sciformix

Trusted **Services.** Built on **Science.**

Global Labeling Managed Services

Enhancing the quality and efficiency of labeling

Growth and Decentralization

Life sciences organizations are expanding into new geographical regions due to various reasons such as business expansion, economic viability and product longevity. This decentralization can, in many cases, slow down processes, reduce operational efficiency and profitability, while delaying product time-to-market. Furthermore, the need for greater quality checks to ensure brand integrity has become paramount in the global marketplace in order to comply with regulatory mandates and manage the resources that are spread across multiple geographies.

In the current global scenario, marketing may be in the United States, production in India, printing in Europe, and quality control in Canada. However, this business model comes with a price – how do you maintain a company-wide quality system that standardizes processes around the world? How do you ensure compliance across regions that have varying global regulatory requirements? How do you maintain quality control with your suppliers and distributors? How do you ensure that your product labels are accurate?

Drivers for Labeling Standardization

While labeling standardization reduces cycle time and costs, the primary drivers are accuracy and quality. Trust in the data that is submitted to regulatory agencies during the approval process prior to a product's release to the market is critical to its success. Additionally, there is significant motivation to reduce costs associated with the process, all while maintaining the integrity of the product. For example, frequent updates to the prescribing information of a product, such as changes to the manufacturing process and new safety side-effects, need to be included in the label.

The process of creating the updates to the prescribing information is largely manual. Someone must review the changes and transcribe them into different formats (leaflets, artwork, etc.). This manual effort is prone to errors. In addition, when an innovator needs to make a change to its labels (for example based on an advisory from the FDA), generic companies must follow suit and make the same change as the innovator. These activities are not core to either the innovator or the generic companies – their expertise lies in delivering new products to the market, and packaging and marketing them. Making label updates is a standalone and discrete activity that can be outsourced to a partner who will improve the accuracy and quality of the labels through the use of the right expertise, processes and tools.

Labeling Challenges

Some common challenges reported in labeling operations include:

- Varying regulatory requirements from country to country
- Growing complexity and need for expertise and deep understanding of how regulations impact the label
- Increasing manual and time-consuming processes which are prone to potential errors

Benefits

By standardizing and harmonizing the global labeling workflow, Sciformix's Labeling Managed Services delivers client's the following benefits:

- Efficiency and scale
- Quality and compliance
- Cost effectiveness

Taking Control of Your Labeling Process

Product labeling is a highly regulated and complex process. The product label can include multiple documents targeted at diverse audiences such as patients, physicians and pharmacists. A product label is very specific and precise in its content, especially with respect to safety data and adverse effects. Furthermore, the label needs to comply with country-specific regulations governing the product.

Changing regulatory requirements and the numerous hand-offs require extensive reviews and proof-reading to ensure that the printed label and all documentation is error-free. This adds significantly to the cost and time, not to mention the possibility of introducing manual errors.

Sciformix's Labeling Managed Services offering is an externally managed, fully integrated platform of services, processes and technology enablers that cover the entire labeling continuum.

Service: Qualified resources that execute global labeling activities on behalf of sponsor

Process: Best-in-class labeling processes with appropriate measures for performance, quality and compliance available for sponsor adoption

Technology Enablers: Pre-configured, ready-to-use solutions to support workflow and content management and control

By employing a best-in-class managed service model, client's reap the following benefits:

Efficiency & Scale

- Utilize qualified external resources, best-in-class processes and integrated technology solutions to accelerate your label development, updates and implementations
- Quickly scale up to meet your global growth aspirations by leveraging local and regional labeling knowledge and delivery capabilities

Quality & Compliance

- Gain visibility and control of the global labeling process via robust workflow management
- Have confidence in the overall operations through measurement and reporting of key performance, quality and compliance indicators

Cost Effectiveness

- Forgo heavy investments for expensive internal resources and technology requiring optimization and customization
- Maintain flexibility for scale-up and scale-down to manage costs
- Leverage tailored end-to-end solutions that optimize resource utilization and appropriate technologies aligned with client needs

Sciformix has been delivering product labeling services to global healthcare companies, and this managed service solution is an integral part of our comprehensive Regulatory Affairs portfolio. We constantly seek to improve our people, process and technology capabilities to deliver consistent, reliable and superior quality result to our clients. This solution is another example of how Sciformix is creating value and enabling better client outcomes.

Regulatory Affairs Portfolio

Preclinical	Phase 1	Phase 2	Phase 3	Post-Approval
Global Regulatory Submissions				
			Clinical trial applications	
			Marketing authorization/drug registration applications	
			Repurposing dossiers	
			Supplements, amendments and variations	
			Responses to deficiency queries	
			Briefing packages and submissions	
Regulatory Writing				
Clinical writing				
Patient narratives, safety profiles				
Quality Overall Summery (QOS)				
Non-clinical overviews and summaries				
Product quality reports				
Process development reports				
Structured Product Labeling				
	Creation and maintenance of global labeling documents and country-specific conversions			
	Labeling updates and amendments submission			
	Artwork preparation			
Regulatory Strategy and Consulting				
	Regulatory strategy support gap analysis			
	Interactions with regulatory agencies			

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Trusted Services. Built on Science.

Sciformix Corporation is a global scientific process organization (SPO) that partners with life science companies to develop, launch and sustain medical products that aim to improve the quality of healthcare worldwide. We collaborate with our clients through the entire product development lifecycle to provide a full range of services from study design to post marketing surveillance and commercialization support.