Fortrea

Efficiently managing manufacturing and R&D supply chain documentation and technical report writing for cosmetic, personal care and over-the-counter products

The role of Material and Product Support Services (MPSS) at Fortrea

As pharma, consumer and personal care organizations develop and launch products, they accumulate a vast amount of product, market, customer and transactional data. The overall beauty and cosmetics supply chain is complex due to the nature of the product development and commercialization process, which can extend for several years.

Health, environment and safety bodies across the countries are now adopting stringent standard measures to protect the interest of people and environment. Chemical manufacturing regulations have also had a significant impact on the industry, influencing everything from product development and production processes to worker safety, environmental impact and business operations.

Beyond creating, maintaining and extracting knowledge from data stores, data management responsibilities can also include monitoring and responding to ever-changing regulatory requirements.

To help pharma, consumer or personal care organizations understand how to efficiently navigate the documentation management landscape and meet the needs of cosmetic, personal care and over-the-counter (OTC) products, this article:

- Provides an in-depth view of the common challenges faced in reducing supply chain risks
- Shares case studies that demonstrate best practices for streamlining product life cycle documentation management
- Discusses key considerations for outsourcing product life cycle documentation and technical writing tasks with a strategic partner

Acknowledging common industry challenges

As a product progresses across the development and commercialization life cycle, its associated supply chain continually evolves each time new suppliers and manufacturing sites are enlisted to support phase-specific needs. Documentation and specifications support the supply chain by providing important product information, such as the raw materials, ingredients, formulas, packaging requirements, finished goods, bill of materials (BOM) and quality procedures, among many others. However, there are several common challenges related to these informational documents and associated data in the product life cycle. These challenges include:

Managing data across diverse systems	It's common to face a lack of data consistency within and across different databases. Organizations need to ensure data is connected across systems, available for a variety of analytics and algorithms and accessible for cost simulations or product recalls.
Communicating to suppliers and third parties about changes	Any changes in the regulations need to be conveyed to the supplier so that the finished goods manufacturers meet the latest regulations. These changes must also be relayed to any production sites and third-party networks that need to adjust their internal operations.
Qualifying alternate vendors and gathering documentation	Alternate suppliers are often enlisted to ensure the availability of high-demand products or supplies to reduce the risk of an unexpected disruption in the global supply chain. This process requires qualification of the supplier and their raw materials, if applicable.
Aligning and managing disparate global specifications	Identical products and stock keeping units (SKUs) may have different information depending on their global region or local consumers' demand for personalization. Organizations often face: • A cumbersome process to create and manage disparate specifications • Limited or non-existent centralization of specifications • Difficulties searching and finding specifications and their associated assets • An overall lack of visibility to report and track specification changes

To reduce the risk of human error and ambiguity in product manufacturing and distribution, pharma, consumer and personal care organizations must ensure that their product specifications are consistent, organized and structured so that any changes can be efficiently shared and applied globally across a product life cycle.

Responding to an increasingly stringent regulatory environment

In response to safety incidents and product recalls over the last five years, several regulatory bodies, such as EU REACH (registration, evaluation, authorisation and restriction of chemicals), UK REACH, Turkey REACH and CSAR (Cosmetics Supervision and Administration Regulation) within China NMPA, have been focusing on standardizing and harmonizing the registration of cosmetics/chemicals. This has involved several areas, including:

Over-the-counter drugs: In recent years, OTC drug regulations have been re-examined to assess emerging safety issues and promote drug innovation. However, due to the increased scientific innovation, current OTC drugs have become more challenging to review and regulate with the initial OTC drug regulation system. This regulatory gap between the OTC drug regulation and currently marketed products is observed through warning letters that issue violations, which are often related to current good manufacturing practices (cGMP), labeling and quality controls.

U.S. cosmetic regulations: The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) represents "the most significant expansion of FDA's authority to regulate cosmetics since the Federal Food, Drug, and Cosmetic (FD&C) Act was passed in 1938."[1] In terms of product life cycle documentation, MoCRA allows the FDA (in certain conditions) to access and copy certain records related to a cosmetic product, including safety records. The Act also requires the assignment of a responsible person who can ensure and maintain records to support adequate safety substantiation of a cosmetic product.

EU cosmetic regulations[2]: According to Article 4 of EU Cosmetic Products Regulation (EC) No. 1223/2009, any cosmetic product that will enter the market or was previously entered in the market must have a designated responsible person who ensures compliance with all regulations. Any relevant question about the product after its entry into the market must be explained and justified by this responsible person. If the regulations are not fulfilled, then that person or the company will face sanctions.

Halal cosmetics[3]: Halal cosmetic products must not contain ingredients derived from pig, carrion, blood, human body parts, predatory animals, reptiles and insects, among others. Cosmetic ingredients derived from permissible animals must be slaughtered according to Islamic law to be considered halal. The preparation, processing, manufacture, storage, and transportation, maintenance of hygiene and pure conditions must also be ensured at all times. The intent of certifying products as halal is parallel with the goals of most quality assurance procedures (e.g., cGMP, HACCP).

Implementing best practices in managing manufacturing and R&D supply chain documentation

A pharma, consumer or personal care organization's outsourcing strategy for managing manufacturing and R&D supply chain documentation can vary based on its product portfolio, internal capabilities, volume and complexity of documentation and product sales. Some organizations may outsource a few of the more resource-intensive tasks of documentation and managing supplier engagements. Other organizations may outsource the entire process to a third party who can centralize their data and manage their documentation.

An outsourcing strategy can be set up in two ways, depending on the volume of product life cycle documentation and technical reporting writing tasks. Two common relationships include:

1. A strategic relationship: The sponsor organization and outsourcing partner actively work together to help each other achieve their respective objectives. Strategic relationships help both parties benefit from long-term commitments, which can include database updates and continuous process improvement. The sponsor organization can also leverage the outsourcing partner to access resources for business-critical projects.

2. A transactional relationship: This is ideal for limited-scope projects, such as updating a fixed number of documents/specifications impacted due to regulatory change or extracting specific information from databases. A transactional relationship often helps extend the sponsor company's internal resources during intense periods.

As with any outsourcing engagement, it is important to consider the setup and ongoing success factors, such as:

- Whether or not to test the engagement with a pilot program before the "go live"
- How to migrate work to the outsourcing partner
- How to manage the outsourcing partner
- How to define key performance indicators (KPIs) and outcome-driven metrics based on a defined service level agreement to track quality, cost and time
- How to use analytical data to guide decision-making in process improvement

It's also helpful to understand the components that can be implemented when outsourcing managing manufacturing and R&D supply chain documentation and how they can demonstrate value to an organization.

Global delivery model
The delivery model should leverage a globally distributed team and offer flexibility to scale up or down, depending upon the evolving needs of the organization's product portfolio. To provide cost-effective services, resources should be managed within a centralized leadership structure.

Compliance and quality assurance
Quality assurance and quality control should include self-review and peer review to ensure compliance is met in accordance with regulatory standards. It is also helpful to follow the FTR (First Time Right) framework to improve compliance, productivity, quality and audit readiness while transparently measuring and reporting performance.

Automation and innovation
After understanding an organization's processes, automation and other innovative solutions can be implemented by the outsourcing partner to uncover additional efficiencies.

Recognizing the value of life cycle documentation management services

Three case studies share how life cycle documentation management services can be applied to ensure data consistency within and across different databases.

1. Addressing urgent supply chain shortages

A multinational corporation was facing significant supply chain disruptions due to the COVID-19 pandemic. Without the availability of packaging film for their medical devices, pharmaceuticals and consumer packaged goods, they would lose up to $2.5 million.

Fortrea suggested an alternative film from a different supplier and tasked their technical writing team to prepare a change implementation plan. In parallel, Fortrea packaging engineers addressed the technical challenges, gathered supporting documents from suppliers andensured all requirements are met. The packaging change was documented, communicated and implemented within a week, preventing any delay in product distribution.

2. Evaluating product specifications to improve customer satisfaction

A global organization needed resources to help them quickly answer patients' ongoing medical queries about their products' ingredients.

Fortrea was enlisted to evaluate the organization's database. They started by analyzing more than 4,000 specifications and checking for the presence of allergens and alcohol as well as determining vegetarian/vegan suitability. The team then coordinated with suppliers and sites to generate documented evidence that could be used to respond to any medical query. This overall process helped enhance operational efficiency, increased product transparency and improved customer satisfaction.

3. Responding to a product recall

An organization's product was recalled by the FDA due to the presence of benzene. Regulators asked the organization to provide evidence that the product was not adulterated and contained acceptable benzene levels.

Within two days, Fortrea reviewed all the documentation to determine the presence of the impurity. In the next five days, more than 2,000 formulas were evaluated for the presence of benzene. Fortrea shared this evidence with the organization and generated documentation for the organization to submit the findings to the FDA and quickly get these products back on the market.

Finding the right outsourcing strategy for your business needs

Timely, consistent and accurate documentation and its associated product data can help drive decision-making in the product life cycle and consumer supply chain processes. By assuming the responsibility of managing the complex processes, transactions and tasks associated with product life cycle documentation, an outsourcing partner can deliver valuable data to an organization and help them stay focused on marketing, product development and customer relationships.

Following regulatory, regional and local requirements, our globally distributed team at Fortrea offers end-to-end documentation management services to leading pharma, consumer or personal care organization. With proven processes for delivering compliant, high-quality and consistent results spanning raw material sourcing and manufacturing, we have annually supported the:

- Management of 15,000+ specifications
- Oversight of 500+ global change control processes
- Maintenance of 1,000+ raw material questionnaires
- Creation of 550+ annual product releases
- Generation of 130+ analytical reports
- Qualification of 100+ raw material suppliers
- Definitions for 1,000+ analytical testing strategies

We invite you to apply our experience and extend the capabilities of your team with our 300+ team members specializing in pharmacy, chemistry, quality assurance (QA) and packaging engineering. Together, we can help your over-the-counter, cosmetics and personal products achieve GDP and GMP compliance with our proactive solutions for documentation management across supply chain departments.

References

1. U.S. FDA. Modernization of Cosmetics Regulation Act of 2022 (MoCRA). https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra Accessed 15 Mar. 2024
2. Regulation - 1223/2009 - EN - Cosmetic Products Regulation - EUR-Lex (europa.eu)
3. Halal Certification for Cosmetics & Personal Care - AHF (halalfoundation.org)

LEARN MORE at fortrea.com

Fortrea