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4 STEPS TO OPTIMIZING THE PRODUCT REGISTRATION PROCESS

Overcome Complexity and Compliance to Improve Visibility and Time-to-Market in the Personal Care & Cosmetics Industry

Table of Contents

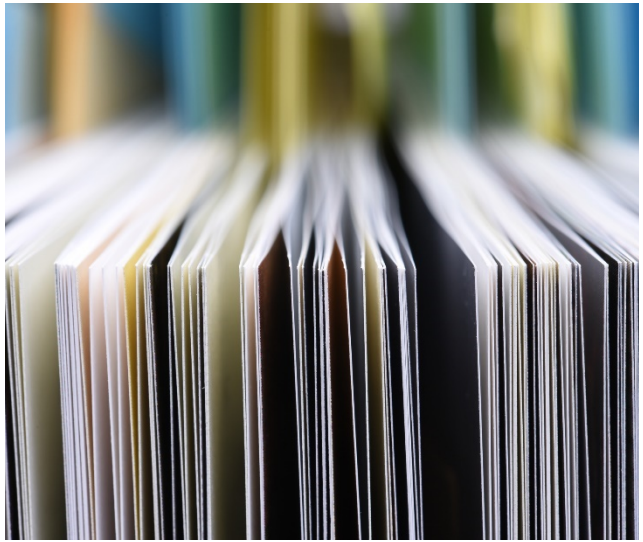
INTRODUCTION

The personal care & cosmetic industries generate more than $260 billion[1] in annual revenues globally, and manages the safety and compliance of a wide range of products, including cleaning products, oral care products, sunscreen, fragrances and hair color, just to name a few.

Globalization, mergers and acquisitions, increased competition and tighter regulations have impacted the personal care products industry. To remain competitive, organizations are evaluating their business processes and identifying where they can reduce risk and create more transparency.

Moreover, companies are seeking opportunities to gain efficiency from limited resources while improving their products' time-to-market.

1 D&B First Research. Industry Profile. August 2017.



One process that has come under scrutiny from personal care product manufacturers is the product submission process. This process is complex and the scope can be global, as it involves documentation, testing and submissions at international, domestic and even local state levels. Any delays or errors can result in lost revenue and increased compliance cost.

This eBook highlights the main current global regulations, identifies the key challenges of the product registration process, and discusses how streamlining and automating the process can significantly reduce delays, errors and unnecessary costs for a product's launch and distribution in its various markets.

NAVIGATING REGULATORY INDUSTRY REQUIREMENTS

Personal care and cosmetic products in the United States (US) and the European Union (EU) are receiving more attention and scrutiny from industry & legislative bodies. These regulations and codes affect the sale, import and export of ingredients and chemicals, and the products that contain these ingredients and chemicals, to ensure public safety.

In the United States, there are principally three main components of the personal care & cosmetics regulatory body. The first is the Food, Drug, and Cosmetics Act of 1938, which gives the US Food and Drug Administration (FDA) the authority to oversee the safety of food, drugs, and cosmetics.

The second is the Cosmetic Ingredient Review (CIR), established in 1976 by the industry trade association with the support of the US FDA and the Consumer Federation of America. The CIR is an independent, non-profit scientific body that ensures the safety of the ingredients used in cosmetics.

In 2016, CIR completed the scientific safety assessment of more than 560 ingredients and a total of 4,770 ingredient safety determinations since the program began.[1]

1 Personal Care Council. 2016: Year in Review. February 2017.

And in 2007, the Personal Care Products Council adopted the Consumer Commitment Code for the cosmetic industry. This code builds on the safety standards published by the CIR and adds new practices such as a Safety Information Summary Program that makes information relevant to cosmetic product and ingredient safety readily available to the FDA upon request.

In European Union (EU), similar regulations have been established to review and approve personal care and cosmetics ingredients. Notably is EU cosmetic regulation 1223/2009, introduced in December 2009, which regulates many of aspects related to the manufacturing, testing, safety, and labeling of cosmetic products. This legislation also includes reporting all "serious undesirable effects" (SUEs) to competent authorities of the Member States. Between July 2013 and May 2016, more than 600 SUE cases were reported.[1]

1 Experiences and Statistical Evaluation of Serious Undesirable Effects of Cosmetic Products in the EU. MDPI. July 2016.

THE REGULATORY IMPERATIVE

In order to distribute products, personal care and cosmetics manufacturers must ensure compliance with these regulations and provide the required testing and reporting to validate product safety, and accurate labeling specifications.

In the event that a substance is considered hazardous by a regulatory agency, the manufacturer may be required to prepare an exposure assessment and risk characterization, which could impact the products documentation and labeling, resulting in a delay in distribution.

Furthermore, as pre-commercial products mature through their product development cycle, registration, and submission activities must be well-planned and executed to ensure compliance requirements are met before products leave the facility.

Within this challenging environment, organizations are counting on Regulatory Affairs (RA) staff to track and manage product registration requirements on a constant basis. Monitoring national, federal, state and local regulations is a challenging task for the RA team, usually comprised of only a few people.

Juggling pre-registrations of new products, re-submissions of products from M&A activities, and managing and updating existing submissions is difficult enough domestically. Add the complexity of monitoring international regulatory requirements, and you have a situation with a high probability of errors and missed deadlines leading to distribution delays and possible missed revenue.

TOP 4 CHALLENGES
OF THE SUBMISSION PROCESS

The product submission and registration process – and the associated constant communication and tracking of deadlines – takes a considerable amount of time and effort. As a result, companies are seeking new solutions to overcome these key challenges and to streamline & automate the process.

1. Data Overload

Imagine a global personal care products company needs to submit and register an active ingredient and its corresponding finished products to ensure global regulatory compliance. This requires a series of different tests for each product to be managed and documented – often using paper-based records and a spreadsheet list to track outstanding tests.

There could be hundreds of tests tracked against 20 different products, resulting in thousands of different transactions and data points. Furthermore the cost to register products with each country or state can cost millions of dollars in registration fees, and can take years to review and approve.

Most manufacturers struggle to maintain and track this amount of data with regulators worldwide. Imagine registering one active ingredient and the 20 new products using that substance with over 80 regulatory agencies worldwide – that's over 1,600 registrations over a number of years.

Furthermore, If an RA employee leaves the company, it could take months to replace and retrain a new employee to manage these existing registrations, as well as future submissions, resulting in delays and missed deadlines that impact multiple product launches.

2. Silo'd Information

Often times when product registration is submitted, it remains in spreadsheets or paper-based records and is forgotten until there is a status update. Often that product registration is not integrated with the manufacturer's change control process, which could impact the approval of the product.

For example, if a product is made in a facility and its specifications are consistently "out of spec", then a change request will be issued to update the standard specification.

If the change is not made to the registration, it could potentially prevent a product from being distributed. As a result, RA managers must constantly investigate across silos of information and disconnected processes to identify changes that have taken place and whether a revision is required to the original submission or a new registration must be submitted.

3. Lack of Data Integrity

Registration data and processes are usually maintained in paper-based records or spreadsheet files saved in a shared drive accessible to other employees in the department. However, the lack of control over documents and changes made by different employees increases the risk of non-compliance. Auditors question the validity of a manufacturer's product registrations when there is uncontrolled access to the spreadsheets and changes to the data are not tracked properly.

In this scenario, companies need to utilize a submission tracking system that documents all updates to a specific record or registration, as well as the date and the employee making the change. This provides a documented view of the entire pre-submission process including any changes prior to and after registration. Companies need to establish a single source of truth to ensure they are making decisions based on current information and can prove compliance to regulators.

4. Limited Visibility and Control

Many companies maintain manual processes, which leads to challenges in timely and accurate tracking of activities. As a result there is limited visibility into the status of a registered product. This can be further compounded if an organization has outsourced all or part of its submission process.

One delay or missed deadline can lead to a product being quarantined or denied approval to import into a specific country, which could impact sales and provide an opportunity for competitors to capture market share.

A 4-STEP APPROACH TO SUBMISSIONS MANAGEMENT

STEP 1: Think Local & Global – and Automate!

The product submission and registration process in the personal care industry is both global and local. RA professionals must ensure compliance with local regulations and maintain global visibility and control over product submissions and registrations.

Therefore, instead of tracking hundreds of submissions and registrations in spreadsheets or paper files, leading companies are leveraging software to automate the tracking and managing of each regulation, its registration date, and required submission information and documentation.

In the event of missing information, automatic alerts can be sent to assigned employees to follow up and coordinate with the regulatory agency to meeting compliance requirements.

In order to obtain the global visibility and control with internal and external parties that are currently missing from this process, organizations implement a centralized solution that allows all users, both internal and external, to enter registration updates, testing results, and changes to provide real-time updates to avoid launch and distribution delays.

STEP 2: Keep Critical Information in Sight

Leading companies are also leveraging automation and analytics and reporting capabilities to easily run comprehensive reports and dashboards that display the status of registrations. These can be used to identify and address potential concerns (i.e. expiring registrations and pending commitments) before they become major issues.

Assigned users can also easily query the system to locate test results associated with a particular product or substance, and transmit documents electronically to regulatory bodies. Submission information – including date, documents and correspondence – is recorded and date submissions can automatically be recorded to document compliance requirements.

STEP 3: Automate Business & Compliance Processes

In addition to capturing relevant data into one integrated system, establish pre-configured workflows with trigger reminders or notifications when certain quantity threshold requirements are met or exceeded. This will help ensure compliance in the consumer marketplace.

For example, in the event that a company manufacturers or imports a specified quantity of a controlled substance per year, an alert can be automatically triggered, and sent to the regulatory and product teams. The alert notifies the teams of the need to supplement registration information with required safety assessment, in order to define risk and operational control conditions.

STEP 4: Create System and Data Harmony

An ideal scenario for a product submission and registration tracking solution is that it should integrate with a manufacturer's core business systems – such as an ERP or LIMS – and automatically pull the required data for product submissions. This allows for the RA manager to quickly and accurately fulfill regulatory requirements.

This integration eliminates the need for manual data entry and ensures that regulatory team members are using accurate, consistent, and up-to-date information when registering or re-registering products, or making changes to existing product registrations.

The solution should also integrate with the manufacturer's global change control process so that it can alert users to product changes that may affect registration and correspondence activities. And it should automatically generate registration and correspondence records required to update registrations in those markets impacted by the change.

In addition, the solution should include document management, publishing and submission software, and safety reporting system, as well as provide users with electronic access to original documents so that correspondence with regulatory authorities and outside testing facilities can be managed and tracked effectively.

THE VALUE OF AUTOMATION

Increase Productivity and Cost Efficiencies

Through process automation and data consolidation, RA professionals can eliminate most of the manual tasks currently associated with the product submission an registration process, reducing administrative costs and enabling them to reassign resources to more value-added activities within the organization.

When the organization knows exactly which product registrations are due at what time, RA professionals can evaluate the available resources in those markets, determine the necessary manpower for meeting upcoming deadlines and assign necessary resources.

With a single centralized system, RA professionals can store and share global product information across the enterprise. This reduces costs by eliminating redundant technology applications and the information technology (IT) resources required to maintain and manage multiple systems.

Furthermore today's cloud technology enables the swift deployment of such a system, coupled with lower start-up costs and an overall lower cost of ownership. This allows personal care and cosmetics companies to realize the business benefits as soon as possible yet with a swift return on investment.

CONCLUSION

RA managers in the personal care and cosmetic industries carry a tremendous burden. They secure and maintain the necessary approvals from regulatory authorities which play a pivotal role in a company's success – ensuring products can be sold in the global marketplace.

New software technologies help RA managers manage the activities of internal team members and third party affiliates to ensure everyone is following the correct procedures, performing the necessary tasks and meeting deadlines. Automation also helps drive down costs associated with inefficiencies, errors and waste, and helps organizations enhance and improve their product and operational risk management strategies.

As a department critical to the success of a manufacturer's operations, Regulatory Affairs needs a solution that:

- ✓ Merges data and process to efficiently manage a complex regulatory space and drive up submission accuracy
- ✓ Enables deep visibility into the entire regulatory management environment to effectively manage the bigger picture
- ✓ Improves management of the submission and registration process, increasing the speed in which products are taken to market
- ✓ Fulfills country, state and regulatory body related requirements to ensure proper authority is granted to sell products in each country

RESOURCES

A holistic approach to product submissions and registration tracking, including dossier management, correspondence and commitment tracking, eases the administration burden, and enables RA professionals to work with greater efficiency and accuracy, all while reducing the costs and risks for the organization.

To learn more about how automation can help streamline chemical substance submissions, please visit www.spartasystems.com or check out the following resources:

Success Story: Personal Care/Consumer Products

Infographic: Product Registration Tracking for the Personal Care & Cosmetic Industries

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