Must register and pay by September 10, 2008)

Regular Registration: U.S. \$1940 (\$1860 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# 716-000-06-159-L04

The American Board of Industrial Hygiene® (ABIH)® This course (#07-1806) has been approved for 3.0 Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification.



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

Microbiological Quality of Water-Based Consumer Products

ID: 1383 Offering #: 0810-503

October 30–31, 2008 • New Brunswick, NJ

Who Should Attend: This course is intended for working microbiologists from cosmetic, household, paint and industrial product companies and their contract labs, who are responsible for solving microbiological problems. Since microbiological quality should involve multiple disciplines, other company representatives who would benefit from this course include:

- Product Development
- Corporate QA/QC teams
- R&D
- QA/QC chemists from manufacturing sites

This course can be valuable to those who request microbiological testing, as well as those who actually do the testing. This course is not intended for personnel in the pharmaceutical industry.

Course Summary: As an integral part of its self-regulation program, the cosmetic industry devotes much attention to the microbiological aspects of quality. This course centers on the primary "problem" products—those based on water. Since many paints, household, industrial, institutional, and specialty products are also water-based, it is not surprising that many of the solutions to microbiological problems encountered by the cosmetic industry are also applicable to these other industries. Informal and open discussion of problems, solutions, alternative methodologies, and the development of products hostile to microbial growth will be emphasized.

The need for, and testing of, preservatives will be covered, as will the avoidance of manufacturing contamination. The importance of generating the information needed to find (and eliminate) emerging contamination—before the finished product is involved—will be stressed. Hence, the emphasis will be toward dynamic early-warning control programs, so that appropriate actions can be taken quickly and effectively to avoid problems with production.

Participants should come prepared to examine their current quality control programs, and re-evaluate their overall microbiological efforts from a preventive microbiology point of view.

Course Directors:

Daniel K. Brannan Ph.D., *Professor of Biology, Abilene Christian University* and **Philip Geis, Ph.D.**, *Section Head, Procter & Gamble Company*

Tuition:

Early Registration (SAVE \$200): U.S. \$1500 (\$1440 with Group Rate*) (Must register and pay by September 4, 2008)

Regular Registration: U.S. \$1700 (\$1640 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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

Mixing of Liquids & Complex Materials

ID: 1115 Offering #: 0811-206

November 10–13, 2008 • East Brunswick, NJ

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

- Chemists
- Engineers
- Formulation scientists
- Pharmacists
- Biologists
- Material scientists

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

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

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$2230 (\$2130 with Group Rate*) (Must register and pay by September 15, 2008)

Regular Registration: U.S. \$2430 (\$2330 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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

Pathways to Skin Penetration

ID: 2149 Offering #: 0810-407

October 20–22, 2008 • Burlingame, CA

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

Attendees may hold a function in the following areas:

- Skin Research and Development
- Formulation Chemistry
- Toxicology and Regulatory Affairs
- Technical Sales and Marketing
- Design and development of topically applied formulations

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1275 (\$1215 with Group Discount*)
(Must register and pay by August 25, 2008)

Regular Registration: U.S. \$1475 (\$1415 with Group Discount*)

ACCREDITATIONS/CERTIFICATIONS



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

The American Board of Industrial Hygiene® (ABIH)® This course (#08-672) has been approved for 2.0 Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification.



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

Powder Mixing Technology

ID: 777 Offering #: 0810-401

October 20–23, 2008 • New Brunswick, NJ

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

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

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

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

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1815 (\$1735 with Group Rate*) | Days 1-4 \$2230 (\$2130 with Group Rate*) (Must register and pay by August 25, 2008)

Regular Registration: U.S. \$2015 (\$1935 with Group Rate*) | Days 1-4 \$2430 (\$2330 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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

Root Cause Investigation for CAPA

ID: 2089

Offering #: 0810-202

October 6–7, 2008 • New Brunswick, NJ

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
- R&D
- Maintenance
- Product/Process Development

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. \$1275 (\$1215 with Group Rate*) (Must register and pay by August 11, 2008)

Regular Registration: U.S. \$1475 (\$1415 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



The American Board of Industrial Hygiene® (ABIH)® This course (#07-1813) has been approved for 2.0 Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification.

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

Science and Risk Based Approach to Commissioning, Qualification & Validation

ID: 1954

Offering #: 0810-203

October 7–9, 2008 • Burlingame, CA

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
- Production
- Technical Services/Validation
- Regulatory Affairs

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 Good Engineering Practice (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 (GEP) 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, Compliance Integrated Project Services (IPS)*

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by August 12, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



The Center for Professional Advancement (CFPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program# 716-000-07-115-L04



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

Surfactants, Colloids and Interfaces

ID: 476 Offering #: 0812-105

December 2–5, 2008 • East Brunswick, NJ

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

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

The course can also be valuable to postgraduate research staff.

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

Course Director:

Dr. Tharwat F. Tadros, *Independent Consultant*

Tuition:

Early Registration (SAVE \$200): U.S. \$2155 (\$2055 with Group Rate*) (Must register and pay by October 7, 2008)

Regular Registration: U.S. \$2355 (\$2255 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



The American Board of Industrial Hygiene® (ABIH)® This course (#08-1148) has been approved for 4.0 Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification.

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

The GLP Study Director

REVISED!

ID: 2136 Offering #: 0810-404

October 23–24, 2007 • New Brunswick, NJ

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
- Study Monitors
- The newly appointed Study Director
- Principal Investigators in the field of preclinical regulatory R&D
- Study supervisors who wish to become Study Directors
- 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.

This course goes further than just presenting the theoretical roles of study managers in the difficult arena of multi-site studies. 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*, Long & Associates International Consulting Ltd.

Tuition:

Early Registration (SAVE \$200): U.S. \$1275 (\$1215 with Group Rate*) (Must register and pay by August 28, 2008)

Regular Registration: U.S. \$1475 (\$1415 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# 716-000-08-505-L04

The American Board of Industrial Hygiene® (ABIH)® This course (#08-670) has been approved for 3.0 Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification.



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

Vendor and Contract Supplier Qualification

ID: 1984 Offering #: 0812-202

December 8–10, 2008 • New Brunswick, NJ

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

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

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

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

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

Course Director:

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

Tuition:

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

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

ACCREDITATIONS/CERTIFICATIONS



The Center for Professional Advancement (CfPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program#716-000-07-170-L04

CfPA is a program sponsor approved by the Pennsylvania Board of Accountancy #PX-002022-L. This course has been approved for these purposes.



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

Validation of Manufacturing and Distribution Computer Systems

ID: 1526 Offering #: 0811-107

November 3–5, 2008 • New Brunswick, NJ

Who Should Attend: This course is a must for both users and developers of FDA regulated systems who want and need to know what the FDA expects and requires, what computer validation is, and what needs to be done to validate a computer-based system. It will benefit:

- Users of Systems
- Information System Professionals
- Quality Assurance and Control Personnel
- Project Managers
- Regulatory Affairs Staff
- System Developers and Integrators
- Vendors

This course is very important for those in the pharmaceutical, biologics, software and related industries because of the FDA's increasing emphasis on computer systems, electronic signatures and records, and the extensive use of ERP and MRP systems.

Course Summary: This course is designed to provide an overview of the various aspects of computer validation and to provide the basis for compliance and implementation. The course addresses the rules, tools, and techniques to develop and implement a validation process or to validate a single system. It provides the basic concepts for validation and offers a framework and the technologies to conduct validation projects.

The emphasis is on the most recent rules and techniques including the relevant CFRs, QSIT, the system life cycle including prototyping, testing, qualifications, electronic signatures and records, data and system security and integrity, vendor management and assessment source code, acquired and developed systems, "shrink wrapped" systems, networks, validation, master plan, the validation project, risk assessment, the QSRs, electronic submissions, SOPs, recall requirements for computer-controlled inventories, network validation, requirements documentation, the trace matrix, mainframes, servers, desktop computers, ERP and MRP packages. This interactive course includes an opportunity to ask specific questions, as well as participate in class exercises. The workbook provides regulations, sample SOPs, Validation tools and FDA reference documentation and material.

Course Director:

Philip E. Sax, *Director, Regulatory Affairs and Quality Assurance for Maquet Inc.*

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by September 8, 2008)

Regular Registration: U.S. \$1940 (\$1860 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# 716-000-06-164-L04



(Please refer to page 17 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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LIVE Online Training:

May 29, 2008	Pharmaceutical Water: Chemistry, System Design and Validation ID# 2211
Jun 3, 2008	Pharmaceutical Water and the International Regulatory Environment ID# 2212
Jun 10, 2008	DQ: A Guide to Protecting Your Interests When Procuring Sensors ID#
Jun 17, 2008	Bringing Nanotechnology to Your Market ID# 2200
Jun 19, 2008	Decorative Cosmetics—Using Absorption and Pearl Pigments ID# 2157
Jun 24, 2008	Control of Microbial Contamination in Manufacture of Sterile and Non-Sterile Products ID# 2215
Jul 22, 2008	Investigation of Microbial Contamination in Sterile and Non-Sterile Products ID# 2216
Jul 24, 2008	Skin Inflammation – Reasons, Prevention, Treatment and Testing ID# 2217
Jul 29, 2008	Biocidal and Plant Protection Products in the EU: Borderlines & Overlaps ID# 2218
Aug 21, 2008	Preservatives and Biocides in Consumer Products ID# 2221

ON-DEMAND Online Training Available Anytime:

- Best Practices in SAS Statistical Programming: Understanding and Applying the QC Plan to Validate Summary Tables (*First in a Two-Part Series*) | ID# 2213
- Best Practices in SAS Statistical Programming for Regulatory Submission: Creating Publication-Quality Summary Tables (*Second in a Two-Part Series*) | ID# 2214
- CAPA – The Heart of Your Quality System | ID# 2124
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- Choosing Sensors, Monitors and Instruments for PAT Programs | ID# 2128
- Color Additive Basics for Decorative Cosmetics | ID# 2186
- Color Selection for Decorative Cosmetics | ID# 2182
- Complaint Systems - The Essential Requirements | ID# 2132
- Computerized Systems Used in Clinical Investigations: the New FDA Guidance | ID# 2184
- Conducting Compliant Endotoxin Testing | ID# 2185
- Cost Effective Quality-by-Design and Critical-to-Quality Tools for PAT | ID# 2127
- Encapsulation: Basic Techniques and Applications | ID# 2196
- Endotoxin Testing: Resolving Interference and Test Validation | ID# 2204
- Equipment Qualification in a Nutshell | ID# 2135
- Everything You Wanted to Know About Antiperspirants in 90 Minutes | ID# 2190
- Evolution of the Pharmaceutical Industry through 2020 | ID# 2198
- Guidelines to In Vitro Skin Absorption Studies | ID# 2202
- Introduction to Skin Aging | ID# 2125
- Practical Steps to Understanding ICH Q9 | ID# 2160
- Risk Hazard Assessment for Validation - ISO 14971 | ID# 2147
- Sunscreens: Global Marketing and Product Trends | ID# 2165
- Taking the Mystique out of Silicones for the Personal Care Industry | ID# 2195
- The International Cosmetic Ingredient Dictionary and Handbook: The Process and Impact for Back Label Disclosure | ID# 2170
- Understanding Pharma: Business Growth and Drivers | ID# 2199
- Three-Part Food Series:
 - Understanding and Using Microbial Sampling Plans for Foods (*First in a Three-Part Series*) | ID# 2208
 - Microbial Shelf Life and Challenge Testing for Foods (*Second in a Three-Part Series*) | ID# 2209
 - Understanding and Using Microbial Computer Modeling in Food Microbiology (*Third in a Three-Part Series*) | ID# 2210
- Three-Part Food Series:
 - HACCP: Hazard Analysis and Critical Control Points – An Introduction and Review (*First in a Three Part Series*) | ID# 2166
 - HACCP: Critical Limits, Monitoring and Corrective Actions – An Introduction and Review (*Second in a Three Part Series*) | ID# 2167
 - HACCP: Verification and Record Keeping – An Introduction and Review (*Third in a Three Part Series*) | ID# 2168

For Complete Information on all of CfPA's Online Training Courses, Visit www.cfpa.com/online-training

General Information

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 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.



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

The American Institute of Chemists (AIC)

The Center for Professional Advancement (CfPA) offers many courses which have a chemical component. Such courses may earn up to 20 Certification Units toward certification by The National Certification Commission in Chemistry and Chemical Engineering, sponsored by The American Institute of Chemists.



ISPE's professional development committee approved CfPA's courses which meet standards for professional development.

CfPA is a program sponsor approved by the Pennsylvania Board of Accountancy #PX-002022-L. This course has been approved for these purposes.



Certain courses in this catalog have been approved for recertification credits by the AACPE 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.



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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)

BCSP – This course meets Board of Certified Safety Professionals (BCSP) criteria for points toward the Continuation of Certification requirements

Locations

CfPA courses on pages 1-15 are held in the following hotels. Please refer to individual course on our website for appropriate location.

New Brunswick, New Jersey:

Hyatt Regency
2 Albany Street
New Brunswick, NJ 08901
Phone: 732-873-1234

East Brunswick, New Jersey:

Hilton East Brunswick
3 Tower Center Boulevard
East Brunswick, NJ 08816
Phone: 732-828-2000

Burlingame, California:

DoubleTree Hotel (SF Airport)
835 Airport Blvd
Burlingame, CA 94010
Phone: 650-344-5500

Boca Raton, Florida:

Hilton Suites Boca Raton
7920 Glades Road
Boca Raton, FL 33434
Phone: 561-483-3600

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

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

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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Registration

ONLINE: www.cfpa.com
 (Please Use Priority Code Below) **PHONE:** 732-613-4500 **FAX:** 732-238-9113 **MAIL:** The Center for Professional Advancement (CfPA)
 P.O. Box 7077, East Brunswick, NJ 08816-7077

Name		Title	
Company			
Address			
City	State/Province	Zip Code	
Phone	Fax	E-mail	

Instructions:
 Please complete Registrant Information, Course Information and Payment Sections. Submit one form per individual registrant.
 Check here if group discount applies (two or more enrollments for the same course, from the same company).

Course Title:	Course ID#	Tuition
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