Innovative Technologies for Efficient and Effective Label Change Process

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Introduction

Within the pharmaceutical industry, the process of drug labeling emerges as a vital conduit for relaying essential medication information to healthcare practitioners and patients. These labels encompass critical particulars like drug names, strengths, indications, contraindications, dosages, and administration instructions. The dynamism of this information, subject to continual updates across the drug's lifecycle, underscores the intricacies and demands of the end-to-end labeling process. Simultaneously, the paramount significance of effective drug labeling in ensuring patient safety and optimizing treatment outcomes cannot be overstated. Neglecting comprehensive drug labeling could lead to grave consequences, potentially compromising patient safety. Thus, recognizing the pivotal role of drug labeling emphasizes the urgency for sponsors and regulators to collaboratively devise a holistic approach to label development that addresses the complexities and critical importance of the process.

In the quest for efficiency and effectiveness, pharmaceutical companies are exploring innovative technologies to augment regulatory professionals — not replace them — for managing and executing label changes. Artificial Intelligence (AI) and Machine Learning (ML) offer transformative capabilities that can automate repetitive tasks, extract relevant data from vast sources, and facilitate accurate translations. By leveraging these technologies, organizations can free up valuable staff time, allowing them to focus on higher-value activities and strategic decision-making.

Efficiency, effectiveness, and cost savings

The process of drug label development involves multiple stages, including core label management, local label management, artwork management, and implementation. Each step demands careful attention to detail, adherence to regulatory guidelines, and coordination among various stakeholders. However, the labeling process can be arduous and complex, often requiring extensive manual effort in searching for relevant information, ensuring accuracy and consistency, and tracking the labeling process throughout the lifecycle.

With the integration of advanced technologies, including AI and ML, among others, pharmaceutical companies can enhance the efficiency and effectiveness of the label change process. By automating tasks such as regulatory information aggregation, labeling intelligence, and

Figure 1: Integration of AI and ML

By embracing AI/ML as enablers, biopharmaceutical companies can foster a collaborative environment where humans and machines complement each other.

artwork creation, these technologies provide a swift and precise approach to handling label changes. Moreover, they offer cost-saving opportunities, as automation reduces the need for extensive human intervention and streamlines resource allocation.

Technologies to enable, not replace

It is essential to clarify that AI and ML are not intended to replace regulatory professionals in the labeling process but rather to augment their efforts. The synergy between technology and human expertise leads to enhanced outcomes, and human judgment remains critical for context understanding, creative decision-making, and addressing nuanced issues that may arise during the process.

By embracing AI/ML as enablers, biopharmaceutical companies can foster a collaborative environment where humans and machines complement each other. As technology automates repetitive and time-consuming tasks, it frees up human resources to concentrate on strategic planning, regulatory compliance, and improving patient outcomes.

The following sections of this paper delve into specific applications of AI/ML technologies in the labeling change process. These include the utilization of Natural Language Processing (NLP) for regulatory labeling automation, AI/ML for content and design automation, and the role of Generative AI and Robotics Process Automation (RPA) in artwork creation. Additionally, the benefits of adopting Structured Component Content Management & Authoring (SCCA) to optimize the label development process are also discussed.
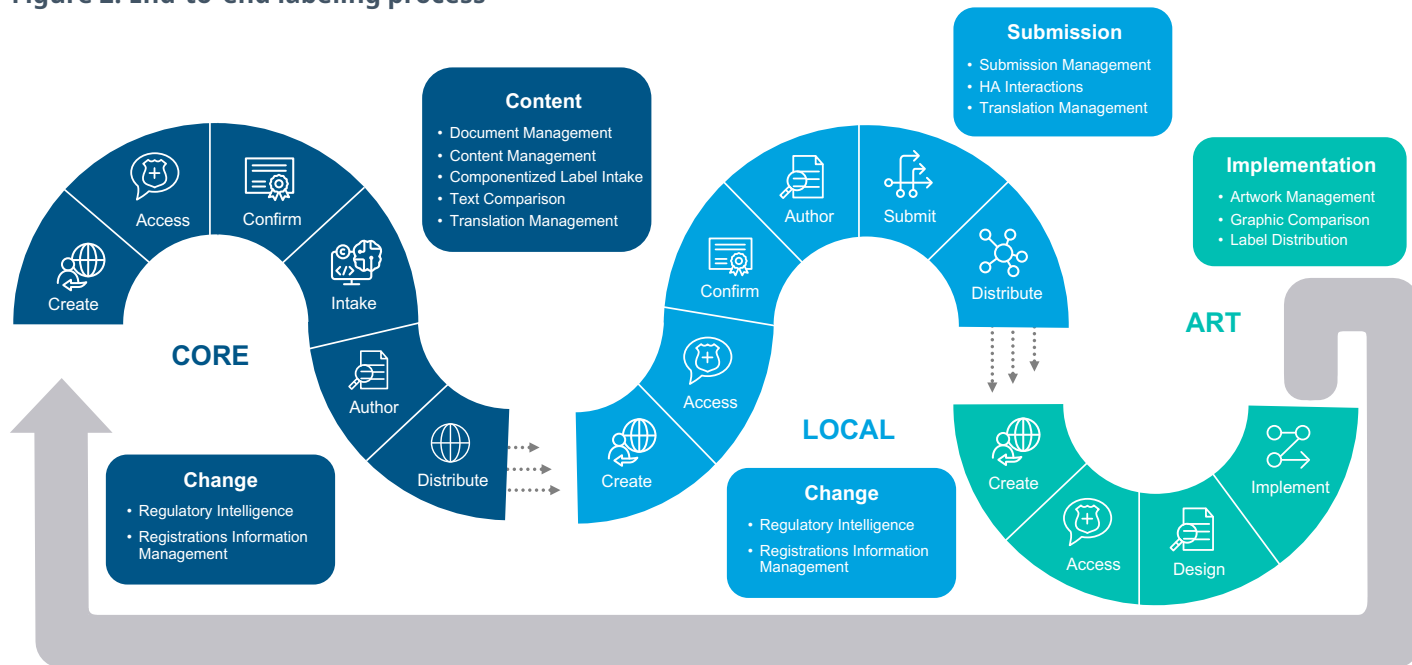
Through a deeper understanding of these innovative technologies, biopharmaceutical companies can make informed decisions and leverage their potential to drive efficiency, ensure compliance, and improve patient safety throughout the label change process.
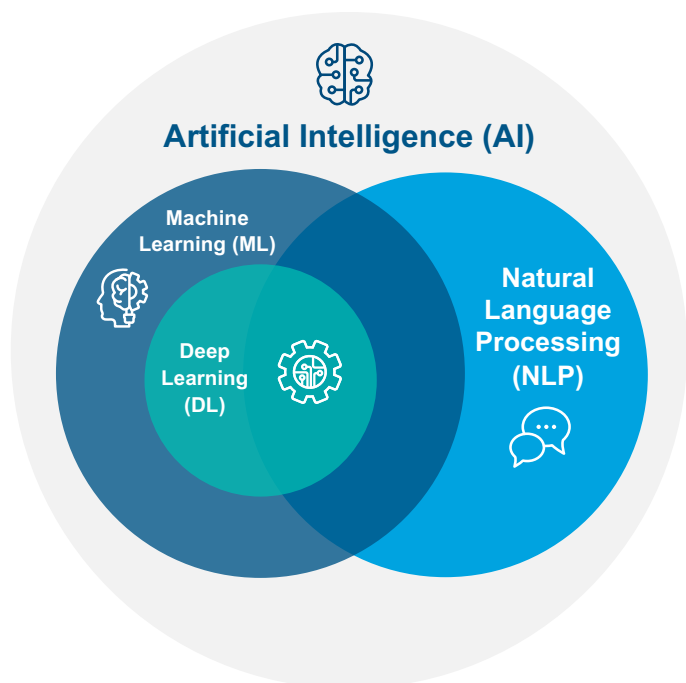
Figure 2: End-to-end labeling process

The end-to-end labeling process consists of three major stages: Core label management, local label management, followed by artwork management and implementation.

The labeling lead initiates the change request routing for the core or local label, as per requirements. Following this, an impact assessment is conducted to evaluate the proposed changes' effect on the core or local label. If the assessment recommends proceeding, the lead is responsible for internal approval, content change, and translation of the approved content.

Subsequently, the approved content, along with clean and track changes, is submitted to the respective health authority, where required. The country (affiliate) awaits the health authority's decision and then routes the approved content for downstream consumption by marketing and artwork teams for design and implementation.

Challenges along the labeling lifecycle

The label change process presents several formidable challenges that can hinder biopharmaceutical companies' efficiency and regulatory compliance. These challenges encompass a range of tasks, each requiring careful attention and coordination.

- **Time-consuming and manual effort:** One of the primary hurdles lies in the laborious and time-consuming nature of manually searching for internally related documents or external responses from competitors or regulatory authorities. Teams responsible for regulatory, medical, and safety aspects can spend a significant amount of time searching for the right labels and pertinent label-based information, diverting valuable resources from other critical activities.

- **Inconsistent and erroneous data:** Ensuring consistency in the updated content poses a considerable challenge. Data collected from various sources might lack uniformity or contain errors, outliers, or irrelevant information. These inconsistencies can arise during data collection, storage, or transmission processes, making it challenging to maintain a cohesive and error-free label.

- **Multiple and international sources:** The label change process requires dealing with a multitude of sources, both domestic and international. While prominent authorities like the FDA and EMA often take center stage, some teams require supplementary English language resources alongside country-specific sources in local languages. Managing and searching for terms and concepts across these diverse sources can be intricate and time-consuming, potentially leading to delays in the labeling process.

- **Multiple concurrent changes:** Navigating the intricacies of drug labeling involves more than just a linear progression from the currently approved version of the label. The process of incorporating changes and obtaining approvals may arise from various sources, including new clinical findings, safety updates, or evolving regulatory requirements. As multiple changes sprout simultaneously, each change demands its own pathway for assessment, approval, and integration. Consequently, these parallel modifications often await validation before they can be merged with other information, thereby reflecting the intricate challenge of managing multifaceted adjustments on a single label.

Addressing these challenges requires innovative solutions and technologies that can streamline processes, automate data retrieval and analysis, and ensure consistent and accurate translations across different languages and regions.

Innovative technologies to address label change process challenges

Emerging technologies such as Machine Learning, Natural Language Processing, Robotics Process Automation, Generative AI, and Structured Component Content Management & Authoring offer promising solutions to enhance the efficiency and effectiveness of the label change process. These technologies bring automation to various tasks, data extraction from text, multilingual label translations, and the creation of new labels based on existing templates or data.

NLP for regulatory labeling automation

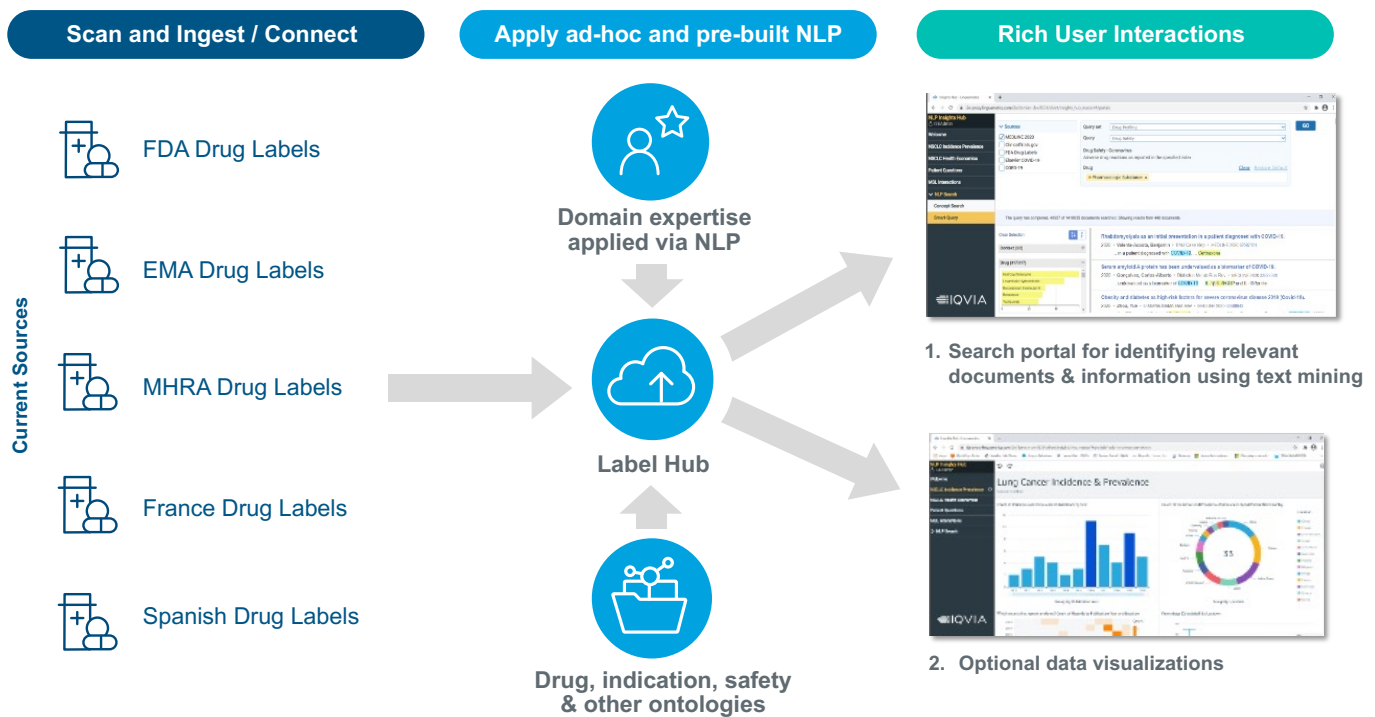### REGULATORY INFORMATION AGGREGATION (RIA)

NLP technology focuses on enabling machines to understand, interpret, and generate human language in a meaningful and contextually relevant way. Leveraging NLP, Regulatory Intelligence tools provide rapid access to current regulations, regulatory insights, and updates from national authorities worldwide. This enables organizations to avoid the resource-intensive process of manually gathering and organizing regulatory information. The benefits include reduced risk of non-compliance, increased efficiency, and improved decision-making. Combined with access to labels for Human Drugs, Biologics, Medical Devices, and IVDs — and the ability to compare requirements across countries and regions — the technology offers substantive insights. Additionally, the tool can access local expert insights through expert summaries.

LABELING REGULATORY INTELLIGENCE

Apart from gathering regulatory guidelines and requirements, NLP technology is instrumental in developing labeling intelligence tools to facilitate the comparison of internal and external labels. The ability to compare the drug label change information is essential in reference to response to similar changes internally and externally. Traditionally, this has been a challenging manual process involving searching for reference information from multiple sources like the FDA and EMA. However, NLP tools can provide a platform that simplifies searching for competitor comparative label changes.

The dynamic nature of drug labeling, with hundreds of new or updated labels published weekly across regions, necessitates sifting through diverse data sources and languages. By leveraging NLP for searching documents from multiple sources and comparing external and internal labels, labeling teams can save time and effort in finding and extracting drug-label information. NLP enhances analysis, enabling teams to extract maximum

Figure 2: Labeling Regulatory Intelligence Overview

| Scan and Ingest / Connect | Apply ad-hoc and pre-built NLP | Rich User Interactions |

Current Sources
- FDA Drug Labels
- EMA Drug Labels
- MHRA Drug Labels
- France Drug Labels
- Spanish Drug Labels

Domain expertise applied via NLP

Label Hub

Drug, indication, safety & other ontologies

1. Search portal for identifying relevant documents & information using text mining

2. Optional data visualizations

value from each label, expediting the process, and ensuring greater accuracy. The solution allows teams to build label searches or deploy pre-built searches to optimize label writing and analytics, culminating in more accurate information during the assessment stage, leading to well-informed decisions in response to proposed changes.

LABEL TRANSLATION AUTOMATION

AI/ML is a powerful suite of technologies that are used to improve the accuracy and efficiency of Document Translation Automation (DTA). This automated approach identifies patterns in translated documents, swiftly converting vast volumes of content from one language to another. By leveraging AI/ML for label translation, pharmaceutical companies can realize significant time and cost savings while ensuring consistent and reliable translations across multiple languages. Labels, as critical components of products, convey crucial information about ingredients, usage, and safety. The translation

of labels, which traditionally proved laborious and expensive, now becomes an automated endeavor with AI/ML at the helm. Identifying patterns in translated labels, such as common grammar errors or translation mistakes, AI enables ML models to learn and avoid repetitive errors. Human translators complement this automation by reviewing and refining translations, ensuring the utmost precision and contextual relevance.

The advent of Document Translation Automation presents a multitude of advantages, including:

- **Swift and Efficient Translation:** Embracing DTA enables rapid and efficient translation of extensive document volumes, unlocking valuable time and resources for biopharmaceutical companies.

- **Cost Reduction:** Automation of the translation process significantly reduces expenses, optimizing budget management and cost-effectiveness.

- **Enhanced Translation Consistency:** By automating translations, businesses achieve heightened consistency in content across languages, bolstering brand coherence and minimizing potential misunderstandings.

- **Expanded Language Reach:** Leveraging DTA widens the scope for businesses to reach diverse global audiences by making content accessible in a multitude of languages.

As global markets expand, the demand for translated content surges, driving the swift growth of Document Translation Automation. However, it is crucial to acknowledge the indispensable role of human expertise. Human translators play a pivotal role in delivering top-notch translations, especially for intricate or technical documents, where context and nuance hold paramount importance. Thus, a successful approach strikes a harmonious balance between automation technology and human proficiency, yielding the best possible translation outcomes.

GENERATIVE AI & RPA FOR ARTWORK AUTOMATION

In the realm of biopharmaceutical products, artwork assumes a paramount role as it stands as the primary interface with consumers, directly impacting patient safety. However, the current artwork creation process faces challenges that call for improvement. Key objectives revolve around enhancing efficiency, streamlining processes, and mitigating potential sources of errors during content transfer. Artwork plays a pivotal role in generating packaging, healthcare provider materials, and consumer communication which in turn play a critical role in educating patients and ensuring their well-being.

Efficiently achieving compliance entails focusing on the real-time processing of artwork output aligned with real-world needs. The foremost consideration guiding artwork creation revolves around ensuring easy access, comprehension, and usability of the latest approved

content in the artwork. Ultimately, patient safety remains at the heart of these endeavors. Consistent and up-to-date artwork effectively mitigates safety issues during patient consumption. Embracing technology to automate the generation of artwork for label packaging and marketing materials proves invaluable. Artwork automation not only enhances efficiency but also aligns with patient safety considerations. Generative AI and Robotic Process Automation (RPA) emerge as potent allies in automating the artwork creation process. Generative AI, a form of artificial intelligence, harnesses existing content and data to generate new outputs, such as images, text, or music. Complementing this, RPA empowers the creation of computer programs that interact with applications and systems like a human user. This powerful combination facilitates various purposes, such as producing label packaging and marketing materials quickly and efficiently, reducing time and cost overheads, ensuring artwork consistency, meeting regulatory requirements, and automating the approval process for artwork.

Secondly, artwork must also be guided from the perspective of the resource creating the artwork, where we aim to minimize errors, reduce efforts,

and eliminate unnecessary complexities. Adopting a structured component content management approach over a document-centric one can significantly aid in the artwork process.

Minimizing errors, reducing efforts, and eliminating complexities form pivotal goals from the perspective of those involved in artwork creation. Embracing a structured component content management approach over a document-centric one significantly aids in the artwork process.

STRUCTURED COMPONENT CONTENT MANAGEMENT & AUTHORING (SCCA)

Structured Component Content Management & Authoring (SCCA) revolutionizes content creation and management with its structured and modular approach. This method enables content to be reused, repurposed, assembled, and rendered for multiple endpoints seamlessly.

SCCA empowers authors to efficiently create, develop, and manage core and local label content while organizing and maintaining large volumes of content alongside complex relationships. Components are meticulously identified, tracked, and version controlled, maintaining their metadata, including contextual re-use permissions, target audience specifications, and localization variants.

Core and local label components are created format-free as reusable text, tables, and image assets, seamlessly compiled into "structured assemblies," resembling classic unformatted documents for authors, offering a granular level of control and visibility. These assemblies can be rendered into different formats, catering to various consuming channels, such as submission to local health authorities, electronic patient information (ePI) portals, or within the packaging artwork supply chain.

Automation plays a crucial role in the SCCA process, facilitating the creation of template assemblies and

components. By leveraging AI/NLP, local labels and translations are generated based on approved core label content, efficiently producing draft local labels.

Innovative AI/NLP algorithms effectively componentize unstructured documents and re-assemble classified components as structured "digital twins" of the source label. During the intake process, legacy label documents are broken down into components, enabling streamlined tracking of changes, updates, versions, and content repurposing through branching from go-live.

The culmination of these efforts culminates in the creation of an intelligent component management repository, playing a pivotal role in realizing structured and component-based authoring at a scalable level. SCCA heralds a transformative approach to content creation, streamlining workflows and empowering biopharmaceutical companies to embrace efficiency, consistency, and compliance.

Conclusion

As with many areas in clinical research and biopharmaceutical commercialization, the industry is increasingly turning to innovative AI/ML technologies to enhance the efficiency and effectiveness of the label change process. These cutting-edge technologies, when combined with human expertise, create a powerful synergy that streamlines tasks and allows professionals to work smarter and more strategically. AI and ML-driven solutions, such as Natural Language Processing (NLP) for regulatory labeling automation and Document Translation Automation (DTA), offer rapid and accurate data extraction, multilingual translations, and improved content consistency. Additionally, Generative AI and Robotics Process Automation (RPA) can help streamline artwork creation, ensuring up-to-date and compliant patient communication.

The key takeaway is that these technologies are enablers, not replacements, for human involvement in the labeling process. By automating repetitive and time-consuming tasks, AI/ML liberates resources, allowing professionals to concentrate on strategic planning, regulatory compliance, and, ultimately, improving patient outcomes. By leveraging automation to handle intricate tasks, biopharmaceutical companies can focus on delivering impactful medications to patients worldwide. As the industry continues to embrace these technological advancements, it is paving the way for a more efficient, effective, and patient-centric future in drug labeling.

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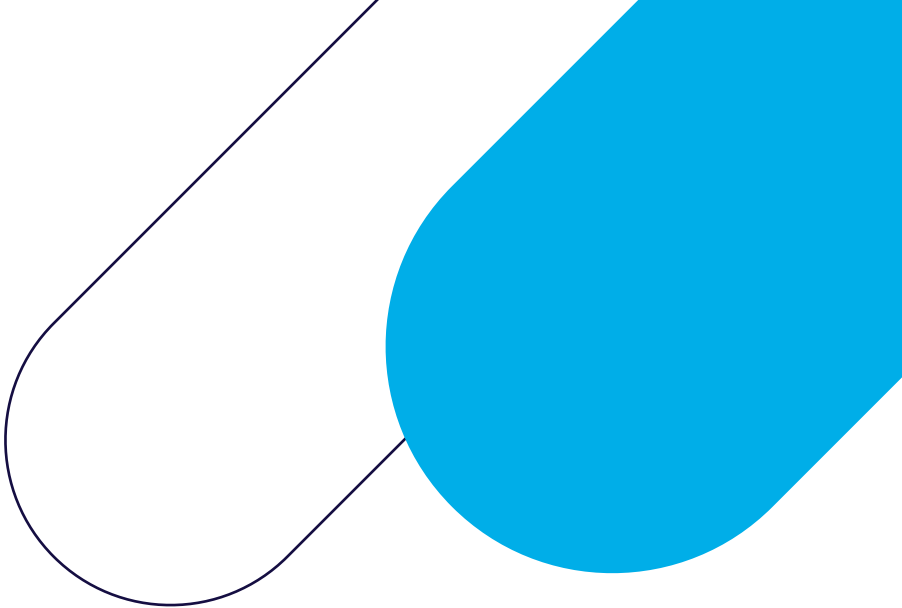MS in Project Management from Drexel University.

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