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IDC TECHNOLOGY SPOTLIGHT

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To maximize global reach and reduce time to market, pharmaceutical and biotech firms must employ new tools to ensure compliance of their product information with local regulatory filing requirements in multiple languages and geographies.

Closing the "Black Hole" of Global Regulatory Labeling Submission for Biopharma

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Introduction

In a global and highly regulated marketplace, pharmaceutical and biotech firms face a challenge in managing regulatory labeling submissions that meet multiple country and regional requirements in many different languages. This process has historically required substantial manual intervention and review by highly paid professionals, contributing to unnecessary costs and delays in medicinal product launches. Biopharma executives hope that new, cloud-based tools will help solve this costly dilemma.

AT A GLANCE

KEY STAT

85% of content management systems including labeling submission software will be cloud enabled within two years.

KEY TAKEAWAY

Cloud-based intelligent multilingual submission systems can help biopharma companies bring their products to global markets faster and at reduced costs.

To market their products globally, biopharmaceutical firms must ensure their product information complies with local regulatory filing requirements. Submissions often need to be revised to reflect in-country linguistic, formatting, and timing mandates. In-country compliance is usually overseen by local affiliates that manage the process internally. Tasks such as translation and formatting are typically outsourced to in-country providers.

For the corporate global regulatory affairs (GRA) function, establishing a link and maintaining compliance between the corporate source of truth that is managed centrally and the in-country labeling information that is on file with the local regulators represent a challenge that could be described as a "global regulatory labeling submission black hole."

Unfortunately, legacy linguistic technologies such as translation management and translation memory systems historically have come up short in capabilities for managing the dynamic nature of the labeling process, leading to substantial manual intervention in categories such as variations and update filings. Manual approaches invite errors and inconsistencies, and they increase the risks of mislabeling and delays while substantially increasing costs and associated overhead.

Consequences of the "global regulatory labeling submission black hole" effect are far reaching and include:

- Compliance issues such as inconsistent labels and improper version control
- Inability to manage data at the component (phrase) level or even the file level
- High costs associated with translation and review tasks performed by highly skilled medical professionals
- Inadequate management of linguistic reviews between all parties, including regulators and medical reviewers

As pharmaceutical companies push forward with their digital transformation efforts, global regulatory information and labeling management systems have emerged as an opportunity to put technologies such as cloud storage, software as a service (SaaS), analytics, and artificial intelligence (AI) to work to reduce costs, errors, and time to market associated with legacy systems by adopting cloud-based, intelligent multilingual submission management (MSM) systems.

Benefits

Cloud-based, intelligent MSM systems specialized for the regulatory environment of the global pharmaceutical industry can offer the following benefits:

- Management of all multilingual labeling content types (not just files)
- Intelligent management of dynamic labeling content such as variations and update filings
- Automatic version control
- Improved compliance, labeling quality, and process visibility
- Global transparency and accountability
- Automated access to and storage of existing labeling content, including origin and version timeline, in the cloud

Embedding structured content and AI into solutions will allow manufacturers to support end-to-end labeling by managing submissions in a nonlinear fashion across versions and submission status in a more cost-efficient and consistent fashion, while integration with corporate source of truth will ensure global compliance and traceability. Cloud content storage and a SaaS delivery model will provide easy content access, global consistency of software versions and capabilities, instant access to new features and revisions, and lower system maintenance costs.

By leveraging the appropriate technology to handle multilingual submission labeling requirements, organizations can expect increased staff productivity, improved process efficiency, and lower costs by minimizing the manual and complex effort required in the current process. This is the first step toward evolving into a sophisticated and automated AI system, which promises to facilitate achievement of these benefits by enabling reuse of labeling content, which provides a secure editing environment and allows for collaboration and automation.

Trends

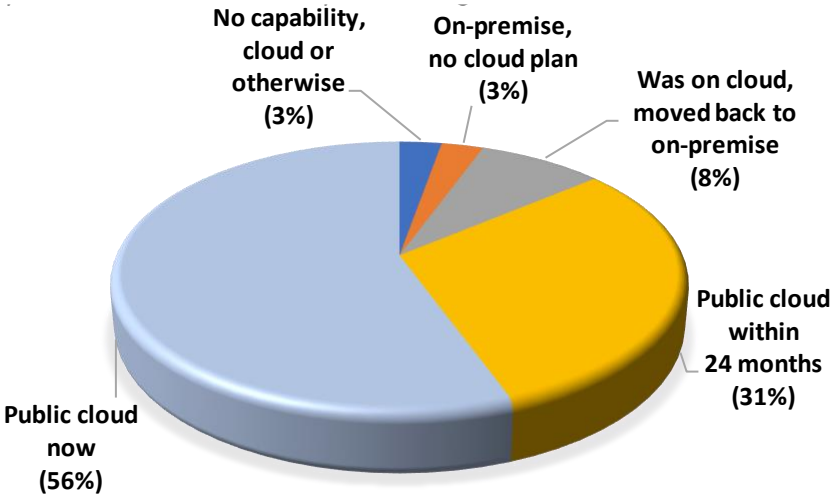
IDC has identified several trends driving interest in cloud-based, intelligent MSM systems. These trends include:

- **Drug innovation.** The biopharmaceutical industry is driving innovation at a rapid pace for new drug discovery as well as reformulation, package and safety information, and generic and biosimilar drug therapies. Likewise, labeling submissions for regulatory agencies are multiplying globally as healthcare improves in the developing world. The rise of specialty and rare-disease drugs also increases the pressure on pharmaceutical companies to reduce product launch times and reach far-flung patient populations.
- **Increased global regulatory labeling submissions.** In the United States (a mature market) alone, there were 314 Food and Drug Administration (FDA) drug approvals in July 2018. Half of those approvals (157) were in response to labeling submissions. That figure compares with 145 in July 2008, 70 in July 1998, and 83 in July 1978. As new drugs reach more countries using many different languages, management of global regulatory labeling submissions is placing greater demands than ever on biopharmaceutical companies.
- **Content management in the cloud.** The pharmaceutical and biotech industries are moving inexorably to the cloud. According to IDC's April 2018 *CloudView Survey* of IT executives in multiple industries, just over 50% of life sciences IT budgets are allocated to cloud-based procurement models (public cloud services including SaaS, enterprise private cloud and dedicated hosted private cloud architectures, virtual private cloud, and hosted container platforms). This proportion is expected to increase to over 60% within 24 months.

  In enterprise content management applications, cloud migration is already substantial, with the majority of installations enabled in the cloud. Over 55% of content management workloads are deployed in a public cloud with another 31% scheduled to be deployed within two years (see Figure 1).

FIGURE 1: ***Content Management in the Cloud***

Q Enterprise content management: More specifically, what are your plans for each workload you indicated to already be running in the cloud?



Unweighted valid n = 36

Note: Numbers do not add up to 100 due to rounding.

Source: IDC's CloudView Survey, April 2018

AI and machine learning are already combining advanced analytics and search capabilities to comb through multiple data sets and suggest next logical actions. These techniques are being applied in content management including labeling submissions to suggest modifications and submissions based on history, existing content and associated timelines, and individual country regulations. Expanded access to data and algorithms in the cloud is increasing throughput and accuracy. IDC expects improvements in system performance to accelerate in coming years.

Considering SDL

SDL is a global provider of language technology and services as well as content management. For over 25 years, SDL has strived to deliver transformative business results for clients by enabling life sciences organizations to globalize their business. Globalization is achieved by leveraging technology and services for global management, translation, and publishing of clients' content.

Regulatory Labeling

The specific in-country requirements associated with health authority local submission processes, such as availability in local languages and formatting, have surged over the years, along with expectations for quality, traceability, and responsiveness. SDL's regulatory labeling solution is designed to efficiently support the translation, review, and management of multilingual submission content while helping each sponsor meet individual agency demands. Coupling the SDL Multilingual Submission Management (SDL MSM) platform with SDL's network of medical linguistic resources can help pave the way toward a true global end-to-end labeling environment for the biopharmaceutical industry. SDL MSM enables reuse of labeling content, which provides a secure editing environment and allows for collaboration and automation.

Challenges

Multilingual submission management solutions face challenges in the market. Many global companies have designed internal processes for local submission by applying more resources to handle increasingly frequent label changes, particularly by regional affiliates. For pharmaceutical companies to relinquish this sometimes inefficient and resource-intensive process, they need to understand the productivity savings of leveraging technology to automate their processes and the up-front commitment of resources required to ensure success.

Conclusion

Biopharma companies will accelerate investment in MSM systems that leverage technology such as cloud computing, SaaS, and AI to increase throughput and accuracy while reducing the costs of manual processes such as translation and formatting. IDC expects these investments to favor suppliers that incorporate these technologies into their standard product offerings with features that focus on vertical (life sciences) processes. Pharmaceutical and biotech firms need to continuously innovate not only in drug development but also in digital transformation of internal and industry processes. Firms will realize improvements in global reach, time to market, and consumer and provider satisfaction through successful implementation of these multilingual systems.

SDL MSM aims to provide a unique and sophisticated multilingual cloud technology that can manage dynamic labeling content globally. SDL has years of experience with pharmaceutical and biotech labeling and content management systems and continues to make investments in these technologies in an effort to be well positioned for continued growth in the life sciences industry. To the extent that the company can address the challenges described in this paper, it has a significant opportunity for success.

SDL continues to invest in pharmaceutical and biotech labeling and content management systems in an effort to be well positioned for continued growth in the life sciences industry.

MESSAGE FROM THE SPONSOR

SDL's Regulatory Labeling Solution, powered by SDL's Multilingual Submission Management (SDL MSM) technology, is designed to streamline multilingual labeling processes and improve staff productivity along with lowering the cost of translation workload. For more information on SDL in Life Sciences, please visit https://www.sdl.com/industries/life-science/.

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