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

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 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.

US COSMETIC REGULATION: FDA CFR TITLE 21 TRAINING

INSTRUCTOR: WEN SCHROEDER

COURSE DESCRIPTION

Today’s consumer product companies face a tremendous task of bringing newer, better products into the market within a much shorter time frame. A successful market entry strategy often incorporates complex configuration of consumer trend analysis, scientific know-how, efficiency in product development and supply chain management. It is also essential to factor in regulatory feasibility analysis early in the game to avoid unexpected, last minute delay in product launch.

Cosmetic products marketed in the US are regulated under the authority of the Food & Drug Administration (FDA). The regulations pertinent to cosmetic products are published in Title 21, Code of Federal Regulations, in particular, parts 700 to 740. In addition, new legislation such as the Safe Cosmetics Act of 2011 is emerging and may lead to more stringent requirements in the foreseeable future.

This course provides an in-depth guide to the US cosmetic legislative framework. Key focus is placed on helping the participants to successfully navigate both existing cosmetic regulations and anticipated future legislation. A brief overview of international regulations will be given to help the participants develop global perspectives. Workshops with actual case studies will be conducted throughout the course to bring the participants closer to the reality of marketing cosmetic products in the US.
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 three-day course is designed for professionals in the personal care, cosmetic and pharmaceutical industries engaged in all phases of cosmetic product development, including:

- Research & Development
- Technology, Formulation & Product Development
- Marketing & Technical Sales
- Regulatory Affairs
- QA & QC Professionals
- Business Decision Makers

FIRST DAY

Introductions & Agenda Review — 9:00am – 9:30am

Global vs. US Cosmetic & Toiletry Market — 9:30am - 10:30am
- The consumers
- The market
- Future trend & outlook

International Cosmetic Regulatory Overview — 11:00am – 12:00pm
- Global legislative fundamentals
- Product definition & classification
- Major regulatory camps around the world

US Cosmetic Regulation - Legislative Background — 1:00pm – 3:00pm
- Historical legislative development
- Legal definition & distinction
- Drug vs. Cosmetic
- The myth of “cosmeceuticals”
- Product classification standards
- What about combination products?

US Cosmetic Regulation – Manufacturing — 3:30pm – 4:30pm
- Control of cosmetic ingredients
- Safety & performance
- Manufacturing requirements
- Registration
- GMPs

Workshop — 4:30pm - 5:30pm

SECOND DAY

US Cosmetic Regulation - Labeling & Claims — 9:00am – 11:00am
- Cosmetic labeling
- Cosmetic advertising & promotion
- Claims substantiation

Workshop - Claims Design & Analysis — 11:30am - 1:00pm

THIRD DAY

US Cosmetic Regulation - In Market Control — 2:00pm – 3:30pm
- Post sale cosmetic products control
- Import requirements
- Process
- Inspection
- Permit, certification & labeling

Workshop — 4:00pm - 5:30pm
- Group exercise- launch a new product in the US
- Group exercise- import a foreign-made product into the US
- Review, recap, questions and answers

US Color Cosmetics Regulation – Background — 9:00am – 10:30am
- Biological perspectives
- Regulatory background
- Terminology & definition
- Regulatory framework

US Color Cosmetics Regulation - Color Additives — 11:00am – 12:00pm
- Exemption & certification
- FDA nomenclature
- Petition for new listing/use
- Labeling

US Cosmetics Regulation - Current Affairs — 1:00pm – 2:30pm
- Workshop on colors - FDA warnings case studies
- Legislation going green- concerning organic, natural & green
- Legislation going small- concerning nanomaterial

Discussion, review, recap, questions and answers — 3:00pm – 4:00pm

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)