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Getting A Jump On Cosmetic GMPs: How Ready Is Your Business?

by Rachel Raphael and Marcha Isabelle Chaudry

Cosmetics companies should familiarize themselves with current good manufacturing practices standards, namely ISO 22716:2007 and NSF/ANSI 455-3-2021, and begin building out their quality programs accordingly. *HBW Insight* guest columnists Marcha Isabelle Chaudry, attorney and founder of The Equity and Wellness Collaborative, and Rachel Raphael, partner at Morgan, Lewis & Bockius, offer preparation tips ahead of US FDA rulemaking.

By the end of 2024, the US Food and Drug Administration is expected to issue a notice of proposed rulemaking on Good Manufacturing Practices (GMPs) applicable to cosmetics sold in the United States. Products that are not manufactured according to these GMPs are considered "adulterated," and the manufacture and sale of adulterated cosmetics are strictly prohibited under the US Food, Drug & Cosmetics Act. This means potentially serious consequences in the form of civil and criminal penalties, injunctions, seizures, and product recalls.

It is critical that cosmetic companies take stock of where they (and any manufacturing partners) stand in terms of GMPs and ensure that they have the necessary systems in place to ensure compliance and the ability to adapt when the FDA provides further guidance later this year. (Also see "*Cosmetics Industry Awaits FDA's Allergen List While Working To Inform GMP Rulemaking*" - HBW Insight, 12 Apr, 2024.)

Where Are We, And How Did We Get Here?

On 29 December 2022, the Modernization of Cosmetics Regulation Act (MoCRA) became law. MoCRA represents a significant expansion of FDA authority over cosmetics and, among other things, requires the agency to issue (1) a notice of proposed rulemaking for new GMP regulations by 29 December 2024, and (2) a final rule by 29 December 2025.

This initiative not only aims to elevate manufacturing standards to national and international safety levels, but also ensures the overall quality and consumer safety of cosmetic products.

To date, the FDA has taken some important steps toward formalizing GMPs for cosmetics under the Modernization of Cosmetics Regulation Act of 2022:

- Draft Guidance Update: On 3 May 2023, the FDA announced its intent to withdraw or revise/reissue existing draft guidance on Cosmetic Good Manufacturing Practices, last revised in June 2013;

- Public Meeting on GMP: On 1 June 2023, the FDA held a public meeting titled "Good Manufacturing Practices for Cosmetic Products." This meeting was part of the FDA's effort to engage with various stakeholders, including industry representatives, consumer groups, and regulatory experts, to discuss the implementation of new GMP standards; and

- Request for Comments: The FDA established a public docket for the meeting, *FDA-2023-N-1466*, after which interested parties were invited to submit comments until 3 July 2023.

There are currently no mandatory federal GMP requirements for cosmetics in the United States, although some states have their own GMP guidelines and safety standards. The forthcoming GMP regulations aim to harmonize US practices with established international norms.

One way forward is *ISO 22716:2007*, an international standard that provides guidelines for the production, control, storage, and shipment of cosmetic products. ISO 22716:2007 emphasizes a quality management system approach, focusing on areas such as risk management, documentation, staff training, equipment maintenance, and handling of complaints and recalls.

An alternative is *NSF/ANSI 455-3-2021*: Cosmetics GMP Certification, a voluntary standard published by the American National Standards Institute crafted to bridge the gap between ISO 22716:2007 and *existing FDA draft guidance*.

By aligning with standards like ISO 22716:2007 or NSF/ANSI 455-3-2021, the FDA can safeguard public health by ensuring that cosmetic products are manufactured under conditions that protect against contamination and adulteration. Although there are benefits to adopting either alternative, many international commentators at the 1 June meeting urged the FDA to consider ISO 22716:2007 on the basis that (1) many companies are already audited and certified under this standard due to its international recognition (including acceptance in Europe), and (2) the widespread familiarity with ISO certification could streamline the adoption process and offer a less burdensome alternative compared with a new standard.

Irrespective of what the FDA's GMP regulations ultimately look like, there's plenty that

companies in the cosmetics industry can do, and need to do, now – from getting familiar with existing GMP standards to engaging experts and conducting pre-compliance reviews.

By taking these steps, cosmetics companies not only will be better prepared for the FDA's forthcoming GMP regulations; they also will enhance their overall operational efficiency and product quality. Early preparation allows companies to more easily adapt to new requirements and ensure the safety, integrity, and competitiveness of their products on a global scale.

What Do I Do Now?

- **GET FAMILIAR WITH EXISTING GMP STANDARDS**: Whether a company manufactures its products in-house or contracts with a third party, all cosmetics companies should familiarize themselves with current GMP standards such as ISO 22716:2007.
- **ASSESS CURRENT PRACTICES**: All cosmetic companies must evaluate their current manufacturing practices (or those of their third-party manufacturers) against ISO 22716:2007 and/or other recognized GMP standards, and identify any gaps in compliance and areas that need improvement, such as documentation processes, quality control measures, or staff training programs.
- **STRENGTHEN THE QUALITY UNIT**: The Quality Unit (QU) is a person (or persons) in the company, independent of production, who are responsible for quality assurance and control. The QU is the backbone of GMP compliance, and companies must ensure that QU has clear, written responsibilities and adequate authority to oversee all quality-related functions. This includes:

  Developing comprehensive procedures for quality control.

  Regular training and updating of staff on GMP requirements.

  Ensuring there are sufficient resources to effectively monitor and enforce quality standards.

- **ESTABLISH ROBUST POLICIES AND PROCEDURES**: Well-defined, written policies and procedures are essential for consistency and GMP compliance. These policies and procedures should cover all aspects of manufacturing, processing, and quality control, and must be regularly reviewed and updated to meet evolving regulatory standards. Among other things, this means:

Creating detailed standard operating procedures (SOPs) for production and process control.

Documenting protocols to ensure that all procedures are followed and correctly recorded, and that employees are properly trained.

Conducting regular audits of documentation practices to prevent discrepancies and errors.

- **IMPLEMENT COMPREHENSIVE STABILITY/CONTAMINATION/CHALLENGE TESTING PROGRAMS**: Stability testing, microbiology testing, and challenge testing are key aspects of any manufacturer's plan to ensure product safety and quality. This means:

  Placing every batch of products into a stability testing program as required by their procedures, in order to guarantee the shelf life and efficacy of the products.

  Using stability-indicating methods and conduct tests in the marketed container-closure system.

  Including broader testing parameters such as microbiology to detect potential microbial contamination, challenge testing to evaluate the antimicrobial protection of cosmetics preservatives, and heavy metals testing to ensure products are free from certain harmful substances.

  Continuously reviewing and updating stability testing procedures to include all products and ensure they reflect real-world conditions.

- **VALIDATE AND MONITOR WATER SYSTEMS**: Given the critical role of water in product manufacturing, processes that ensure the water system meets microbial and chemical purity standards are non-negotiable. This means:

  Regularly monitoring and testing water systems to prevent contamination.

  Implementing preventative measures and taking quick, corrective actions in the event of a deviation.

  Maintaining detailed records of water quality testing and system maintenance.

- **ENHANCE CLEANING AND SANITIZATION PROTOCOLS**: Companies that manufacture and process cosmetics need to ensure proper cleaning and validation, which is essential to

prevent contamination and cross-contamination. This means:

Developing and maintaining comprehensive cleaning validation studies that include all equipment and products.

Using accepted methods and detergents for cleaning.

Regularly reviewing and updating cleaning protocols to account for product and equipment changes.

- **MANAGE CHANGES WITH A ROBUST CHANGE CONTROL SYSTEM**: Cosmetic companies need to meticulously manage changes in manufacturing processes, equipment, and materials to avoid unintended consequences, such as compromised product stability or contamination. To do so, companies should implement a change control system that documents changes (and justifies those changes with appropriate validation); reviews and approves changes through the QU before implementation; and monitors the effects of changes post-implementation to ensure they deliver the intended benefits without compromising quality.
- **PREPARE FOR AUDITS AND INSPECTIONS**: Regular audits (internal and of any contract manufacturers) help identify compliance gaps before those gaps become problems. This means:

  Conducting periodic internal audits to assess compliance with GMP regulations.

  Preparing for external inspections by making sure that all areas of manufacturing are compliant and all supporting documentation is in order.

  Using findings from publicly available FDA warning letters issued to other companies in the industry and guidance documents to preemptively address potential compliance issues.

- **SET UP A COMPLIANCE TEAM**: Establish a dedicated team responsible for the company's GMP compliance and/or ensuring compliance of any third parties that are involved in the manufacturing process. This team should oversee the implementation of GMP practices, monitor regulatory updates, and ensure that the organization adjusts its operations in line with evolving guidelines.

Marcha Isabelle Chaudry is the founder of *The Equity and Wellness Collaborative* (EWC), which specializes in comprehensive compliance management, offering tailored solutions that ensure brands meet regulatory requirements efficiently. By focusing on areas such as facility registration, product listing, adverse event reporting, label compliance, and safety assessments, EWC equips businesses with the tools and knowledge needed for seamless MoCRA compliance.

Rachel Raphael is a *partner* at Morgan, Lewis & Bockius LLP. Rachel regularly defends clients against claims for unfair business practices and false advertising. She also advises consumer products, personal care, and cosmetics companies on the many issues that arise over the product life cycle. As a litigator and regulatory counselor, Rachel offers valuable insights on how to successfully mitigate the legal risks associated with MoCRA compliance.

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