Accredited Technical Training for the Pharmaceutical, Biopharmaceutical, Clinical and Medical Device Industries

January – May 2009 U.S. Course Offerings

Course Topics in this Catalog Include:
- Applied cGMPs for Pharmaceutical and Allied Industries
- Best Practices in SAS Statistical Programming
- Critical Process Cleaning and Cleaning Validation
- Guidelines for Skin Absorption Studies
- Orphan Drug Application and Submission
- Process Validation for the Pharmaceutical and Medical Device Industries
- Root Cause Investigation for CAPA
- 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 Available

www.cfpa.com
## January–May 2009 U.S. Courses

### Welcome

For over 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
- E-mail: onlinetraining@cfpa.com

For Upcoming Online Courses See Page 20

### 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
- E-mail: clientsite@cfpa.com
- www.cfpa.com/client-site

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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.
Active Pharmaceutical Ingredients

April 27–29, 2009 • New Brunswick, NJ

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

- Pilot and commercial production
- QA/QC
- Technical Services
- Regulatory affairs
- Process development
- Validation
- Regulatory Agency Investigators

The presenters discuss requirements for a GMP compliant API operation, everyone’s role in achieving compliance, and penalties for noncompliance.

Course Summary: This course prepares attendees to meet the challenges they face in the heavily regulated pharmaceutical industry. API manufacturers must ensure that GMP principles are applied to API production and there is extensive focus on relevant operational, control, and regulatory activities with specific examples. This information is essential for successfully meeting GMP requirements that are sometimes only incompletely expressed by official regulatory guidance documents including ICH Q7.

Some of the topics discussed are design, construction, and qualification of GMP production facilities; selection, qualification, and cleaning of equipment; process development and technical transfer; validation principles and process validation. Regulatory agency compliance oversight, and duties of the quality unit to establish and manage systems required to maintain compliance will be discussed. Throughout the program there are interactive class exercises. On the last day of the course, participants receive instructions on managing an FDA inspection followed by a workshop in which participants prepare written responses to simulated FDA-483s (List of Inspectional Observations) based on actual FDA observations. The exercise will result in a valuable exchange of information and approaches with your colleagues.

Course Director:
Richard G. Einig, Ph.D., RAC, CQA , Pharmaceutical Quality Assurance Consultant

Tuition:
Early Registration (SAVE $200): U.S. $1750 ($1670 with Group Rate*) (Must register and pay by March 2, 2009)
Regular Registration: U.S. $1950 ($1870 with Group Rate*)

Analytical Methods Validation for FDA Compliance

March 2–4, 2009 • New Brunswick, NJ

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 January 5, 2009)
Regular Registration: U.S. $1940 ($1880 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS

The Center for Professional Advancement (CPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation.

The CEU rate is 0.1 CEU per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program# 716-000-09-127-L04

(Please refer to page 21 for full description of each Accreditation)
Annual Product Reviews (APRs) for Pharmaceuticals

ID: 1998  Offering #: 0901-502

January 28–29, 2009 • New Brunswick, NJ

Who Should Attend: This course should benefit those who need to know how APRs for drug products and/or active pharmaceutical ingredients should be designed, organized and otherwise managed.

The course will benefit individuals in:
- Quality Assurance
- Quality Control
- Production
- Regulatory Affairs
- Technical Services
- Site & Corporate Management

It should also be of interest to suppliers to the industry.

Course Summary: The FDA's cGMP regulations require that an annual review (commonly called "Annual Product Review") be performed for all drug products. The EU GMP regulations and also the ICH Q7A guideline for the GMP's for active pharmaceutical ingredients have corresponding detailed requirements. In each case, there is a general requirement that the quality of each product be reviewed at least once per year "to determine the need for changes in specifications or manufacturing or control procedures" and that any adverse or unexpected trends be identified so that corrective action can be taken. It is indicated that the review should encompass a representative number of batches and include considerations of recalls, product complaints, returned & salvaged products and investigations performed as a result of deviations encountered during production. The wording used is very broad and provides little guidance on what details should be addressed.

This course sets out to define what details should not only satisfy the FDA's expectations but should also help meet the firm's economic goals of understanding product quality & identifying areas for correction & improvement. The course includes a consideration of the system by which APRs can be effectively and efficiently prepared and issued as well as the details which the SOP should address.

A Team Presentation by:
Dr. Alan J. Smith, Pharmaceutical Quality & Technology Consultant and Dr. John G. (Jerry) Lanese, President, The Lanese Group, Inc.

Tuition:
Early Registration (SAVE $200): U.S. $1275 ($1215 with Group Rate*) (Must register and pay by December 3, 2008)

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

Applied cGMPs for Pharmaceutical and Allied Industries

ID: 610  Offering #: 0903-402

March 23–25, 2009 • Burlingame, CA

Who Should Attend: This is an ideal course to acquire current applications of cGMPs. It offers latitude for discussion of fundamental as well as evolving regulatory initiatives and other complex issues. The course is distinguished for benefit to domestic as well as non-US enterprises, including the following:
- Positions – Analysts, Directors, Engineers, Executives, Investigators, Internal Auditors, Managers, Operators, QA/QC, Research, Supervisors, and Trainers
- Industries – Academia, Biogeneric, Biological, Biopharmaceutical, Combination Product Manufacturers, Consultants, Contract Manufacturing, Dietary Supplements, Health Care, Legal Pharmaceutical, Regulatory, and Many Others.

Course Summary: This course takes you through Current Good Manufacturing Practice (cGMP) in the pharmaceutical and allied industries. Topics covered include legal requirement for cGMP in the Federal Food, Drug, and Cosmetic Act and related regulations. It addresses practical aspects of personnel, facilities, equipment, components, manufacturing, laboratory, packaging, labeling, and QA/QC and provides an excellent forum for training personnel in cGMPs. The faculty consists of individuals with long and distinguished experience in the field. Throughout this course, the relevance of FDA inspections commonly surfaces. There is special emphasis on discussing procedures and practices of the regulatory agency to help firms comprehend management of FDA relationships.

Course Director:
Wayne A. Mazanec, Former FDA Assistant Regional Director–Pacific Region, and Regulatory Consultant

Tuition:
Early Registration (SAVE $200): U.S. $1740 ($1660 with Group Rate*) (Must register and pay by January 26, 2009)

Regular Registration: U.S. $1940 ($1860 with Group Rate*)
Best Practices in SAS Statistical Programming

March 26–27, 2009 • New Brunswick, NJ

Who Should Attend: This course is intended for anyone directly or indirectly responsible for the creation, content or validation of summary tables, data lists and graphs used to support research, drug or medical device efficacy and safety in a regulatory submission. Professionals in the pharmaceutical, biotechnology and medical device industries who want to be 21 CFR Part 11 compliant in relation to the SAS programming environment will benefit from this unique course. Effective and practical solutions to address real-world issues will be provided.

This course is recommended for:

- SAS Statistical Programmers
- SAS Statistical Managers
- Director, Statistical Programming
- Statisticians
- Clinical Data Managers
- Quality Assurance Specialists
- Medical Writers
- Regulatory Affairs Associates
- CRO’s
- Health Care Professionals
- Research Universities

Course Summary: This intense two-day course focuses on the validation process to assure that correct, consistent and reliable summary tables are reproducible. In addition, a variety of effective methods for producing standard and custom summary tables will be provided. SAS data sets used in the course are CDISC ready. Discussions will focus on proven techniques to address real-world issues. Get your SAS technical and validation questions answered and learn efficient tips for producing a quality regulatory submission in a timely manner. Students will receive a CD containing all tools and SAS macros reviewed in the course.

Course Director:
Sunil Gupta, Associate Director, Quintiles Inc.

Tuition:
Early Registration (SAVE $200): U.S. $1275 ($1215 with Group Rate*) (Must register and pay by January 29, 2009)

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

Calibration in the FDA Regulated Industry

January 26–27, 2009 • New Brunswick, NJ

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 who 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 December 1, 2008)

Regular Registration: U.S. $1475 ($1415 with Group Rate*)
cGMP for Pharmaceutical Production Supervisors

ID: 604 Offering #: 0905-202

May 5–7, 2009 • 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
- Group leaders of incoming inspection

It is most beneficial to manufacturing personnel involved in:

- Packaging
- In-process inspecting
- Maintenance and warehousing

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. $2040 ($1960 with Group Rate*)
(Must register and pay by March 10, 2009)

Regular Registration: U.S. $2240 ($2160 with Group Rate*)

CMC Submissions in CTD Format

ID: 1989 Offering #: 0902-201

February 9–10, 2009 • Boca Raton, FL

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

- Regulatory Affairs
- Chemistry and Analytical Departments
- Pre-formulation

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

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

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

Tuition:
Early Registration (SAVE $200): U.S. $1275 ($1215 with Group Rate*)
(Must register and pay by December 15, 2008)

Regular Registration: U.S. $1475 ($1415 with Group Rate*)
Compliant Handling and MDR Reporting

March 23–25, 2009 • Buringame, CA

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

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 January 26, 2009)
- Regular Registration: U.S. $1940 ($1860 with Group Rate*)

Critical Process Cleaning and Cleaning Validation

January 14–16, 2009 • Boca Raton, FL

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 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 November 19, 2008)
- Regular Registration: U.S. $1940 ($1860 with Group Rate*)

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.
Documentation Management and Control

February 23–24, 2009 • New Brunswick, NJ

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

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

Course Summary: FDA regulations such as Good Manufacturing Practice (GMP) for drugs and medical devices, Good Laboratory Practice (GLP), Good Clinical Practice (GCP), as well as quality system standards like ISO 9000, require that documentation, such as standard operating procedures, plans and various types of records, be in place. These regulations, however, do not provide any guidelines to the industry on how to set up and manage documentation systems. This course provides hands-on methodology and techniques on how to identify what systems require document coverage; how to flowchart operations to identify what type of documentation is required; and how to set up, implement and manage the maintenance of such documentation systems to ensure continuous compliance. Types of documentation addressed include: quality manuals, policy manuals, standard operating procedures, work instructions, forms, records, logs, protocols, etc. The course also covers areas related to computer validation documentation, such as validation protocols and 21 CFR Part 11—Electronic Records and Signatures. Emphasis is placed on controls that need to be in place to ensure proper manipulation of documentary systems.

Course Director:
Renée B. Galkin, Quality Management Consultant

Tuition:
Early Registration (SAVE $200): U.S. $1275 ($1215 with Group Rate*)
(Must register and pay by December 29, 2008)

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

Drug Product Stability and Shelf Life

March 2–4, 2009 • Boca Raton, FL

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 January 5, 2009)

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

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.
Generic Drug Approvals

May 4–6, 2009 • 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 FDAs regulations and guidances on both paper and electronic ANDAs.

Course Co-Directors:
Michael A. Swit, Esq., Vice President, Life Sciences at The Weinberg Group Inc.
Robert Anderson, VP Scientific Affairs, Nycomed US, Inc.
Rebecca Dandeker, of Counsel, K&L Gates

Tuition:

Early Registration (SAVE $200): U.S. $1740 ($1660 with Group Rate*)
(Must register and pay by March 9, 2009)

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

GMP for Dietary Supplements

March 12–13, 2009 • 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 January 15, 2009)

Regular Registration: U.S. $1475 ($1415 with Group Rate*)
Good Laboratory Practices (GLP)

March 16–18, 2009 • Boca Raton, FL

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
• Those newly assigned GLP responsibilities
• Quality Assurance Staff
• 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 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, Long & Associates International Consulting Ltd.

Tuition:
Early Registration (SAVE $200): U.S. $1740 ($1660 with Group Rate*)
(Must register and pay by January 19, 2009)
Regular Registration: U.S. $1940 ($1860 with Group Rate*)

Granulation, Tableting & Capsule Technology

March 23–26, 2009 • Boca Raton, FL

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
• Manufacturing/Production
• Purchasing
• Engineering Support

Course Summary: The main aim of this course is to review the science relating to tabletted 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 January 26, 2009)
Regular Registration: U.S. $2355 ($2255 with Group Rate*)

ID: 545 Offering #: 0903-302

ID: 541 Offering #: 0903-401
Hydrogenation Technology

April 27–29, 2009 • 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 March 2, 2009)
Regular Registration: U.S. $1940 ($1860 with Group Discount*)

INDs, NDAs vs CTDs Global Regulations

March 9–11, 2009 • Burlingame, CA

Who Should Attend: This course is specifically designed for personnel in the pharmaceutical and biotechnology industries who need a detailed understanding of what comprises an IND, NDA, BLA, ANDA, SINDA, and CTD. This includes but is not limited to those involved in:
- Pre-Clinical Research
- CMC Components
- Regulatory Affairs
- Management
- Clinical Research
- Quality Assurance
- Product Development

Participants should have a basic understanding of new product development and/or regulatory affairs in order to best comprehend the lectures presented in this course.

Course Summary: The content of this course is designed to present the intricate parts of INDs, NDAs, BLAs, ANDAs, SINDAs and CTDs. These regulatory submissions for drug and biologic products will be based on the requirements of the US Code of Federal Regulations, the ICH Guidelines for global submissions and the EU Directives. Specifics of the IND, NDA, BLA, ANDA, SINDA and CTD will be detailed for safety, quality, and efficacy. Non and pre-clinical data, clinical data and CMC data to achieve product approvals globally will be enumerated for expediting new product approvals. Other subject areas include:

- FDAs internal structure, policies, and procedures
- GCP, GLP and GMP regulation requirements for INDs, NDAs, BLAs, ANDAs, SINDAs, CTDs and Drug Master Files
- The FDA review process for new product approvals, including FDA/Industry Meetings and Liaison
- Acceptance of foreign data for new product approvals, EU Directives on global submissions.

Course Director:
Dr. Richard A. Guarino, President, Oxford Pharmaceutical Resources, Inc.

Tuition:
Early Registration (SAVE $200): U.S. $2040 ($1960 with Group Rate*) (Must register and pay by January 12, 2009)
Regular Registration: U.S. $2240 ($2160 with Group Rate*)
Guidelines for Skin Absorption Studies

February 19–20, 2009 • New Brunswick, NJ

Who Should Attend: The course will explain the importance of evaluating skin absorption of compounds from topically applied formulations for safety assessment, mechanistic studies and prior to conducting clinical studies. This course will benefit professionals in the cosmetic and pharmaceutical industries especially:

- Skin research and development scientists
- Formulation chemistry experts
- Toxicology and regulatory affairs specialists
- Technical sales and marketing professionals
- University and allied health care professionals

Course Summary: In vitro skin absorption testing is part of recommended regulatory guidelines in the USA and of global interest to assess safety of exposure to chemicals when applied topically. The Personal Care Council (formally CTPA), the OECD (Organization for Economic Co-Operation and Development), WHO (World Health Organization) and SCCP (Scientific Committee of Consumer Products) - have all issued guidelines to address absorption of compounds from cosmetic formulations. The objective of these guidelines is to obtain quantitative and/or qualitative information on the amounts of chemicals that may penetrate the skin transdermally into the blood circulatory system during “real time” use.

Since in vitro studies have been demonstrated to provide reliable, reproducible data, for topically applied formulations when the skin is the target of action it is imperative that an understanding of penetration patterns be developed in order to allow for better product development as well as conservation of both resources and time in the process of product design.

This unique course will describe the importance of evaluating skin absorption of compounds from topically applied formulations. This description is an essential context for safety assessment, mechanistic studies and fundamental to conducting clinical studies. It will also review key parameters in the guidelines and provide tools for further research.

Course Director:
Nava Dayan, Ph.D., Skin Care Research Expert

Tuition:
Early Registration (SAVE $200): U.S. $1275 ($1215 with Group Rate*) (Must register and pay by December 29, 2008)
Regular Registration: U.S. $1475 ($1415 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS

The Center for Professional Advancement (CIPA) 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# 716-000-09-318-L04

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

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

January 21–22, 2009 • Boca Raton, FL

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

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 of 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 November 26, 2008)
Regular Registration: U.S. $1475 ($1415 with Group Rate*)
Lyophilization Technology

March 30 – April 1, 2009 • 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 2, 2009)

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

Microbiological Control and Validation

May 18–20, 2009 • Burlingame, CA

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 Discount*)
(Must register and pay by March 23, 2009)

Regular Registration: U.S. $1940 ($1860 with Group Discount*)
Microencapsulation and Particle Coating

February 9–11, 2009 • New Brunswick, NJ

Who Should Attend: The course should be of value to those working in microencapsulation, as well as to those in industry and research laboratories who would profit from a thorough presentation and discussion of the many techniques and the characteristics of the microcapsules formed from them. It should be of particular interest to personnel in the following industries:

- Pharmaceutical
- Cosmetic
- Bioengineering
- Food
- Chemical
- Agricultural

Course Summary: This program will provide an up-to-date assessment of available encapsulation techniques. Each lecturer will present the basic chemical and physical principles of their processes, as well as a discussion of specific techniques and applications. The aim of the program is to provide an understanding of the unique advantages and difficulties of each major microencapsulation technique. Emphasis will be placed on proven techniques, results and actual applications in various industries. The instructors, all of whom are recognized experts in their areas, will present the latest available information regarding the processes in which they specialize. The lectures are structured to encourage open discussions between lecturers and participants.

Course Director:
Dr. James D. Oxley, Senior Research Scientist, Department of Microencapsulation, Nanomaterials, and Process Engineering, Southwest Research Institute

Tuition:
- Early Registration (SAVE $200): U.S. $1740 ($1660 with Group Rate*)
  (Must register and pay by December 15, 2008)
- Regular Registration: U.S. $1940 ($1860 with Group Rate*)

Non-Clinical Drug Safety Evaluation & Drug Development

March 9–12, 2009 • New Brunswick, NJ

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

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

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

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

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

Course Director:
Dr. Shayne C. Gad, Principal of Gad Consulting Services

Tuition:
- Early Registration (SAVE $200): U.S. $2155 ($2055 with Group Rate*)
  (Must register and pay by January 5, 2009)
- Regular Registration: U.S. $2355 ($2255 with Group Rate*)

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.
February 9–10, 2009 • New Brunswick, NJ

Who Should Attend: This course is intended for professionals within the pharmaceutical and biopharmaceutical industries. It will be especially beneficial for:

- Document Managers
- Regulatory Affairs Personnel
- Managers and Directors of Regulatory Submissions
- Those involved in clinical trials

Course Summary: Orphan Drugs, designed to treat or prevent diseases affecting fewer than 200,000 persons, have a special FDA status. Fees are waived; exclusivity protection is provided and there is some additional flexibility in experimentation and approval. Orphan Drug Status is awarded after agency review of a submitted Orphan Drug Application.

This two-day seminar provides hands on guidance, FDA evaluation criteria and submissions checklists. Participants who bring a planned submission topic to the course will develop a comprehensive application outline over the two days of the program.

By the end of the course you will have a specific outline for your regulatory submission.

Course Director:
Dr. Sandy Weinberg, Associate Professor, Heath Care Management, Clayton State University

Tuition:
Early Registration (SAVE $200): U.S. $1275 ($1215 with Group Rate*) (Must register and pay by December 8, 2008)
Regular Registration: U.S. $1475 ($1415 with Group Rate*)

May 4–6, 2009 • New Brunswick, NJ

Who Should Attend: This training is designed for personnel involved in packaging in the following industries: pharmaceuticals; medical devices; personal care products; cosmetics & toiletries; nutraceuticals; and biopharmaceutical industries. It will be especially beneficial to:

- Development
- QA/QC
- Purchasing
- Regulatory Affairs
- 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 9, 2009)
Regular Registration: U.S. $1940 ($1860 with Group Rate*)
Pilot Plant and Scale-Up Studies

ID: 1882  Offering #: 0902-204

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

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

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

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

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

Tuition:
Early Registration (SAVE $200): U.S. $1825 ($1745 with Group Rate*) (Must register and pay by December 17, 2008)
Regular Registration: U.S. $2025 ($1945 with Group Rate*)

ACCREDITATIONS/CERTIFICATIONS

(Please refer to page 21 for full description of each Accreditation)
Process Validation for Packaging of Pharmaceuticals and Medical Devices

April 29 – May 1, 2009 • New Brunswick, NJ

Who Should Attend: This program is prepared for personnel in pharmaceuticals, medical devices, personal care products, cosmetics, toiletries, and the veterinary medicines industries.

It will benefit those employed in packaging in:

- Development
- Technology
- Processing
- Suppliers
- QA/QC
- Auditing
- Engineering
- Regulatory Affairs
- Project Leading
- Purchasing
- Outsourcing
- Marketing

Extensive knowledge of validation is not required.

Course Summary: This course provides a structured approach to validation practices, to ensure the packaging of a drug, medical device or allied product, conforms to its predetermined specification. Targets are: consistent quality to the consumer, compliance with regulatory requirements, safety, cost effectiveness, long term financial and other benefits to the company.

The need to translate customer/user requirements to measurable specifications, followed by controlled processing is explained. Emphasis is on practical ways of implementing validation, using protocols, SOP’s, planning, statistics, process controls and other tools. The Validation-Master Plan/Protocol, protocols, templates for IQ, OQ and PQ, and change controls are all detailed with text.

The course covers the essentials of validation and gives details of validating; a push-through-pack machine, packaging line, cleaning and sterile pack integrity. Specific tasks and requirements of the various functional groups involved are covered in depth. Regulations are given special attention and prospective, concurrent and retrospective validation will be discussed critically. Vendor/supplier assessment and auditing are crucial and will be outlined.

Exercises in small groups and discussions will offer participants practice to develop skills to prevent or eliminate faults, failures and rejects in processing.

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 4, 2009)

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

Process Validation for the Pharmaceutical and Medical Device Industries

May 14–15, 2009 • Burlingame, CA

Who Should Attend: This course is intended for professionals involved in the pharmaceutical and related industries, including, but not limited to:

- Quality Assurance
- Production
- Engineering
- Process Design and Development
- Quality Control
- Regulatory
- Research and Development, and software

Course Summary: Validation of manufacturing processes in the cGMP environment is recognized by the medical manufacturing industries and by the regulatory agencies in the U.S., E.U. and Japan. This course will give the attendee an overview and understanding of the validation process, how to organize it and carry out process validations, key areas to look for during an audit, and assist managers in overall planning.

Various approaches to validation will be discussed with actual examples of successes and failures of industry validation experiences.

Participants are invited to bring examples of their own validation issues to be discussed during the case studies session.

Course Director:

Tuition:
Early Registration (SAVE $200): U.S. $1275 ($1215 with Group Rate*) (Must register and pay by March 19, 2009)

Regular Registration: U.S. $1475 ($1415 with Group Rate*)
Root Cause Investigation for CAPA

April 15–16, 2009 • Burlingame, CA

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 and 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 February 18, 2009)
Regular Registration: U.S. $1475 ($1415 with Group Rate*)

Skin Product Development

March 18–20, 2009 • Burlingame, CA

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

• Research and Development  • Technical Sales  • Formulations Development  • Marketing

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

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

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

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

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

Course Director:
Nava Dayan, Ph.D., Skin Care Research Expert

Tuition:
Early Registration (SAVE $200): U.S. $1740 ($1660 with Group Rate*) (Must register and pay by January 21, 2009)
Regular Registration: U.S. $1940 ($1860 with Group Rate*)

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.
## Suspensions and Emulsions in Pharmaceuticals and Food

### Course Description:
This course is designed to provide a set of theoretical and practical tools for those interested in working with dispersed phases and predicting and understanding their sometimes complex behavior. The participant will learn to use the materials and processes needed to create dispersed-phase products, and to effectively solve problems arising during development. Troubleshooting existing commercial product problems will be emphasized as well. The theoretical underpinnings of emulsion and suspension behavior will be described to provide a backdrop for discussions of specific emulsifying and suspending systems. Current methods to analyze the behavior of dispersed phases will be described, as will methods to measure and predict stability of the products. Processing and scale-up issues specific to the type of equipment needed to create dispersed phases will also be discussed.

### Course Co-Directors:
- Larry D. Ford, Ph.D., Research Principal, Kraft Foods Global Inc.
- Edgar N. Jaynes, Jr., Ph.D., CQE, Technical Transfer Liaison, Banner Pharmacaps Inc.

### Tuition:
- **Early Registration (SAVE $200):** U.S. $1740 ($1660 with Group Rate*)
  - (Must register and pay by February 9, 2009)
- **Regular Registration:** U.S. $1940 ($1860 with Group Rate*)

### Who Should Attend:
This program will benefit:
- Scientists
- Engineers
- Managers
- Technicians

Who work in the following areas:
- Product Development
- Process Development
- Continuous Improvement
- Pilot Plant Operation and Scale-Up
- Research and Development
- Regulatory Affairs/Quality Control
- Technology Transfer Managers

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

### Who Should Attend:
This overview course is intended for those having specific responsibilities in the areas of sterile drug product science and technology. It will be of particular value to those in:
- Research
- Production
- Development
- Quality Assurance and Control

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

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

### ACCREDITATIONS/CERTIFICATIONS
- The Center for Professional Advancement (CPA) is accredited by the Accreditation Council for 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 # 716-000-09-208-L04

**For course information, go to [www.cfpa.com](http://www.cfpa.com)**

*Please note course topics, dates, and locations subject to change. Please refer to our website for the most current information.*
Technical Writing in the Pharmaceutical and Allied Industries

January 12–14, 2009 • New Brunswick, NJ

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

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

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

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

Participants are asked to bring five copies of two non-proprietary writing samples for review during the course:
- One memo/letter or e-mail consisting of several paragraphs
- One longer letter/memo/report of 2-3 pages in length

Course Director:
Pamela W. Gilbert, M.A., Professor of English, Victor Valley College

Tuition:
Early Registration (SAVE $200): U.S. $1780 ($1700 with Group Rate*) (Must register and pay by November 17, 2008)
Regular Registration: U.S. $1980 ($1900 with Group Rate*)

U.S. FDA Drug Development and Compliance

March 23–25, 2009 • 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 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 January 26, 2009)
Regular Registration: U.S. $1940 ($1860 with Group Rate*)

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.
Vendor and Contract Supplier Qualification

May 27–29, 2009 • 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
- QA/QC
- Distribution
- Packaging

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 April 1, 2009)
Regular Registration: U.S. $1940 ($1860 with Group Rate*)

Writing SOPs for cGMP Compliance

May 18–19, 2009 • Burlingame, CA

Who Should Attend: This basic course is designed for professionals involved with manufacturing in the pharmaceutical and dietary supplements industries. It has been most beneficial to:

- Those who are responsible for, or may be involved in, writing or revising “Standard Operating Procedures” for bulk or finished pharmaceuticals.
- Suppliers of drug components including raw materials, containers, closures, and other packaging materials.

You should possess a working knowledge of Current Good Manufacturing Practice (cGMP) regulations or have had prior cGMP training before attending this course.

Course Summary: This two-day practical course is designed to detail a step-by-step outline for writing “Standard Operating Procedures” and to adapt this outline for use in many specific applications.

Although the FDA’s Current Good Manufacturing Practice regulations state requirements for “Standard Operating Procedures,” this is the one area most likely to be cited by the FDA upon an inspection. During this course, you will acquire a better understanding of what the FDA is looking for. Methods used for compiling information, assignment of responsibility for departmental procedures, control of procedures and documentation, and instruction on technical writing will also be discussed.

Open workshops will offer direct solutions for your particular problems, as well as demonstrating the process of writing procedures for so called “gray areas.” The workshops are designed to allow you to construct a written procedure for a hypothetical manufacturing situation.

This course is particularly helpful to those involved with manufacturing in the pharmaceutical and vitamin industry. Emphasis will be placed on new plant start-up, plant revision, companies experiencing rapid growth or expansion, and how to improve regulatory compliance through procedures.

Course Director:
Gary Callahan, Vice President of Operations, Drug Division, Robinson Pharma, Inc.

Tuition:
Early Registration (SAVE $200): U.S. $1275 ($1215 with Group Rate*) (Must register and pay by March 23, 2009)
Regular Registration: U.S. $1475 ($1415 with Group Rate*)

For course information, go to www.cfpa.com

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Dec 11, 2008 Introduction to Pharmaceutical cGMP | ID# 2244
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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 job enhancement.

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

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

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.

CfPA courses on pages 1-19 are held in the following hotels. Please refer to individual course on our website for appropriate location.

Burlingame, California:
- DoubleTree Hotel (SF Airport) 835 Airport Blvd
- Sheraton Gateway Hotel 600 Airport Boulevard
- Hilton Suites 2000 Airport Blvd
- Embassy Suites Hotel 6111 Airport Boulevard
- Hyatt Regency 1000 Hyatt Regency Rd
- Sheraton 10000 Triton Blvd
- Hilton 1100 Entertainment Way

Boca Raton, Florida:
- Hilton Suites Boca Raton 7920 Glades Rd
- Embassy Suites Hotel 661 North West 53rd St
- Hyatt Regency 2400 NW 8th Ave
- Hilton 661 North West 53rd St
- Park Central 901 North West 53rd St

New Brunswick, New Jersey:
- Hyatt Regency 2 Albany Street
- New Brunswick 900 Raritan River Drive
- Hilton 2450 Kissam Rd
- Embassy Suites Hotel 6611 Hotel Circle
- Park Central 900 Haddonfield Rd

Ft. Mitchell, KY:
- The Drawbridge Inn 24774 Royal Drive
- Fort Mitchell 2500 Royal Drive

Locations

The American Board of Industrial Hygiene (ABIH)

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, 313.271.5000, ext. 516.

The American Board of Industrial Hygiene (ABIH) for recertification. (See specific course for details)

For course information, go to www.cfpa.com

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Accredited Technical Training for the Pharmaceutical, Biopharmaceutical, Clinical and Medical Device Industries
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Course Topics in this Catalog Include:
- Applied cGMPs for Pharmaceutical and Allied Industries,
- Best Practices in SAS Statistical Programming,
- Critical Process Cleaning and Cleaning Validation,
- Guidelines for Skin Absorption Studies,
- Orphan Drug Application and Submission,
- Process Validation for the Pharmaceutical and Medical Device Industries,
- Root Cause Investigation for CAPA, Vendor and Contract Supplier Qualification

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