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A Successful Model for Outsourcing Core Labeling Activities

Increasing efficiency, enhancing quality, and delivering compliance

Life Science organizations are expanding into new geographical regions to expand business and product longevity. This decentralization can, in many cases, slow down complex processes, reduce operational efficiency and profitability, and delay time-to-market. One such process is product labeling. By automating time-consuming, error-prone activities organizations can improve efficiency and quality, while ensuring that local regulations are met.

Biopharmaceutical product labeling is a highly regulated and complex process. “Product labeling” is generic nomenclature that includes the actual label on the product, the package insert, and labels on any packaging material. The product label can include multiple documents targeted at various audiences such as patients (patient information leaflets, medication guides, instructions for use, etc.), physicians and pharmacists (package inserts). A product label is very specific 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.

A product label from an innovator pharmaceutical company, prior to commercialization, is drafted by the pharmaceutical company and is reviewed and approved by the applicable regulatory agencies, based on regulations and guidelines.

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On the other hand, a generic product label is based on the innovator label having already been approved by the regulatory authority. While a generic company's portfolio may include 300 products, the Reference Listed Drug (RLD) label could be sourced from 20 to 30 different innovator companies, compounding the complexities in referencing and tracking of RLD updates.

Labels are an essential part of the marketed product since they provide comprehensive information about the drug. They also represent a significant percentage of the manufacturing cost and commercialization risk.

Moreover, a product with a wide geographical footprint would require labels in each country/region to comply with local regulatory guidelines. These multiple labels increase the risk of having non-uniform information disbursed globally for the same product.

Each label update involves input from multiple stakeholders like regulatory, legal, quality and manufacturing personnel. The sheer number of reviews makes data management, version control and audit trails prerequisites to the labeling process.

The Labeling Process

Product labeling is a collaborative process, from initiation of a clinical trial to commercialization, with multiple sources of inputs and hand-offs that ultimately resulting in a Company Core Data Sheet (CCDS).

The CCDS includes all the relevant information on the product to be labeled, and any local labeling information for different geographies are derived from this.

Every CCDS developed could require multiple changes depending on the markets where the drug is sold and on the product formulations. Complexity increases when these regional labeling documents (local product documents) need to be in the local language, with differing content. These regional adaptations in turn need to be updated whenever there is a change in the CCDS.

Changing regulatory requirements and the numerous hand-offs make the process more complex. The existing process of developing a product label is human resource intensive and therefore requires extensive reviews and proof-reading to ensure that the printed label is error-free. All of these factors significantly add to cost and time, not to mention the possibility of introducing manual errors.

Labeling as a "Managed Service" Enables Scale, Performance, Quality and Compliance

Labeling as a Managed Service is an externally managed, fully integrated platform of services, processes and technology enablers that cover the entire labeling continuum.

It is comprised of best-in-class:

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

Processes: Best-in-class labeling processes with appropriate measures for performance, quality and compliance

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

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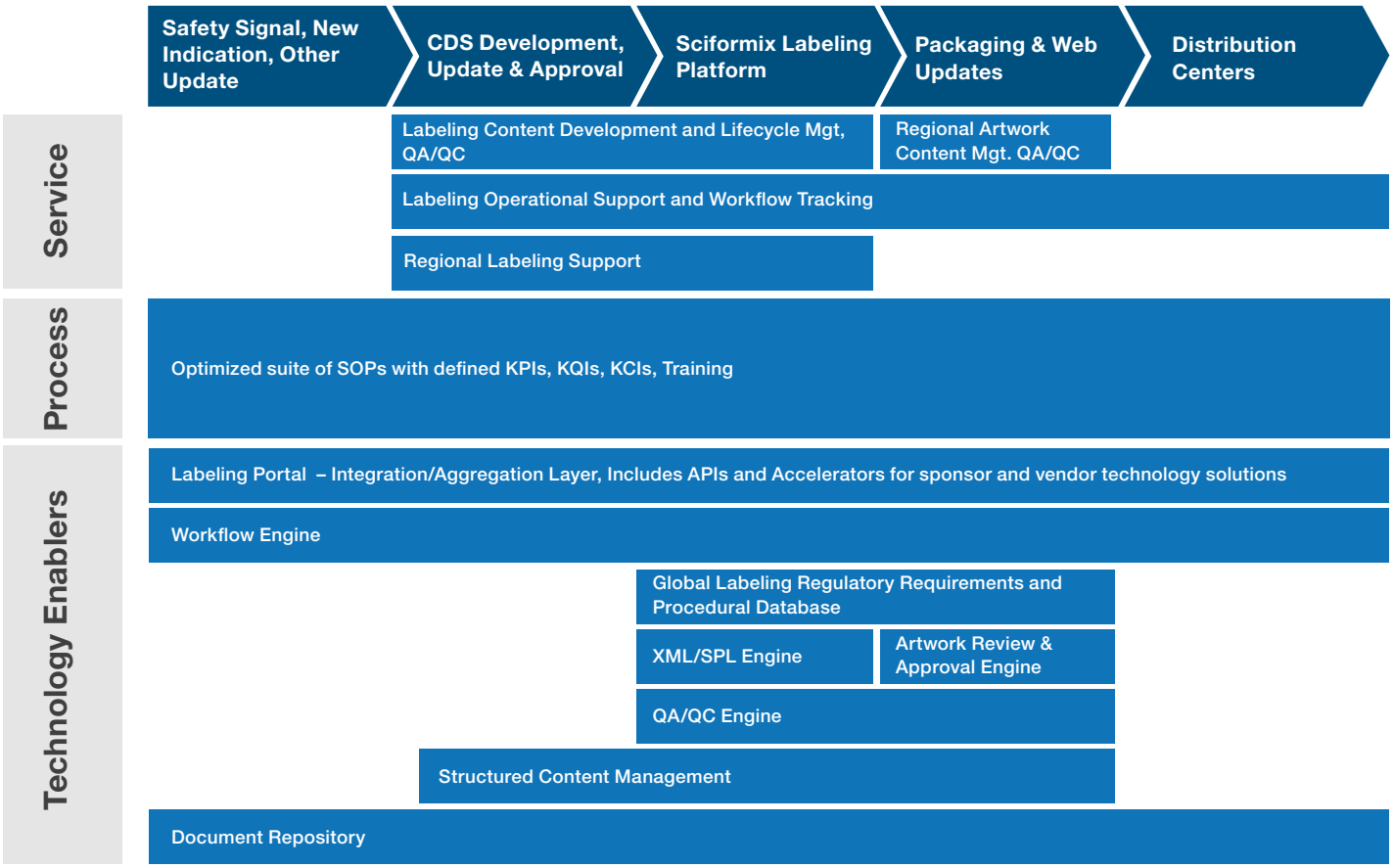
End-to-End Labeling Workflow

Successful organizations require a streamlined workflow management model that includes document management, version control and standardization/synchronization of processes such as labeling and artwork content across geographies.

Having a portfolio of products across multiple regions means organizations must comply with the requirements of multiple regulatory agencies. Reliance on people-intensive, paper-based processes results in errors and time-consuming quality control. Moreover, each version of the product label requires its own artwork for the final printed label, necessitating another series of manual processes. Today, product labeling comprises disparate processes at different locations, based on country-specific preferences. In our experience, a streamlined workflow management process, along with a document management system that allows for version control, and standardizes label and artwork content, makes the task easier and more accurate, since it synchronizes content and versions across geographies.



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How is Labeling as a Managed Service Implemented?

Organizations can successfully outsource core labeling activities on a global scale by partnering with a vendor who can tailor a solution that meets your current and future needs. Sciformix's will work with you to assess your unique situation, build and implement a tailor-made solution, and partner with you to continually support your needs throughout the product lifecyce.

Our goal is to help you expand internationally and grow your portfolio, while, all while maintaining quality and compliance at a reduced cost.

Assessment

- **We partner with you to clearly assess your unique situation and need for Global Labeling support in terms of services, process and technology**
- **We help you define your business case and value drivers to facilitate decision making on platform investment**

Solution Build

- **We will develop a tailored solution for you on the principles of the managed services platform**
- **The solution model will be considerate of your current situation with ability to scale in the future, i.e. additional services and technologies**

Implementation

- **We will implement the solution through our proven delivery capability, providing process and technology integration support, global training on process and technology and project management leadership**

Lifecycle

- **Your success is our goal. We will closely partner with you throughout the transition an steady state cycle to ensure platform performance meets your needs**
- **We will continue to support platform effectiveness through a transparent and proven governance model that puts client outcomes at the center**

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Your Ambitions	Your Realities
• Expand internationally • Grow your portfolio • Maintain quality & compliance	• Manage cost as you grow • Manage external expectations for labeling quality and control

If one or more of these apply to you, than Labeling as a Managed Service may be right for your organization!

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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. Sciformix consistently delivers scientific insight, improved productivity, and high quality results, in every engagement, through a deep understanding of the regulations governing the global life science industry.

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