

WHITEPAPER

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# Driving Compliance and Efficiency for End-to-End Drug Product Labeling



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Managing drug product labeling remains a challenge for many life science companies. Quickly updating product labels in all affected markets in response to new data (safety and non-safety), required changes by regulations, and other factors is critical and demanding, particularly for companies with global operations. The task is further complicated by reliance on poorly integrated legacy systems and fragmented manual processes that make it hard to map and manage content interdependencies. A new, better approach to drug product labeling is needed.

Life science companies need to manage and track global and regional data across the product labeling life cycle. Typically, life science companies facilitate those activities by establishing a Company Core Data Sheet (CCDS) that serves as the product's master label. The CCDS includes the drug's efficacy and minimal safety characteristics and serves as the internal reference for the product information. As a drug candidate moves through development, cross-functional teams continually update the Development Core Data Sheet (DCDS)/CCDS with new data, including but not limited to toxicology data, CMC, and clinical and safety information. The process continues after a product comes to market and new data is collected.

When a safety signal is spotted, companies gather and present the data needed to assess whether the CCDS needs to be updated, and if so, they should make the necessary revisions. The process requires cross-functional collaboration.





Regional Product Information (RPI), the labeling associated with a product in each market, is typically driven by the CCDS (or other reference labels, if applicable). Changes to the CCDS that are relevant to the respective regions/countries will drive updates to the RPI in that respective market, necessitating internal review and approval as well as submission to the health authority. Equally, the health authority requirements can trigger changes to the RPI that force companies to update the local labels and evaluate the impact on the CCDS.

Multiple teams are involved in the labeling governance process. The executive labeling committee liaises with the labeling team, which in turn interacts with the country-specific labeling representatives. These teams need effective tracking and reporting tools to keep labeling information aligned and compliant. Today, the industry lacks sufficient tools to ensure labelling compliance.

## Why labeling-specific systems matter

Keeping all information about a product up-to-date in all markets is a daunting challenge. A labeling system needs to align a CCDS with each respective local label that leveraged the CCDS as a source label, such as by ensuring a specific version of the USPI is aligned with the appropriate and respective version of the CCDS. This challenge is further complicated after factoring in the number of countries/regions in which the product is marketed, requiring even more tracking and reporting of local labels to the CCDS.

The task of tracking the CCDS versions to local labels across various markets becomes more challenging when content varies from one regional label to the next. The complexity created by such divergences is compounded by the need to track content from one document to content of another document.

Labeling functions within life science companies are still continuing to use legacy document management systems that do not support content tracking across documents or even the ability to track multiple versions and branches from one document to the next. In many cases, labeling functions are resorting to using Excel-based tools or homegrown solutions for basic tracking and reporting, which doesn't do justice to the level of detail and compliance requirements needed. Furthermore, these "band-aid" solutions prevent streamlined operations between global and regional teams.



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Life science companies not only need to have visibility to the latest approved version of a product label in each market, but they also need to know the history of that label and how it evolved over time with revision of statements to address new data or to comply with regional regulations. The traceability of content history requires the consistent tracking of decisions and history of changes from one version of the label to the next.

Inconsistencies and errors occur when labeling teams are burdened with using document management systems that are not designed to specifically support the labeling process and cannot efficiently manage data and information standards across the regional or global labeling life cycle. Reliance on manual processes exacerbates the situation by raising the risk of human error. Manual processes also force life science companies to hire and retain resources to manage such tedious tasks. The outcome is a labeling operation function that is inefficient with a high risk of non-compliance.

The inefficiencies addressed above have resulted in many complications, including but not limited to:

- Failure or delay in the submission of safety variations required to update the safety sections within the label
- Superseded versions of documents still being live on a marketing authorization holder's website
- Missing clinically important safety information such as contraindications and special warnings
- Failure to maintain the authorized product information in all regions through submission of an appropriate variation application
- Deficiency letters issued in response to submissions for approval of non-compliant labels

Health authorities take label non-compliance very seriously because it can threaten patient safety or provide a healthcare professional inaccurate information about the product's efficacy and safety. An error on a label can also reduce public confidence in the drug manufacturer or the product itself.

## How DirectusPRO improves labeling operations

Red Nucleus's DirectusPRO labeling management, tracking, and reporting solution is uniquely designed to address the life science



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industry's labeling challenges. It is the only process-driven labeling management system that provides unmatched functionality in comparison to other products that claim to be able to support labeling management. With DirectusPRO, life science companies can ensure the consistency and compliance of their labeling operations while eliminating inefficiencies.

DirectusPRO is creatively designed to be a game-changing solution in the industry, addressing many functionalities that currently don't exist in other systems today, some of which are provided below:

- **Safety signal management**

- o Allows the user to log and track signals by recording the information, including Signal Description and ID, the Signal Source, the Recorded Date, the Review Date, the Signal Type, the Confirmed Date, whether the signal is Global or Regional, the Change Type, and any additional attached documentation
- o The signal can be tracked using its specific ID, which is tracked from identification and confirmation through the label life cycle and implementation

- **Enables operational excellence by ensuring information flows efficiently from the source document, such as the CCDS, to all local labels**

- o Simplifies the management of global labeling operations
- o When a labeling update is required, the change from the CCDS is disseminated to the regions, who may or may not adopt the change (depending on its applicability in that respective region); in either case, the system is able to track that decision

- **Collaborative structured content authoring and management**

- o Enables multiple authors to author a document at the same time with ready-to-use templates
- o Enables content tracking, reporting, and streamlining operations, including pull and reuse of content
- o Facilitates the automated collection, extraction, and consolidation of data for filings and other needs
  - For example, labels contain up to 70% of the data and information needed for European pharmacovigilance



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report submissions and regulatory filings that follow the Identification of Medicinal Products (IDMP) standards

- However, the information remains inaccessible unless product labels are developed in a structured content authoring platform
- Extracting data from non-structured labels is very challenging and time-consuming; DirectusPRO automates the process to equip companies to populate pharmacovigilance and IDMP filings quickly

- **MS Word-like document editor with an XML backbone and editing functionality**

- o Complemented by redlined and annotated label management capabilities

- **Labeling history and health authority correspondence management**

- o Easily see the full history of a label, along with the correspondence to/from the health authorities and the summary of the changes made throughout the labeling life cycle
- o The summary and history of changes are always linked to the associated label and other supporting information

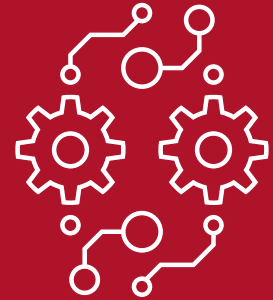
- **Tracking and monitoring of labeling compliance**

- o From the source document to all the local labels and the various simultaneous labeling updates that may occur for a particular product

- **Comparison and alignment across labels and versions of labels**

- **Notifications and reminders to all stakeholders involved in the labeling process**

- o Coupled with visual cues and reminders, these notifications keep everyone involved in a project up-to-date and ensure key stakeholders know when their input is needed
- o Tracking activity against assigned action items and due dates and automatically resending prompts to those who are behind on certain actions
- o Ensures communication between global and regional teams is transparent with efficient follow-up where needed



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- **Automated naming and version convention**

- o Eliminating manual entries that result in significant variations from stakeholder to stakeholder that result in challenges to find and access information
- o Unique versioning allows easy management of simultaneous variation of local labels, which is currently very cumbersome to track and manage in industry-wide document management systems

- **Fully developed document repository with an intuitive user interface and context indexing capabilities**

- o Enables users to quickly find and access the information they need

- **Open APIs**

- o Enables integrations with other systems such as Registration Tracking solutions and Artwork systems to complete an end-to-end solution

- **21 CFR Part 11 compliance**

- o Designed to enable a full audit trail with reporting capabilities

## Accessing the benefits of DirectusPRO

Life science companies that implement or employ DirectusPRO realize a range of benefits, from efficiency gains to the mitigation of significant regulatory risks to their business. A key part of being compliant is being able to report that you are compliant, and DirectusPRO simplifies that task through its broad range of functionality, including but not limited to its tracking and reporting capabilities. Ultimately, the system enables labeling teams to consistently fulfill their primary function: ensuring the labeling is always up-to-date for patient safety.

Red Nucleus provides DirectusPRO as part of a suite of life sciences system, process, and learning solutions developed and supported by its more than 400 full-time employees. Life science companies that partner with Red Nucleus get the support of a team dedicated to creativity, quality, flexibility, and on-time delivery, equipping them to thrive today and as their labeling needs continue to evolve in the future. ■



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Red Nucleus is the premier provider of learning, performance, and process solutions for the life sciences industry. We work exclusively within the life sciences industry to ensure our team intimately understands your business, products, processes, and challenges. Our team is composed of more than 400 full-time employees whose commitment to creativity, quality, and on-time delivery is unrivaled in our space.

For more information, please visit <https://www.rednucleus.com>