BARTLEY D. MAXON[1], UMA J. KALE[2]
1. Dow Home & Personal Care, Midland, USA
2. Dow Consumer Solutions, Midland, USA

A supplier's perspective: implementing a framework for quality in an evolving regulatory environment

The space between regulatory imperative and consumer demand requires an unprecedented level of partnership between ingredient supplier and finished goods manufacturer

KEYWORDS: Regulatory compliance, formulations, quality control, ingredient suppliers.

ABSTRACT

Consistency in meeting high product performance standards is a hallmark of quality control. But in a global marketplace where the regulatory landscape varies by jurisdiction, consumer preferences evolve along cultural and regional lines. With this, one product category blurs into another and a real challenge for suppliers is developing a quality system that flexes and adapts to accommodate a range of consumer and commercial needs and a dynamic regulatory environment. To help suppliers meet both product quality and cost efficiency, companies need a formalized quality management system that addresses the regulatory complexities of a global supply chain while meeting the needs of their customers, end-use consumers and regulators.

INTRODUCTION

In the past, tracking industry trends and regulations fell squarely on the finished goods manufacturer. Supply chains operated within defined borders and brands did business within specific regions. Today, the globalization of the personal care market, the speed at which consumer trends come and go, the plethora of government regulations and the growing demand for cosmeceutical products collectively create an environment which increases responsibility on the ingredient supplier to understand regulatory trends and requirements. This article reflects on the complex global regulatory environment as it relates to current and emerging standards for cosmetics ingredients and presents a supplier's perspective on establishing a cost-effective quality management system for ingredients used in a wide range of applications.

MOVING TARGETS

As demonstrated in Figure 1, much of the cosmetics industry lacks an overarching global standard. In the United States, the industry is largely self-regulated but is overseen by the Food & Drug Administration (FDA). The Cosmetic Ingredient Review (CIR) Expert Panel reviews and assesses the safety of ingredients used in cosmetics (well over a thousand such ingredients to date) and works with the FDA, the cosmetics industry and consumers in an effort to keep cosmetics safe.

However, the list of substances prohibited or restricted by regulation in the United States identifies 11 items. Other jurisdictions are more regulated with greater oversight from government agencies. These jurisdictions include the European Union and Brazil, where prohibited or restricted cosmetic ingredients number in the hundreds.

In addition to jurisdictional variation, the growing popularity of multi-functional cosmetics adds yet another layer of complexity to the personal care supply chain. Scientific advances and growing consumer demands have given rise to product categories that straddle the traditional boundary between cosmetics and pharmaceuticals. Products that make therapeutic claims or offer functional properties beyond cleansing or changing the appearance of the body often fall under a regulatory "grey area". These products, like sunscreens or anti-acne treatments, are regulated as cosmetics in some jurisdictions and as over-the-counter (OTC) pharmaceuticals elsewhere.

Whether defined by jurisdiction or function, it's critical to stay current on the regulatory status of ingredients. The vast majority of jurisdictional regulations and best practices are under nearly continuous scrutiny and revision. For example, updates to EU regulations add restrictions to the use of nanotechnology and animal testing. In the United States, legislation has been introduced that would grant the FDA greater regulatory oversight. In Japan, some cosmetic ingredients are already classified in the quasi-drug category.

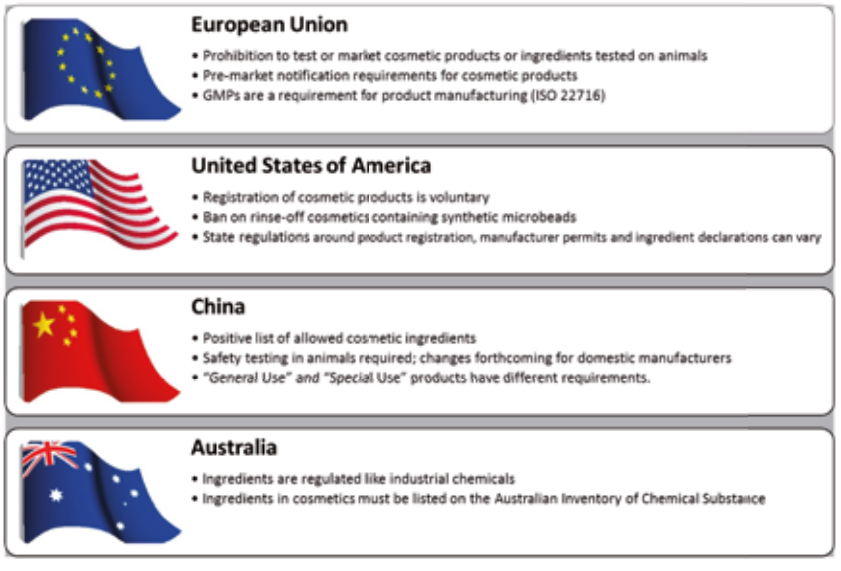

Figure 1. Diversity in global cosmetic product regulation

SINGULAR SOLUTION

Even as industry guidelines and regulations are fractured by jurisdiction and product category, the cosmetics industry is more competitive and more global than ever. Factors which influence the quality control of cosmetic ingredients vary by region and product function, which creates challenges for brand owners. Throughout the supply chain, there is a desire to operate under a single quality solution that meets global compliance. This is a challenging task for both the supplier and finished goods manufacturer. For example, higher qualification expectations often calls for increased traceability, process control and change management on the supplier side. As demonstrated in Figure 2, these and other factors associated with stricter regulations generally result in higher ingredient costs. A quality system for active pharmaceutical ingredients and excipients requires a higher investment and greater time and resources to design and implement, than one for producing cosmetic ingredients.

Figure 2. Impact of product category and regulatory complexity on cost of finished product.

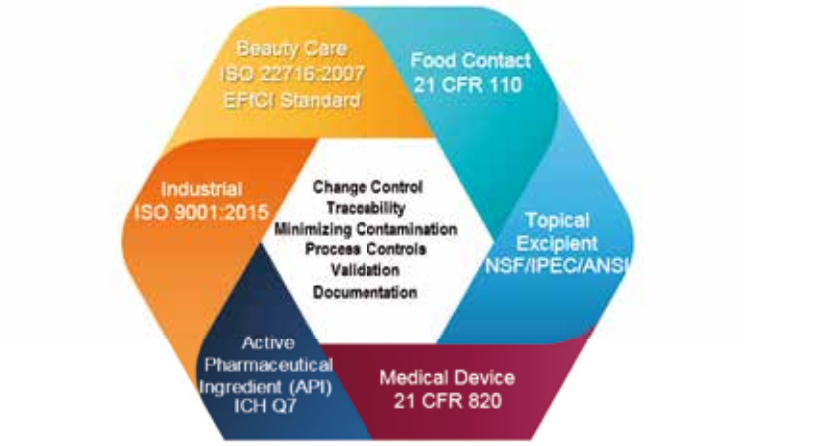

Figure 3. Quality system requirements and standards aligned with various uses of a given ingredient.

AN INCREASE IN REGULATORY COMPLEXITY IS ACCOMPANIED BY AN INCREASE IN FINISHED PRODUCT COST

An important factor that impacts cost is the decreasing level of flexibility in manufacturing operations and quality requirements as product categories move from industrial grade to topical pharmaceuticals. At one end of the spectrum, ISO 9001 is a standard that gives suppliers and producers the flexibility to adapt their quality system requirements to meet varying industry needs. It does not define the end use of an ingredient nor does it prescribe specific requirements. At the other end of the spectrum, the Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients is specific to pharmaceutical applications and prescriptive in its requirements.

WALKING THE QUALITY-COST TIGHTROPE

Figure 3 presents a sampling of the variations that a supplier can face in standards and regulations by ingredient category and further highlights the complexity of quality control and regulatory compliance for the manufacture of ingredients which fall under cosmetic and pharmaceutical classifications. Under these circumstances, a static standard of quality control may meet the desired objectives in one product category, but fall short in another. Conversely, the next highest standard may require significantly greater effort to assure quality output with an associated increase in cost. The biggest challenge for suppliers is establishing a flexible quality system which can effectively balance customer expectations and emerging trends – all while remaining compliant with current regulations and remaining cognizant of commercial impact.

Figure 3 outlines the requirements for each category from industrial to cosmetic and pharmaceutical with increased controls across the spectrum.

As the end use application or ingredient category moves from industrial to pharmaceutical there are increased requirements for validation, documentation and testing making the holistic view of one category to another vastly different.

END USE FAMILIARITY

The intended end use of a given ingredient is critical to understanding the regulations, regulatory guidelines and industry standards that govern. As a global supplier of basic, intermediate and specialty products, many chemical companies find themselves operating across the regulatory landscape and touch a broad spectrum of finished product categories. For instance, silicones are widely used in the cosmetic, OTC and topical pharmaceutical product segments for superior aesthetics and multi-functionality. They are also used as release agents in food applications and pharmaceutical active ingredients in anti-flatulent drug products. A specific example is polydimethylsiloxane (PDMS), which is a multifunctional ingredient found in skin care products (INCI: Dimethicone), skin protectant products (Dimethicone NF), medical devices and active pharmaceutical ingredients (APIs).
Methylcellulose is another example of a material that crosses product category lines. It is used as a replacement for gluten in food, an excipient in pharmaceuticals and an ingredient in shampoos and other cleansing products.

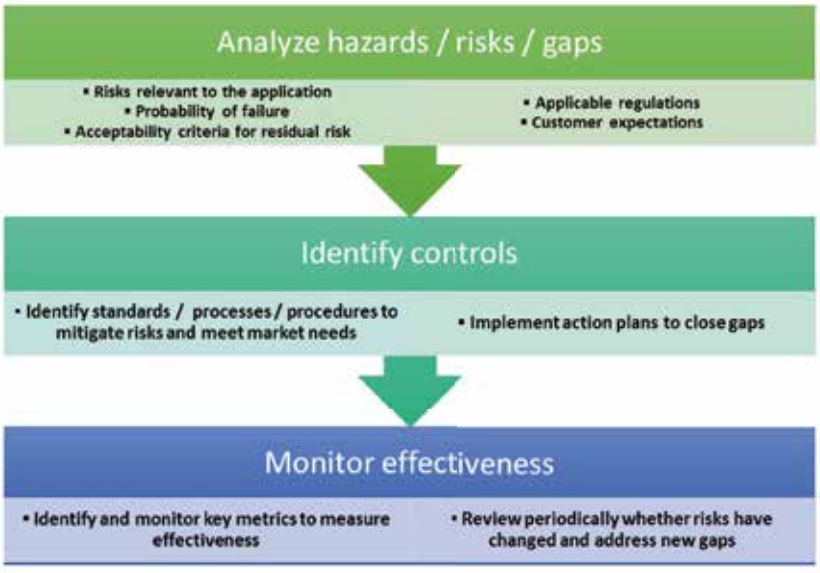

Figure 4. Key elements of quality risk management.

To help formulators and brand owners navigate the regulatory waters of these and other multi-functional ingredients, the supplier's quality management system must balance a full range of factors. This includes regulatory and industry standards, adaptation to emerging trends and adherence to product performance. On top of this, many finished goods suppliers have additional supply chain and quality expectations, all of which impact the cost to manufacture. To meet these factors the quality framework would be built on quality risk management principles that identify three key steps in the process: risk analysis, mitigation and review; shown in Figure 4.

Successful implementation of the three step risk management process demands an unprecedented level of transparency between ingredient supplier and finished goods producers to determine the "where" and "why" of end-use applications. An extra layer of consideration is to determine the customer's own set of expectations as well, such as a sustainability claim they'd like to achieve with their product, which could impose additional constraints further. An ingredient manufacturer must work closely with its customers to understand use, evaluate governing standards and regulations and apply these factors to an efficient manufacturing process with control, monitoring and reporting systems. Key questions to explore in partnership include:

- What markets are the products sold to?
- What are the end-use applications?
- What are the end-use product claims?
- Is the product being sold globally or in specific regions?
- Is the product fit-for-use in the intended applications?
- Are the current controls and procedures effective in mitigating or minimizing risk?
- Are there defined regulatory requirements for these markets or applications?
- Do regulations differ by jurisdiction?
- How do you comply with these regulatory requirements?

WORKING TOGETHER

The growth of multi-functional cosmetics and regional variations in product categories, standards and regulations presents both challenges and opportunities in today's global marketplace. Through partnership, transparency and a flexible framework, suppliers can establish a quality system with manufacturing processes and controls that can satisfy the desired balance of customer expectations, industry standards and emerging trends. ■

ABOUT THE AUTHORS

Bart Maxon *is a Senior Technical Service and Development Scientist for Dow Consumer Solutions with a focus on silicone chemistry, skin care formulation/application development, drug delivery, immunodiagnostics development, and product stewardship/regulatory compliance for life sciences applications. Bart holds two Bachelor of Science degrees: BS Biology from Central Michigan University and BS Chemistry from Northeastern Illinois University.*

Uma Kale *is a Senior Specialist for Dow Consumer Solutions, focusing on regulatory compliance for the Medical segment, and was a technical leader for research projects in drug delivery. Prior to that, she worked in the Pharmaceutical industry. Uma holds a PhD in chemistry from the University of Massachusetts (Amherst) and an MBA from the University of Michigan (Ann Arbor).*