COBBLESTONE

NEW!

COURSE ID 3131

Modernization of Cosmetics Regulation Act (MoCRA) Readiness

How the expansion of FDA authority to regulate cosmetics impacts your company

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

- Overview of Modernization of Cosmetics Regulations Act (MoCRA) of 2022
- 2024 Requirements
- 2025 Roadmap
- Overview of FDA decision tool and Cosmetics Direct
- Q&A and Discussion
- Conclusion and Recap

about the course

The FDA has expanded their authority with the Modernization of Cosmetics Regulations Act (MoCRA) to regulate the cosmetics industry. This regulation requires cosmetic product manufacturers to adhere to specific requirements at key deadlines to ensure the safety of cosmetics products that are used by consumers daily.

This 90-minute accredited training course will provide participants with an overview of MoCRA, focusing on the scope, regulation expectations, and deadlines set forth by the FDA. The course aims to address each of the various requirements discussed in the act, including facility registration, submission of product listing, new label requirements, monitoring of serious adverse events, GMP compliance, and safety substantiation testing. The course objectives include delving into each of these requirements to understand scope, actions needed, and timeline constraints associated with compliance to the act. Additionally, participants will have knowledge on consequences of not adhering to requirements.

By the end of the course, attendees will understand what their company needs to do to comply with this act in 2024 and plan for 2025.

Live attendees will have the option to directly ask questions to the instructor.

A webcam, microphone, and speakers/headset are highly encouraged for maximum participation capability.

who should attend

This course is designed for professionals within the cosmetics industry, including brand owners, manufacturers, packagers, and distributors.

These professionals include, but are not limited to, personnel that work at:

- Cosmetic brand or product owners
- Contract cosmetic packagers
- Cosmetic distributors
- Contract cosmetic manufacturers
- Quality personnel in cosmetics
- Suppliers to the cosmetic industry

The course is valuable for individuals at a wide range of cosmetic companies and will be beneficial in determining how facilities of various sizes may be considered under MoCRA.

learning objectives

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

- Identify and explain the importance of the Modernization of Cosmetics Regulations Act (MoCRA) of 2022
- Demonstrate understanding of MoCRA, including the areas of the industry in scope and the detailed requirements associated with each phase set forth by the FDA.
- Develop and plan your 2025 initiatives to ensure compliance.
- Apply the FDA decision tree tool for MoCRA for various scenarios.
- Navigate Cosmetics Direct for product listing.
- Outline the consequences that may apply if the MoCRA compliance requirements are not met.

course outline

Review of Learning Objectives

Overview of Modernization of Cosmetics Regulations Act (MoCRA) of 2022

- Background on MoCRA
- Overview MoCRA Contents
- Consequences for failure to comply

2024 Requirements

- **MoCRA – Who does this apply to?**
  - MoCRA scope
  - Exemptions
- **Requirements**
  - Facility Registration
  - Product Listing
  - FDA Recall
  - Label Updates
- **Deadlines**
  - Phase 1 Requirement Deadline
  - Phase 2 Requirement Deadline

2025 Roadmap

- **Requirements**
  - Adverse Events
  - GMP Compliance
  - Safety Substantiation Testing
- **Deadlines**
  - Phase 3 Requirement Deadline

Overview of FDA Decision Tool and Cosmetics Direct

- Review FDA decision tree/tool
- Navigation of Cosmetics Direct

Q&A and Discussion

- Open floor for questions
- Practical experiences with MoCRA compliance implementation

Conclusion and Recap

- Key Takeaways
- Additional Resources for Further Learning and MoCRA Support

Question and Answer Session

Assessment Opportunity

course instructor

Kevin Linde is an Illinois Professional Engineer with over 27 years of extensive experience in the pharmaceutical and FDA regulated industries. He is the CEO of cGMP Consulting, a company specializing in serving FDA-regulated industries such as pharmaceuticals, medical devices, cosmetics, biotechnology, and dietary supplements, that offers a comprehensive range of services. Kevin has led a team of experienced engineering and quality assurance consultants that have assisted numerous industry-leading companies in identifying and remediating gaps while implementing cGMP requirements. He also offers tailored support to cosmetics companies, including facility registration, product listing, regulatory compliance, and customized GMP systems aligned with MoCRA requirements. Kevin has worked on a wide variety of Quality, Engineering and Validation projects for several clients in the US and abroad. He has provided consulting services including audits, system design, user requirements specifications development, commissioning, qualification, and process validation.

Kevin graduated with a Bachelor of Science in Chemical Engineering from the University of Missouri – Columbia in 1996. He attained his Illinois Professional Engineer license in 2006 and has played a pivotal role in assisting numerous individuals in obtaining their licenses.

Accreditations

International Accreditors for Continuing Education and Training (IACE)
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 1.5 contact hours, or.2 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)
Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.