PAYMENT
$2150.00 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 information regarding partnership discounts or how your organization can become a partner with CfPIE.

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
Learn from the Leader

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.

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

HOW TO REGISTER

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COURSE DESCRIPTION
The guidance on marketing applications for drugs and biologics, known as the Common Technical Document (CTD), was finalized by the International Conference on Harmonization (ICH) in 2003. Today the CTD format is highly recommended for marketing applications in the United States, and is mandatory in other regions, including Canada, Japan, and Europe.

The eCTD format has become mandatory in key markets for electronic submissions. Since January 2010, the European Medicines Agency has required all applications in the centralized procedure use the eCTD format. In the US, the eCTD format has become a requirement for all New Drug Applications, Biologics License Applications and Abbreviated New Drug Applications following the 2012 reauthorization/update of the Prescription Drug User Fee Act (PDUFA). Further, the Generic Drug User Fee Act and Medical Device User Fee Act also impose mandatory electronic submissions to FDA.

This course, while focusing on the US requirements, also provides a quick overview of current regulatory guidelines of eCTD in major world market including North America, the European Union, and Asia-Pacific. It aims to introduce tools to assist the participants in formulating effective strategies in the development, compilation, and submission of US-compliant eCTDs. The structure of the eCTD, its content and granularity for the modules will be introduced, along with a review of the specifications, scope, requirements for the architecture and functionalities, as well as its impact on the pharmaceutical industry.

ELECTRONIC COMMON TECHNICAL DOCUMENT (ECTD) SUBMISSION TRAINING - US VS EU, WITH GLOBAL INSIGHT
INSTRUCTOR: WEN SCHROEDER
FIRST DAY

Session 1: Introduction and Overview
About market authorization & electronic submission around the world
- Regulatory background
- Authorization procedures
- Submission standards
- Assessment procedures
- Mutual recognition
- eCTD today
- CTD & ICH

Session 2: eCTD Fundamentals – the Basics
Overview of eCTD
- eCTD basics and terminology
- eCTD architecture
- The XML backbone
- File formats
- XML specification
- Document type, definition, attributes, etc.

Session 3: eCTD Fundamentals – Dossier Preparation
- eCTD hierarchy
- Structure
- Organization
- Specifications
- Modularity
- Compilation of regulatory submissions
- What is submission ready
- Documents & templates
- Document logistics
- Document control
- Document granularity
- Bookmarks, hyperlinks, cross-references, etc.

SECOND DAY

Session 4: eCTD Review & Validation
Overview of the regulatory review process
- Technical validation process & requirements
  - Validation criteria
  - Tools
  - Interpretation
  - Common errors

Session 5: Workshop – Building a submission based on eCTD format
- Group exercise
- Case studies
- The dreaded Refuse to File (RTF)
- Best practice - document authoring
- Becoming eCTD-compliant
- Challenges & issues
- Submission planning & strategy

Session 6: eCTD Lifecycle Management
Getting to know the eCTD lifecycle
- Change management of an evolving dossier
- Did we capture all?
- How to manage obsolescence?
- Document control & tracking
- Get the right tools and/or the right partners

Session 7: Workshop – eCTD Lifecycle Management

Session 8: Global Comparison & Contrast
Regional Requirements in key world market: United States, Canada, Asia-Pacific and the European Union (Centralized Procedure)
- Global submission planning & coordination
- Tools & strategies

INSTRUCTOR CREDENTIALS
Wen Schroeder is the founder and president of SEKI Cosmeticals. With 20+ years of industrial experience, 30 US patents and author of numerous publications, Ms. Schroeder is an internationally recognized lecturer on cosmetic science & regulatory affairs. Her lecture topics cover a wide range of areas including chemical management and biocide regulations, food, drug and cosmetic law. She is a key expert for numerous cross-governmental aid programs including the ASEAN-EU Programme, under the European Commission, for Regional Integration Support in cosmetic & pharmaceutical GMP and testing. Ms. Schroeder is scientific advisor to Taiwan External Trade Development Council and previously taught courses addressing cosmetics, food, OTC drugs, biocides and chemical management topics. She served on the Personal Care Products Council and is active in the Society of Cosmetic Chemists and the Regulatory Affairs Professional Society.

Ms. Schroeder is the editor of a newly published book, Sustainable Cosmetic Product Development by Allured Books, which is the first comprehensive technical reference work in this field for the cosmetic and personal care industry.

WHO SHOULD ATTEND
This course is designed for professionals of the biotechnology and pharmaceutical industries who are currently, or planning to become, involved in the development of regulatory submissions using the electronic Common Technical Document (eCTD). The program is particularly suitable for project team members interested in gaining a practical understanding of regulations, tools, and required submission processes:
- Regulatory Affairs / Regulatory Operations
- Submissions Management
- Authors of CTD Sections
- Technical and Clinical Writers
- Documentation Teams
- Project Management
- Information Technology and Information Systems

HOTEL INFORMATION
The Hilton LAX, Los Angeles, CA (CPPIE room rate of $167/night if booked 3 weeks in advance of the course date)
The Desmond Hotel & Conference Center, Malvern, PA (CPPIE room rate of $141/night if booked 3 weeks in advance)
Club Quarters Hotels, Boston, MA (CPPIE room rate of $255/night if booked 4 weeks in advance)
DoubleTree by Hilton London - Victoria (CPPIE room rate of £199.00/night if booked 4 weeks in advance)