Quality System Design for Cosmetics Product Manufacturing

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A quality management system (or quality system) comprises the organizational structures, responsibilities, resources, procedures, processes and information systems for implementing quality management activities to maximize product quality outcomes. A quality system may also be required by individual country regulatory bodies around the world. For cosmetic products being marketed and distributed within the United States, a quality system helps to ensure your company manufactures these products in accordance with the expectations of the U.S. Food and Drug Administration. A quality system should be designed for and focused on implementing your quality policy and objectives within the specific context of your particular business organization, and the characteristics of your company’s particular business model and approach to manufacturing cosmetic products.

Quality Systems Implementation of Good Manufacturing Practices

Implementing a quality system is a crucial part of regulatory compliance. Good Manufacturing Practices (GMPs) constitute the FDA’s approach for establishing the requirements for manufacturing most FDA-regulated product. GMPs, however, are often no more than a set of requirements or expectations on the part of the FDA for a company to take action with respect to a particular topic. In contrast, a comprehensive, well-designed quality system provides a formal, documented framework that permits a company to efficiently and effectively achieve business outcomes for manufacturing quality products, in addition to providing the basis for regulatory compliance. For companies that manufacture and distribute cosmetics, a cosmetic quality system will greatly further a company’s ability to meet the FDA’s June 2013 Cosmetics GMP guidance.

FDA’s June 2013 Cosmetic Good Manufacturing Practices Guidance

FDA has recently issued a new guidance denoting their base expectations for cosmetic GMPs. This document, dated June 2013, is called, “Guidance for Industry: Cosmetic Good Manufacturing Practices.”
The cosmetic GMP guidance is intended to help ensure that cosmetic products are consistently manufactured to a quality appropriately associated with their intended use, including both manufacturing and quality control procedures. The FDA also states that if you are a manufacturer, you can reduce the risk of adulterating or misbranding cosmetics by following the GMP statements found in this guidance.

In comparison to traditional GMP requirements, a typical quality system is designed with a structure and format that will most easily facilitate the ability of the company to meet not only regulatory requirements and expectations, but also, the needs of the business in achieving its manufacturing and production objectives. The basic structure is often shown as a hierarchy of documents with the following elements:

**Quality System Provide the Structure to Enable GMP Compliance and Business Benefits**

Properly designed quality systems can yield significant business and risk-avoidance benefits. These include: a solid foundation to support GMP compliance; reliable satisfaction of customer needs and expectations; control and enhancement of vendor/supplier management programs; and reduction of quality problems such as scrap, waste, and failure to meet customer desires. Given FDA’s aggressive enforcement focus on offshore supply chains, a well-architected quality system can help reduce the risk of import holds/detentions and product destruction. A robust quality system also provides uniform and consistent approaches to procedures, tasks, vendor and customer interactions, fulfillment outcomes, audit performance, inspection outcomes, and business financial performance. Operational and quality records developed from the procedural requirements of a robust quality
Designing a Quality System for Cosmetic Manufacturing

Once a decision is made to establish and implement a quality system, a comprehensive implementation plan should be developed. There are several stages or phases to any typical quality system implementation plan.

Phase 1 - Preparation and Planning Phase

This initial phase is critical to properly identify, prioritize and finalize the goals and objectives for both the quality system and the manufacturing organization in general. As part of this phase, you will need to assess resource needs and management support within your organization. Activities within this phase include collecting information on your work processes, and performance of a formal gap assessment/analysis.

Phase 2 – Design Phase

In the design phase, it is important to establish the primary and secondary topical coverage of the quality system; prepare system description and system integration documents; define or develop process flowcharts or other visual aids showing key and secondary processes; and finally, start development of your quality manual, policies, standards, standard operating procedures, work instructions, quality records, workflows, quality metrics, management reports, etc. As with any product, building, or other design efforts, the ultimate functionality of a design subject is determined largely by the quality and rigor of the design process. When designing quality systems, there are many key design characteristics that must be considered, including groupings of subject matter; determination of the appropriate document “levels” for each topic; robustness of different quality system elements to ensure alignment to

“Compliance with GMPs for cosmetics can reduce the risk of products being adulterated or misbranded.”

US FDA
business model considerations; and resource availability or computer-based systems availability to ensure proper execution of designed systems and business processes. Proper determination of “how much” and “where” in quality system design will go a long way towards making a quality system easier to use, and ultimately more effective and cost-efficient.

Phase 3 – Pilot Phase

In certain organizations, it may make sense to consider implementation of a pilot program to experience and understand the need to make any tweaks or adjustments, prior to full implementation.

Phase 4 – Implementation Phase

Since a quality system generally comprises the complete set of operational practices within a manufacturing organization, implementation of a new or revised quality system can be extremely complicated. It is recommended that a quality system be implemented in phases. Foundational system components such as change management, training and document management and administration should be implemented first. Foundational systems will provide the capability to control and correct, where necessary, further implementation activities.

Implementation of a quality system will be a complicated project, and should be managed by a competent project manager, and supported by appropriate executive stakeholders. Implementation activities and measures of implementation success should be reviewed regularly by all involved stakeholders. Assumptions made during design phases must be challenged to ensure final design implementation will achieve organizational objectives.

Phase 5 – Monitoring Phase

Upon the official completion of a quality system implementation, a formal monitoring system should be implemented to ensure continued overall system effectiveness. This monitoring program should include both a “management review” process and the collection of relevant data to support meaningful outcome metrics. To get the most significant organizational benefits, review metrics and quality system outcomes data should be reviewed and acted upon at the highest levels of the organization. Corrections and changes to systems should be driven pursuant to well-crafted CAPAs to ensure changes will be effective and well-documented.
**Quality System Design for Cosmetics Should Encompass Ingredient & Product Safety**

It is important for a quality system to include policies and procedures that support regulatory requirements that govern the safety of the final product and its ingredients. The quality system should be designed to encompass appropriate testing to ensure product safety. Cosmetic products and ingredients do not need FDA premarket approval; however, companies and individuals who manufacturer or market cosmetics have a legal responsibility to ensure their products are safe to use. FDA has advised manufacturers to use whatever testing is necessary to ensure the safety of their products and ingredients before they are introduced to the market. Cosmetic manufacturers also need to ensure that they meet all regulatory requirements for product labeling. Regulations currently in place prohibit or restrict the use of certain ingredients in cosmetic products and require warning statements on the labels of certain types of cosmetics. Cosmetic products imported into the U.S. must comply with the same regulations, and both products and ingredients must meet the same criteria for safety and labeling, as those produced domestically. FDA can take action against cosmetics that are on the market that do not comply with established regulatory requirements or against the firms or individuals who violate the law.

**Achieving Success with a Quality System**

Establishment of a robust quality system for cosmetic manufacturing gives your company a cohesive, coordinated, and synchronized formal infrastructure to achieve success in meeting the FDA’s requirements and expectations for cosmetic manufacturing and distribution. It is important to remember that no matter how you choose to structure your cosmetic quality system, that you make sure that it covers the elements necessary to meet FDA requirements and expectations, and also, facilitates the desired business outcomes of your organization.

For further information, or to request assistance with restructuring or implementing a quality system, please contact Compliance Architects®, a leading provider of quality and compliance services to FDA-regulated industry, at 888.734.9778, or, visit our website at compliancearchitects.com.

John C. (Jack) Garvey  
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