COBBLESTONE

COURSE ID 1522

Regulatory Compliance for the Personal Care Products Industry: EU/US/States

DIRECTED BY

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12 HOUR

ACCREDITED COURSE

Course Topics Include:

- Regulatory Framework and Legislative Authority
- Regulated Ingredients and Issues
- Mandatory Labeling and Trouble Claims
- GMPs and Testing Standards
- The Product Information File
- Registration, Listing and Notification
- Enforcement Priorities
- Legislative Initiatives
- A Look into the Future

about the course

Since in many countries, Personal Care products do not require Health Authority review and approval prior to marketing, there is often confusion about what product claims can be made, what labeling is required, and what ingredients cannot be used. Without knowledge of the regulations in each country, non-compliant product is often detected by Health Authorities once the product enters the marketplace. This typically results in a costly product recall.

This intensive 12-hour accredited course will provide an in-depth overview of the regulatory requirements for personal care products in the United States and the European Union, including additional requirements in the states.
It will review the regulatory bodies, enforcement tools and the relevant legislation and guidance to inform regulatory compliance. This will include key agencies having jurisdiction over cosmetics, with emphasis on the U.S. FDA, the European Commission, and the state of California, among others.

There will be a detailed discussion of ingredient restrictions based on their function in the finished formulation. In addition to a full review of labeling requirements, we will consider how claims impact a product's regulatory classification and its acceptability to the regulator, with examples to demonstrate the restrictions, risks and current enforcement priorities.

who should attend

This course is intended for all those involved in the regulatory aspects of cosmetics, OTC drugs and personal care products especially:

• Regulatory Affairs Practitioners, including Attorneys and Paralegals	• Research and Product Development Personnel
• Corporate compliance officers	• Marketing Personnel
• QC and QA Professionals	• Cosmetic Chemists

learning objectives

Upon completion of this course, you will be able to:

- Compare and contrast the requirements for cosmetics and cosmetic drugs
- Classify a product to know which requirements apply
- Determine the impact of state laws on certain types of products
- Check formulations, labeling and claims for compliance
- Build a testing plan that meets FDA expectations
- Decide whether to report an adverse event
- List the pre-market requirements and in-market controls to avoid regulatory action

course outline

Review of Learning Objectives
Regulatory Definitions, Classification and Claims

- **Regulatory framework relating to personal care products in the United States and the European Union**
  - Federal regulatory bodies
  - The role of the (member) states
  - Regulatory definitions

- **Avoiding unapproved claims on cosmetics**
  - FDA warning letters
  - EU Cosmetic Claims Guidelines
  - Examples of recent cases and problem areas

- **Exercises:**
  - Classify products based on claims
  - Recognize trouble claims

Ingredients and Product Labeling
Ingredients:

- Overview of permitted, restricted and permitted lists
- California's Proposition 65 and State Chemicals of High Concern
- The role of the U.S. Cosmetic Ingredient Review (CIR) and the EU Scientific Committee on Consumer Safety (SCCS)

Exercises:

- Review mock formulas for problem ingredients
- Labeling requirements
    - Labeling basics
    - The Drug Facts Box in brief

Exercise:

- Create a composite US/EU label

Safety, Quality and Registration:

- **Product Safety**
    - The general obligation of Safety
    - Safety testing practices
    - The EU Safety Assessor

Good Manufacturing Practices standards

- ISO 22716 vs FDA Inspection Checklist
- Highlights of stability and microbiology testing standards

- The EU Product Information File

Pre- and Post-Market, Enforcement, and the Future:

- Registration, Reporting and Listing
- U.S. Voluntary Cosmetic Reporting Program
- U.S. Drug Listing
- EU Cosmetic Product Notification Portal highlights
- Summary of state reporting requirements for certain types of products, such as:
    - California Safe Cosmetics Program
    - Children's Chemicals of High Concern

Exercise:

- Enforcement priorities
- Legislative initiatives, such as
    - Federal Cosmetic Modernization
    - Cosmetic transparency bills
    - Over-the-Counter Drug Reform
- Trends and a look into the future

Assessment Opportunity

course instructor

Jennifer R. Martin is currently Director of North America Regulatory Affairs, for the Colgate-Palmolive Company. In her current role, she determines strategy and regulatory pathways for Colgate's complete portfolio of personal care, home care and oral care businesses. Prior to joining Colgate, Jennifer was Global Director of Regulatory, Toxicology and Government Affairs for Edgewell Personal Care, LLC, a standalone company spun off from Energizer Holdings. Before joining Energizer, Ms. Martin was Director of Regulatory, Product Safety and Formula Control for Limited Brands and she also worked in Scientific Regulatory Affairs for the Gillette Company.

She began her career at the Cosmetic, Toiletry and Fragrance Association (CTFA, now known as the Personal Care Products Council or PCPC), where her most recent position was Director of International Technical and Regulatory Affairs. Ms. Martin received her Master's Degree in International Affairs from American University and her undergraduate degree in History and Spanish from the Maryland university system.

additional faculty

Sandra Browne, Sr. Global Regulatory Manager Edgewell Personal Care

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 12 contact hours, or 1.2 CEUs. For further information, visit www.iacet.org