



CfPA

The Center for Professional Advancement
Accredited Technical Training Worldwide

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Accredited Technical Training for the Pharmaceutical, Biotechnology, and Clinical Industries

Course Catalog

April – June 2008 U.S. Course Offerings

Course Topics in this Catalog Include:

- Analytical Methods Validation for FDA Compliance
- Good Laboratory Practices (GLP)
- ICH Q9: Managing Risk in Pharmaceutical Manufacturing **NEW**
- Lyophilization Technology
- Role of PAT and QbD in Biologic Drug Production **NEW**
- U.S. FDA Drug Development and Compliance




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

April - June 2008

Training for the Pharmaceutical, Biotechnology, and Clinical 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 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 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

Active Pharmaceutical Ingredients

ID: 840 Offering #: 0804-105

April 2-4, 2008 • New Brunswick, NJ

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

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

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

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by February 6, 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# 716-000-08-127-L04



(Please refer to page 15 for full description of each Accreditation)

Analytical Methods Validation for FDA Compliance

ID: 1887 Offering #: 0806-101

June 4-6, 2008 • Isla Verde, Puerto Rico

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

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

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

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

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

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

Course Co-Directors:

J. Mark Green, Ph.D., *Principal Investigator*, Bristol-Myers Squibb Medical Imaging

David E. Wiggins, *Associate Director of Analytical/Stability R&D*, Schering-Plough Consumer Health Care Products

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by April 9, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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This course (#07-1812)

The American Board of Industrial Hygiene® (ABIH)® 3.0 Certification Maintenance Points by The American Board of Industrial Hygiene (ABIH) for recertification.



(Please refer to page 15 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.

Calibration in the FDA Regulated Industry

ID: 2026 Offering #: 0801-502

May 29-30, 2008 • Isla Verde, Puerto Rico

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

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

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

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

Course Director:

Dr. Jerry Lanese, *President*, The Lanese Group, Inc.

Tuition:

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

(Must register and pay by April 3, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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The American Association of Family and Consumer Sciences has approved this course for 12 Professional Development Units.



(Please refer to page 15 for full description of each Accreditation)

cGMP for Pharmaceutical Production Supervisors

ID: 604 Offering #: 0804-101

April 1-3, 2008 • New Brunswick, NJ

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

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

It is most beneficial to manufacturing personnel involved in:

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

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1990 (\$1910 with Group Rate*) (Must register and pay by February 5, 2008)

Regular Registration: U.S. \$2190 (\$2110 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Conducting Effective Quality Audits

ID: 1681 Offering #: 0805-201

May 5-8, 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 Discount*) (Must register and pay by March 10, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Drug Product Stability and Shelf Life

ID: 599 Offering #: 0806-406

June 23-25, 2008 • Isla Verde, Puerto Rico

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 April 28, 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# 716-000-06-156-L04*

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 15 for full description of each Accreditation)

Drug Specifications for APIs and Drug Products

ID: 1918

Offering #: 0805-204

May 5-8, 2008 • Burlingame, CA

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

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

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

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

Course Director:

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

Tuition:

Days 1-3

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

(Must register and pay by March 10, 2008)

Regular Registration:

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

Days 1-4

\$2055 (\$1955 with Group Rate*)

\$2255 (\$2155 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



The Center for Professional Advancement (CFPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; certificate will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program# 716-000-06-172-L04

The Center for Professional Advancement 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 15 for full description of each Accreditation)

Fundamentals of Biotechnology NEW

ID: 2197 Offering #: 0805-405

May 19-22, 2008 • New Brunswick, NJ

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

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

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$2155 (\$2055 with Group Rate*) (Must register and pay by March 24, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Generic Drug Approvals

ID: 1462 Offering #: 0805-301

May 14-16, 2008 • New Brunswick, NJ

Who Should Attend: This **overview** course is intended for personnel from generic and brand name drug manufacturers and bulk drug substance suppliers who seek a broad and thorough understanding of the legal, regulatory, and practical aspects of developing and compiling Abbreviated New Drug Applications (ANDAs) and obtaining FDA approval of generic drugs, including:

- Regulatory Affairs
- QA/QC
- Legal/Compliance
- Technical/Scientific/Research
- Management
- Manufacturing

Course Summary: When Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Waxman-Hatch Act"), it enabled the pharmaceutical industry to seek approval via an ANDA of generic versions of the vast majority of drugs approved by FDA since 1962. New, complex requirements were imposed on persons seeking FDA approval of these generic drugs. Congress also created incentives to encourage development of new branded products, including extended patent protection and periods of non-patent market exclusivity.

This course will review the basic provisions of the Waxman-Hatch Act; the information and data required for an ANDA; which drugs are eligible for submission under an ANDA and why; the role of patent protection and market exclusivity; pitfalls and pointers in dealing with the FDA review process; bioequivalence testing; and changing pending ANDAs and Drug Master Files (DMFs). Particular attention will be given in the course to the impact of FDA's regulations and guidances on both paper and electronic ANDAs..

Course Co-Directors:

Robert J. Anderson, Esq., *Vice President, Scientific Affairs, Nycomed*
Michael A. Swit, Esq., *Vice President, Life Sciences at The Weinberg Group Inc.*
Gary L. Yingling, Esq., *Partner, Kirkpatrick & Lockhart Preston Gates Ellis LLP*

Tuition:

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

(Must register and pay by March 19, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Good Laboratory Practices (GLP)

ID: 545 Offering #: 0806-401

June 23-25, 2008 • Burlingame, CA

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:

Mr. David Long, *Consultant*

Tuition:

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

(Must register and pay by April 28, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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The American Board of Industrial Hygiene® (ABIH®) 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 15 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.

April 7-9, 2008 • Ft. Mitchell, KY

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

It would be of particular benefit to:

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Discount*) (Must register and pay by February 11, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 15 for full description of each Accreditation)

ICH-Q7: Harmonized GMPs for API Production and Control

ID: 2091

Offering #: 0805-302

May 14-16, 2008 • New Brunswick, NJ

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

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

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

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by March 19, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

ICH Q9: Managing Risk in Pharmaceutical Manufacturing



ID: 2158

Offering #: 0804-104

April 2-3, 2008 • New Brunswick, NJ

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

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

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

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1275 (\$1215 with Group Rate*) (Must register and pay by February 6, 2008)

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

IQ/OQ/PQ

ID: 1808

Offering #: 0806-303

June 17-18, 2008 • New Brunswick, NJ

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 April 22, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

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 15 for full description of each Accreditation)

Laboratory Control System

ID: 2047 Offering #: 0806-403

June 25-27, 2008 • New Brunswick, NJ

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

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

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

Course Director:

Dr. John G. (Jerry) Lanese, *President, The Lanese Group, Inc.*

With Presentations by: Dr. Alan J. Smith, *Pharmaceutical and Technology Consultant*

Tuition:

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

(Must register and pay by April 30, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Lyophilization Technology

ID: 279 Offering #: 0804-206

April 7-9, 2008 • Burlingame, CA

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, *Co-Founder/Chief Scientific Officer, BioConvergence LLC*

Tuition:

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

(Must register and pay by February 11, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Packaging of Pharmaceuticals

ID: 42

Offering #: 0805-202

May 6-8, 2008 • New Brunswick, NJ

Who Should Attend: This course 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. \$1740 (\$1660 with Group Rate*) (Must register and pay by March 10, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Patent Law for Managers, Engineers & Scientists

ID: 520

Offering #: 0804-502

April 28-29, 2008 • Northbrook, IL

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

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.

In addition, recent US Supreme Court decisions along with new USPTO rules will effect how to approach protecting intellectual property.

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 Co-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. \$1275 (\$1215 with Group Rate*) (Must register and pay by March 3, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 15 for full description of each Accreditation)

Pathways to Skin Penetration

ID: 2149 Offering #: 0806-108

June 5-6, 2008 • New Brunswick, NJ

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 April 10, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Pharmaceutical Quality Assurance and Control

ID: 224 Offering #: 0804-501

April 28-May 2, 2008 • Boca Raton, FL

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

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

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

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$2350 (\$2055 with Group Discount*) (Must register and pay by March 3, 2008)

Regular Registration: U.S. \$2550 (\$2255 with Group Discount*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Pharmaceutical Technology Transfer

ID: 2095

Offering #: 0806-202

June 11-12, 2008 • New Brunswick, NJ

Who Should Attend: This course is intended for individuals from

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

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

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

Course Director:

Walter G. Chambliss, *Professor of Pharmaceutics, University of Mississippi*

Tuition:

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

(Must register and pay by April 16, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Preparation, Packaging and Labeling of Clinical Trial

ID: 858

Offering #: 0806-102

June 2-4, 2008 • New Brunswick, NJ

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

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

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

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1770 (\$1690 with Group Rate*) (Must register and pay by April 7, 2008)

Regular Registration: U.S. \$1970 (\$1890 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 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.

Role of PAT and QbD in Biologic Drug Production



ID: 2163

Offering #: 0804-303

April 15-16, 2008 • New Brunswick, NJ

Who Should Attend: This comprehensive quality system workshop will benefit professionals who are involved in the entire biologic drug chain, from development through unit operations to product fill, storage and release to market, including:

- PAT and QbD Team Leaders and Members
- Quality and Efficiency Personnel
- Manufacturing Operations Personnel
- Product Development Teams
- Technology Transfer Personnel
- In-process and Finished Goods Analysts
- Biologic Excipient Suppliers
- Analytical Instrument and Manufacturing Equipment Suppliers
- Managers tasked with biologic product development and evolution

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

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

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

Course Director:

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

Tuition:

Early Registration (SAVE \$200): U.S. \$1275 (\$1215 with Group Rate*) (Must register and pay by February 19, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Root Cause Investigation for CAPA

ID: 2089

Offering #: 0805-101

May 1-2, 2008 • Isla Verde, Puerto Rico

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 Discount*) (Must register and pay by March 6, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



(Please refer to page 15 for full description of each Accreditation)

Scale-Up and Post Approval Changes Guidelines (SUPAC & API Changes) ID: 1948 Offering #: 0806-201

June 9-11, 2008 • New Brunswick, NJ

Who Should Attend: This course is intended for personnel in the pharmaceutical industry involved in the development of drug dosage forms including:

- Process Development
- Technical Service
- Pilot Plant
- Quality Assurance
- Regulatory Affairs
- Research & Development
- Production

It will also be of value to personnel wanting a comprehensive understanding of FDA guidelines and requirements relevant to changes in formulation, equipment and process in the following fields:

- Analytical Services
- Product development
- Production
- Quality Assurance
- Project Management

Course Summary: This course will provide a basic understanding of the FDA Scale-up and Post Approval Changes Guidelines & the recent 2004 guideline on Changes to approved NDA or ANDA. This also addresses the impact of withdrawal of the FDA BACPAC I guideline on changes in API synthesis. The issues affecting batch size scale-up/ scale-down, various post approval formulation component or composition changes, site of manufacturing changes, manufacturing process changes, and/or equipment changes will be addressed along with the issues affecting analytical methodology, packaging and labeling changes. The course will focus on: The criteria that determines the level or degree of change; The type of study data or information that must be generated to support changes at each level; The FDA recommended chemistry manufacturing & control tests to support each level or degree of change; The type of in-vivo or in-vitro testing required to support the various levels of degrees of change. Case examples will be employed to allow the students to determine the type of data that are required to support the level of changes proposed.

Course Director:

Mukund "Mike" Yelvigi, Director, Development Planning Chemical and Pharmaceutical Development, Wyeth Research Laboratories

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Discount*) (Must register and pay by April 14, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Tablet Production for Operators and Supervisors

ID: 1428

Offering #: 0804-401

April 21-23, 2008 • Isla Verde, Puerto Rico

Who Should Attend: This course is intended for personnel needing a quick, yet comprehensive, survey of tablet production. Those who have gained valuable information from this course include:

- Senior Process Operators
- Newly Promoted Supervisors
- QA Personnel
- Warehouse Personnel
- Packaging Personnel
- Regulatory Affairs Specialists

This course is not intended for higher level technical and senior managerial personnel, for whom other related courses are available.

Course Summary: This course provides an orientation and understanding of bulk tablet production for process operators and first-line supervisors. The course begins with the basic aspects of tablet formulating and the unit operations necessary to produce production quantities. All aspects of granulating, compressing, coating, printing, cleaning and documenting will be covered. The application of cGMP, as applied to tableting operations, will also be presented.

Important supporting operations such as tool and die maintenance, tablet inspection, basic validation principles, sanitation fundamentals, proper materials weighing techniques and equipment automation will be presented.

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

Course Director:

Fred A. Rowley, Director, Watson Pharmaceuticals

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by February 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# 716-000-07-167-L04



(Please refer to page 15 for full description of each Accreditation)

April 7-9, 2008 • New Brunswick, NJ

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

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

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

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

Course Co-Directors:

Mary L. Richardson, *Vice President Regulatory Affairs*, Mission Pharmacal Company
Gary L. Yingling, Esq., *Partner*, K&L Gates

Tuition:

Early Registration (SAVE \$200): U.S. \$1740 (\$1660 with Group Rate*) (Must register and pay by February 11, 2008)

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

ACCREDITATIONS/CERTIFICATIONS



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(Please refer to page 15 for full description of each Accreditation)

Upcoming July–August 2008 Courses

<u>ID No.</u>	<u>Title</u>	<u>Location</u>	<u>Dates</u>
669	Aerosol Technology	Northbrook, Illinois	July 15-18
1915	Antiperspirant and Deodorant Technology: Principals & Applications	New Brunswick, NJ	July 16-17
2012	cGMP Auditing - Strategies for Compliance	New Brunswick, NJ	August 11
1989	CMC Submissions in CTD Format	New Brunswick, NJ	August 4-5
1350	Cosmetic Product Formulation	New Brunswick, NJ	August 4-6
1867	Critical Process Cleaning and Cleaning Validation	Burlingame, California	July 7-9
1866	Documentation Management and Control	Burlingame, California	July 14-15
2050	Excipient GMPs	New Brunswick, NJ	July 21-23
541	Granulation, Tableting and Capsule Technology	Burlingame, California	August 18-21
1019	Gums and Hydrocolloids	New Brunswick, NJ	August 11-13
2076	Hair Product Development	New Brunswick, NJ	August 7-8
774	Microencapsulation and Particle Coating	Northbrook, Illinois	August 11-13
520	Patent Law for Managers, Engineers and Scientists	New Brunswick, NJ	August 14-15
1358	Pharmaceutical Process Development	New Brunswick, NJ	July 28-30
187	Preparing for and Surviving an FDA Inspection	New Brunswick, NJ	August 12-13
2085	Process Analytical Technology (PAT)	New Brunswick, NJ	July 22-2
1789	Process Validation for Packaging of Pharmaceuticals and Medical Devices	New Brunswick, NJ	July 28-30
1050	Skin Product Development	New Brunswick, NJ	August 25-27

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 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 the courses noted in this catalog 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.*



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.



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 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 details)

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



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 Association of Family and Consumer Sciences has approved this course for 12 Professional Development Units.

Locations

CfPA courses on pages 1-14 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

Boca Raton, FL

Embassy Suites Hotel
661 NW 53rd St
Boca Raton, FL 33487
Phone: (561) 994-0041

Ft. Mitchell, Kentucky

Drawbridge Inn
2477 Royal Dr
Covington, KY 41017
Phone: (859) 341-2800

Burlingame, California:

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

Embassy Suites SF Airport

150 Anza Blvd,
Burlingame, CA, 94010
Phone: (650)-342-4600

Northbrook, IL

Northbrook Hilton
2855 N Milwaukee Ave
Northbrook, IL
Phone: (847) 480-7500

Isla Verde, Puerto Rico:

Embassy Suites San Juan
8000 Tartak Street, Isla Verde
Carolina, Puerto Rico 00979
Phone: (787)-791-0505

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.

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.

Introducing

Online Training

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

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

Advantages of CfPA's Online Training:

- Convenient** – Access CfPA Online Training from your office, home or on the road - anywhere around the world
- Interactive** – Actively participate with instructor and participants in a virtual classroom through the use of polls, Q&A and other online tools
- Topics** – All courses taught by leading industry experts, topic areas are similar to our public courses and include basic concepts to the latest advances
- Accredited** – Training programs are accredited and/or certified
- Easy to Use** – All you need is a computer with an internet connection, and a phone line
- Cost Effective** – Save on travel costs and time out of the office
- On-Demand** – Previously held courses are available for viewing when it is convenient for you

For more information on our Online Training:

Go to www.cfpa.com/onlinetraining or E-mail onlinetraining@cfpa.com

Customized Training Through

Client Site Programs

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

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

What are the advantages to a Client Site Course?

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

How to arrange a Client Site Course:

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

Registration Form

ONLINE: www.cfpa.com <small>(Please Use Priority Code Next to Address When Registering)</small>	FAX: 732-238-9113	MAIL: The Center for Professional Advancement (CFPA) P.O. Box 7077, East Brunswick, NJ 08816-7077
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Instructions:

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

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

Registrant Information

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

Course Information

Course Title	Course ID#	Tuition
Total \$		

Payment

Check: Payable in US funds to: **The Center for Professional Advancement**

Credit Card: Visa Mastercard American Express Discover

Card #: _____ **Exp. Date:** _____

Cardholder Name: _____ **Signature:** _____

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

ID: 2138 - Offering: 0801-802 - BID: C7-389

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