

## Complying with Cosmetics Manufacturing Regulations with an ERP Solution

How an ERP solution keeps you compliant and maximizes efficiencies in a shifting landscape

Ready for What's Next, Now





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### Introduction

Like their counterparts in other industries, cosmetics manufacturers know that quality products and efficient operations can make or break a business. But unlike other industries, cosmetics manufacturers are faced with a stronger – yet uncertain – regulatory future.

The U.S. Food and Drug Administration (FDA) oversees the cosmetics industry under the authority of two central laws: the Federal Food, Drug and Cosmetic Act (FD&C Act) and the Fair Packaging and Label Act (FPLA). While these laws have long been on the books, they haven't been consistently enforced due to a lack of funding and resources.

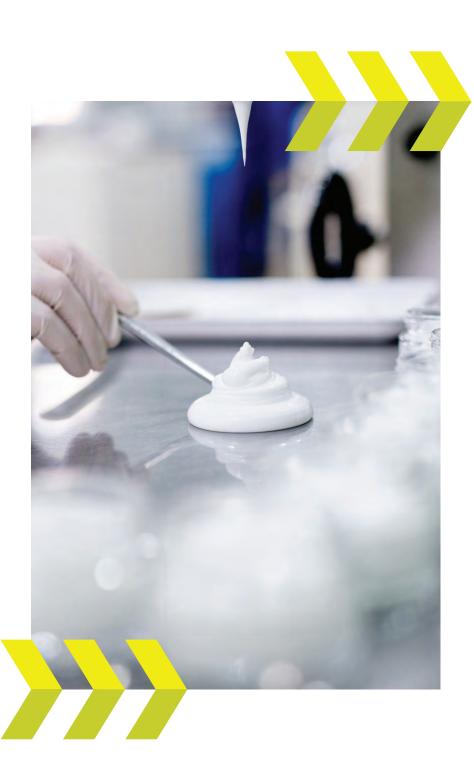
#### That's about to change.

According to the U.S. Department of Health and Human Services' budget overview, the FDA's 2021 budget is expected to increase by ten percent over 2020. It includes increased cosmetic user fees and more inspectors to ensure the safety of cosmetics products, especially in light of the growing volume and complexity of domestic and imported materials. Consumers are also pushing for more oversight, such as the Safe Cosmetics Modernization Act that seeks to "assure the safety of cosmetic products by examining ingredient safety, establishing manufacturing processes, tracking and quickly addressing adverse health impacts from potentially unsafe products..."

These established and proposed regulations can improve the safety, quality and consistency of cosmetic products and make certain that substandard manufacturers are playing by the same rules as the rest of the industry. They also mean manufacturers should expect closer scrutiny of their operations and practices from regulators and their own customers.

While the exact timing of these changes is still unclear, new or better enforced regulations are inevitable. As an industry that constantly reinvents itself, manufacturers need to establish the technology and solutions that will ensure safe, quality materials from trusted suppliers – no matter the trend. The better you can align your manufacturing operations with current Good Manufacturing Practices (cGMP), the less hassle and time you will need to spend proving you are in compliance.





#### **How can an ERP Solution Help?**

Your core business technology is instrumental in helping you meet increased scrutiny and regulations. Specifically, an enterprise resource planning (ERP) solution can tackle your mission-critical business functions (manufacturing, quality, inventory, financials and sales), while linking all of your information through integrated business intelligence (BI) functionality. You gain security, stability and total visibility of your information in real-time so you can operate more efficiently.

An ERP solution built specifically for cosmetics batch processing manufacturers provides unparalleled functionality and visibility. It can adapt to your needs as products change and regulations shift, so you don't have to be tied to an outdated process or risk falling out of compliance. It goes beyond the basics of an accounting and Microsoft® Excel-based system, or even a one-size-fits-all ERP solution, to give you the precise functionality and intelligence for your operations.

In this eBook, we'll examine specifically how an ERP solution built for cosmetics manufacturers can help you navigate a shifting regulatory landscape, as well as tighten your efficiencies and increase profitability throughout your operations.

#### Why ERP?

- Better manage regulatory compliance
- Achieve the highest product quality and consistency
- Gain greater visibility and control of inventory
- Strengthen customer loyalty

#### **ERP for Process Manufacturers**

Our comprehensive ERP solution is designed for batch manufacturers that produce cosmetics, defined by the FD&C Act as "articles intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness or altering the appearance."

At Aptean, we have in-depth experience working with the cosmetics manufacturing industry and we provide specific functionality to maintain compliance with ever-changing regulations, including the FD&C Act, FPLA and cGMP requirements.

Put simply, we develop ERP software solutions for batch process manufacturers. With our complete solution, you have the power to make smarter decisions more quickly and profitably.





## Managing Shifting Regulations Successfully

An industry-specific ERP solution goes beyond ensuring compliance with long-standing rules to help you meet requirements for the very latest regulations, whenever they arise. For example, the Personal Care Products Safety Act requires, in part, that companies submit ingredient statements to the FDA and keep abreast of any FDA review that establishes limits or conditions for the use of an ingredient. This could include changing labeling requirements or adjusting the amount of an ingredient that can be used in the final product.

An ERP solution has the flexibility and knowledge to help you adapt to new demands – whether they come from the government or from your own company standards. Your company is able to tighten and manage security at all levels, accurately log transactions and conform to best practices. In addition, auditing tools, supporting data records and reporting standards give you peace of mind that no matter how the rules are changing and evolving, your ERP solution will help you stay up-to-date.

Let's take a look at a few key areas that will help you navigate regulatory requirements and achieve compliance in a shifting landscape.

#### **Formulation**

Maintaining consistency and quality of your products is what drives customer loyalty. Therefore, you need to have exceptional controls over all factors involving the production of your finished goods, including your complex, multiple-level formulas and your specific manufacturing process. In an industry that's closely in tune with changing customer trends, you're creating new formulations relatively frequently while meeting consumer expectations for consistent product purity and quality.

An ERP solution built for the cosmetics industry will allow a chemist to create new formulas, denote material specific instructions, utilize mixed units of measure, observe physical properties, record manufacturing instructions, set up quality control tests, track changes and distinguish costs for labor, material and overhead all from within one system.

#### Labeling

Accurate material and product labeling is a must for cosmetics manufacturers, especially in light of the FPLA. An industry-specific ERP solution provides more accurate support of labeling practices for properly labeling inventory than a generic, one-size-fits all technology. Accurate information for handling such as vendor, lot, expiration and allergen information can be printed directly on the finished good label.

#### **Quality Control**

Quality control tools that reflect batch manufacturing realities will accurately track and factor considerations such as scrap losses or a mineral's particle size. As your volumes increase, product lines are added or SKUs grow, an ERP solution that knows the cosmetics industry will maintain consistent quality across your operations. For example, it can factor variations in materials and help you determine whether to use more or less product to maintain consistency and compliance.

And don't forget about your suppliers. Are they providing safe and reliable ingredients? Are you confident that they're in line with FDA regulations? Industry organizations, such as The Independent Cosmetic Manufacturers and Distributors, have called for universal, global standards for safety and quality throughout the supply chain. The quality capabilities of your ERP solution can help qualify your suppliers by providing material specifications on the purchase order and testing against these specifications upon receipt of goods.

An ERP solution can provide features for non-conformance logging, corrective and preventative action reporting and document control as part of its quality management features. Complete quality control routines more quickly and accurately, and speed up the turnaround time for your inbound and outbound materials. If you come across an error in a product, electronically manage and report what went wrong and where, as well as how the issue will be resolved. The ability to accurately track quality issues in real-time will better position you and your organization when dealing with regulatory or certification concerns.





#### **Inventory Visibility**

Granular track and trace capabilities in your ERP solution are key to keeping you in compliance. Knowing what makes up your inventory, the status and quality of that inventory, managing expiring inventory, allergens and where each component is at all times are paramount data points that can determine the success of your business.

An industry-specific ERP solution gives you greater visibility to help control costs, reduce expired inventory and better track all inbound production and outbound materials. It takes into account material yield or loss factors for better planning, costing and margin analysis. It knows what material is out on the floor, in production or in current work areas. Knowing this information will determine the timing and quantity of purchases and production, as well as how much inventory to buy, stage, use and how products are impacting your bottom line.

Let's take a closer look at some specific areas within inventory visibility, why they are important for staying compliant and how an ERP solution can give your operations an edge.

#### Track and Trace

Many of the ingredients that you regularly work with must be handled, stored and monitored properly to maintain their efficacy. For example, specific raw materials, such as certain oils, may have a short shelf life and can go rancid quickly. With the increased focus on natural or organic ingredients, as well as the aforementioned Safe Cosmetics Modernization Act that increases the FDA's ability to examine ingredient safety, shelf life may become an even greater issue and the need to monitor and transform the ingredients into a stable state will become even more important to the success of your business.

An ERP solution can help manage storage, attributes and visibility of inventory, as well as support the processes and labeling requirements can help workers handle the ingredients more efficiently. Managing the stability, quality and expiration is important – especially because many of these ingredients are costly.



#### Lot Tracking

Lot tracking is a huge concern for many cosmetics manufacturers

– but few have mastered it on their own. With detailed lot tracking
abilities, an ERP solution can determine not only the location of a lot
number, but can also track the timing, quantity and upstream and
downstream use of that lot number from receipt to customer received.

For instance, when paraben is used in multiple batches or recipes, you must know every place where the preservative was used, which products it was used in and where those products are located. If your facility handles an allergen like dyes, you need to track them for storage and handling, recall reporting, managing cleans and more. An ERP solution with this level of detail allows you to more easily isolate a safety issue and forecast the extent to which a product has been affected, including which items have been contaminated and where they originated.

An ERP solution gives you greater visibility into your operations so that you can increase the efficiency of your production flow, fulfill orders more accurately and improve your percent-of-service to your customer base. Any ERP vendor should understand that lot tracking is central to your operations. These capabilities should be a core offering of any ERP solution.

#### **Audit Trail**

To meet regulations, computer-generated and time-stamped audit trails are needed to track and record changes to critical data and confirm the integrity of the recordings, including digital signatures. For cosmetics companies, this means features like a robust bill of materials tracking log with audit trail capabilities for formula creation, modification, revisions and activation status, a complete work order audit logging report of all material transactions and computer-generated user and time-stamped audit trails with detailed records.

#### **Ensure Compliance, Build Loyalty with an ERP Solution**

Your whole business is riding on compliance and customer satisfaction: Operating with manual processes or storing information on disparate spreadsheets is simply too costly and inefficient, especially when you're dealing with new regulations or responding to more frequent inspections.

In the trend-right, yet highly regulated world of cosmetics, there are enormous benefits to utilizing an ERP solution developed specifically for your industry. Its advanced and relevant functionalities ensure compliance and the flexibility to meet future demands, while supporting the trust that consumers have in your brand and products.

#### More ERP solution benefits for cosmetics manufacturers

- > Effective batch sizing and scaling
- Comprehensive multi-phase project accounting
- ▶ Robust R&D functionality
- Custom labeling and packaging



#### **Developed, Sold and Installed by Us**

As a leading mid-market ERP software solution for the process manufacturing industry, we pride ourselves on our ability to serve the unique needs of the cosmetics industry. Our customers can have peace of mind knowing they have a single source to deal with at every phase – no resellers who lack support or third-party installers who lack knowledge of the software. And rather than offshore or third-party technical support, we provide live, dedicated assistance from our team at our home office.

Avoid the headache and costly mistakes of an ERP solution that doesn't understand industry best practices or have the flexibility to respond to your needs. Aptean Process Manufacturing ERP delivers a single, real-time solution with interactive dashboards that provide everything from broad, graphical snapshots of productivity to granular details of project financials.





#### **Aptean Process Manufacturing ERP Meets** your Business Needs

#### Manufacturing

- > Formula and Recipe Management
- Production Planning and Scheduling
- Manufacturing Execution
- Allergen or Other Key Attributes / Chemical Properties

#### **Financials**

- AR and AP
- General Ledger
- Lot / Batch Costing
- Project Costing
- > Payroll / HR

#### Quality

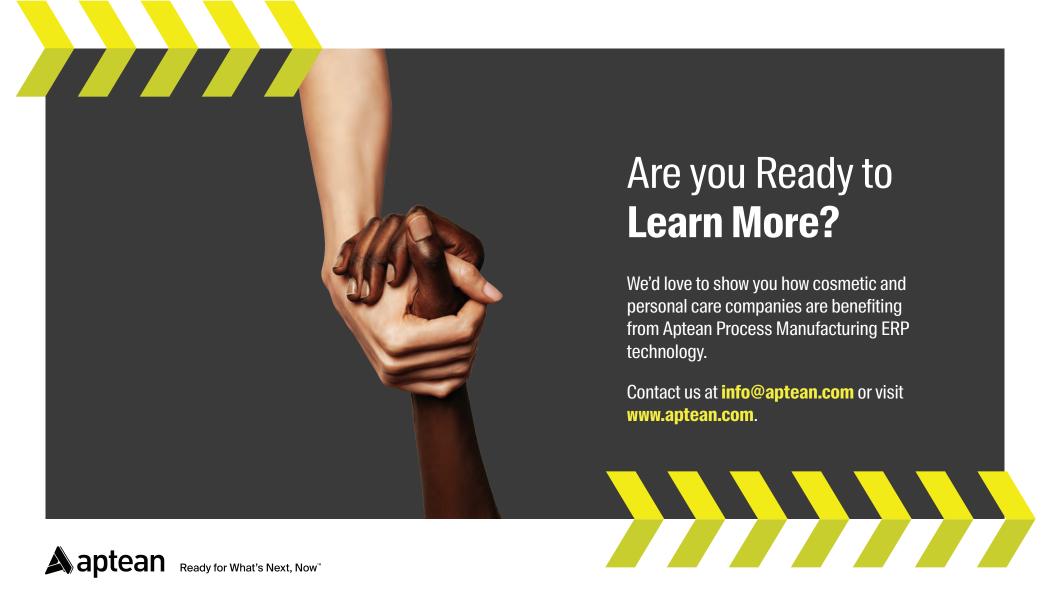
- Quality Control
- Lot Traceability
- Certification and Validation Tools
- > FDA Compliance and Validation
- GHS / SDS

#### Sales

- Quoting and R&D
- Order Entry
- CRM
- Contract Management
- > EDI

#### Inventory

- Purchasing
- Inventory Control
- Material Requirements Planning
- Warehouse Management



Aptean provides very specific industries with very specific ERP, supply chain management, and customer experience solutions. In today's fast-paced, highly competitive economy, organizations don't have time to waste forcing homegrown software, spread-sheets, and one-size-fits-all solutions to do things they were never designed to do. Aptean is on a mission to end those work-arounds – with industry-specific solutions instead of generic software, expert support instead of making you go it alone, and a steady influx of new ideas instead of the status quo.

For more information, visit www.aptean.com.