PAYMENT

$2650.00 PER PERSON (INCLUDES BREAKFAST & LUNCH)

EARLY BIRD DISCOUNT

If you register at least thirty days in advance you will receive a $200 discount on the course.

ADDITIONAL DISCOUNTS

Contact us at 610-648-7550 or info@cfpie.com for additional discounts on multiple registrations.

CANCELLATION POLICY

All cancellations must be in writing and are subject to a $350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher good for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the $350.00 cancellation fee.

If a registered attendee does not cancel and fails to attend, neither a refund nor voucher will be issued. All course cancellations must be in writing and emailed sent to info@cfpie.com. Registrants are responsible for contacting the hotel and canceling their room reservations.

CFPIE reserves the right to alter the venue, if necessary.

Substitution Policy - Classroom Courses

Substitutions are accepted at no penalty with written notification from the original registrant in advance of course. All substitution requests must be in writing and emailed to info@cfpie.com.

CfPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.

ABOUT CfPIE

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In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

HOW TO REGISTER

1. Go to http://www.cfpie.com
2. Go to “REGISTER HERE” and select your course.
3. Create an account and register for your course.

The Center for Professional Innovation & Education, Inc.
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PREPARING THE CMC SECTION FOR NDAS/INDS/CTDS

COURSE INSTRUCTOR: MARIA A. GEIGEL

June 5-6, 2017
Malvern, PA

November 6-7, 2017
Los Angeles, CA

COURSE DESCRIPTION

This course includes an overview of the International Conference on Harmonization (ICH) process and the organization of the CTD, detailed information and discussions related to each element required in the drug substance and drug product sections of NDAs and INDs. The course will emphasize the requirements related to drug substance starting materials, drug substance and drug product specifications, impurities, stability, and pharmaceutical development reports. It will also discuss the use of Drug Master Files (DMF) and preparation of the CTD Quality Overall Summary (Module 2).

WHO SHOULD ATTEND

This course is designed for personnel involved in preparing the chemistry, manufacturing and controls (CMC) section of a NDA or IND and for personnel who are not involved in CMC document preparation but want an overall understanding of what is involved for both the drug substance and drug product.

Please note: This course covers the requirements for synthetic, small molecules and does not address biologics. Biologics are addressed in our course “CMC Regulatory Compliance for Biopharmaceuticals, Biosimilars and Other Biologics”

INSTRUCTOR CREDENTIALS

Maria A. Geigel is an independent consultant with MAG Associates, LLC. Her primary area of expertise is in regulatory affairs for Chemistry, Manufacturing and Controls (CMC). This experience covers synthetic active ingredients and all types of dosage forms.

With over thirty years of industry experience, she has prepared CMC sections of DMFs, INDs, NDAs, ANDAs and European Community dossiers – the most recent of these in CTD format. She has also developed regulatory strategies for worldwide registrations; assisted companies with complex regulatory/compliance issues and interacted with chemical and pharmaceutical manufacturing facilities to assure preparation of approvable submissions.

Prior to consulting, Ms. Geigel held various positions in Regulatory Affairs at Syntex (now Roche) and was Director of Technical Regulatory Affairs and Laboratory QA at Janssen Pharmaceutica. In addition to her CMC experience; Ms. Geigel is also versed in Quality Assurance and has evaluated manufacturing and analytical facilities, defined Standard Operating Procedures (SOP), prepared facilities for inspection, provided GMP training and responded to numerous observations from the FDA.

Ms. Geigel – bilingual in English and Spanish – received her M.S. in Organic Chemistry from the University of Colorado and her M.B.A. in Management from Golden Gate University.

https://www.linkedin.com/in/maria-geigel-7650207

HOTEL INFORMATION

The Desmond Hotel & Conference Center, Malvern, PA (CfPIE room rate of $132/night if booked 3 weeks in advance)

The Hilton LAX, Los Angeles, CA (CfPIE room rate of $143/night if booked 3 weeks in advance of the course date)

FIRST DAY

9:00 – 10:00 ICH Process and CTD Organization

- ICH Background/Working Groups
- CTD Modules
- Granularity

10:00 – 4:30 Requirements for the Drug Substance (Module 3 of CTD)

S.1 General Information: Nomenclature, Structure, General Properties

S.2 Manufacture

- Manufacturers
- Description of Manufacturing Process and Process Controls
  - Flow diagram, Process Narrative and Controls
- Control of Materials
  - Starting Materials, Reagents, Solvents, Auxiliary Materials
- Control of Critical Steps and Intermediates
- Manufacturing Process Development (Q11)

S.3 Characterization

- Elucidation of Structure
  - Other Characteristics: Physicochemical properties and solid-state Forms
- Impurities
  - Types (organic, inorganic, residual solvents)
  - Specified vs unspecified
  - Specifications
  - Reporting, Identification and Qualification Thresholds
  - Qualification
  - Genotoxic Impurities

S.4 Control of the Drug Substance

- Specifications
- Analytical Procedures
- Validation of Analytical Procedures
- Batch Analyses
- Justifications for Specifications
- Control Strategy

S.5 Reference Standards

S.6 Container Closure System

S.7 Stability

- Stability Protocol and Data Evaluation
- Forced Degradation/Stress Testing
- Photostability
- Stability Summary and Conclusion
- Post-approval Stability Protocol and Commitment
- Stability Data

4:30 – 5:00 Drug Master Files (DMFs)

- What is a DMF
- Types of DMFs
- Why are they used
- How are they used

SECOND DAY

9:00 –2:30 Requirements for the Drug Product (Module 3 of CTD)

P.1 Description and Composition

P.2 Pharmaceutical Development (Q8)

- Components of the Drug Substance
- Formulation Development
- Manufacturing Process Development
- Container Closure Development
- Microbiological Attributes
- Compatibility

P.3 Manufacture

- Manufacturer
- Batch Formula
- Description of Manufacturing Process and Process Controls
- Control of Critical Steps and Intermediates

P.4 Control of Excipients

P.5 Control of the Drug Product

- Specifications
- Analytical Procedures
- Validation of Analytical Procedures
- Batch Analyses
- Characterization of Impurities
- Justifications for Specifications

P.6 Reference Standards

P.7 Container Closure Systems

- Primary, Secondary, Functional and Non-Functional Secondary Packaging

P.8 Stability

- Stability Protocol and Data Evaluation
- Photostability
- Forced Degradation Stress Testing
- In-use studies
- Stability Summary and Conclusion
- Post-approval Stability Protocol and Commitments
- Stability Data

2:30 – 3:00 CMC Appendices/Regional Information

- Executed Batch Records
- Method Validation Package
- Comparability Protocols

3:00 – 3:45 Quality Overall Summary (Module 2 of CTD)

3:45 – 4:00 FDA Interactions

- Meetings and Preparations
- FDA Questions and Responses