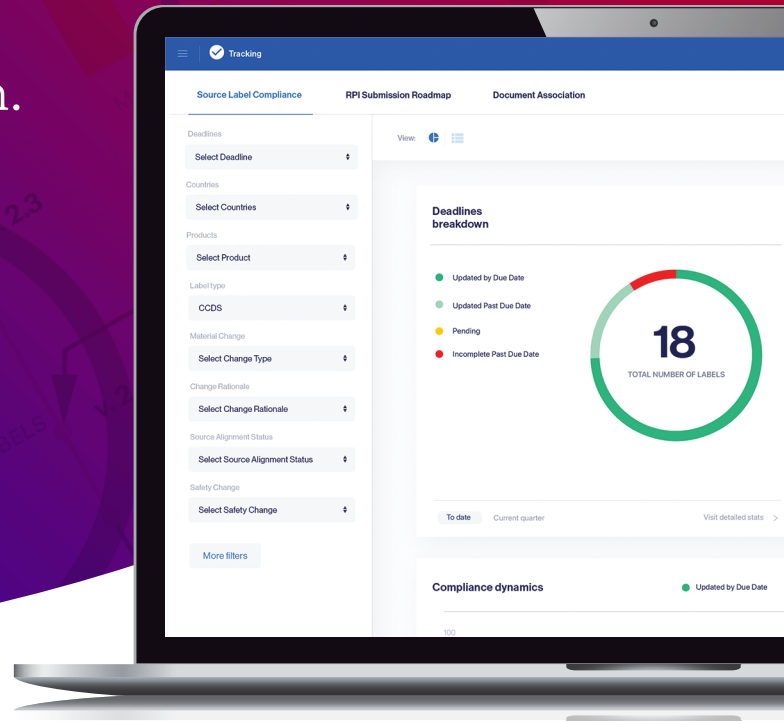


# DirectusPRO

A unique label management, tracking, and reporting solution.

The only comprehensive global labeling system that addresses the market gap in providing a system that can effectively and efficiently enable a global end-to-end labeling process.



## Drive Operational Excellence

Ensuring efficient information flow from source label (CCDS or other) to local labels and across all local labels

## Stay Compliant

Ensuring consistent scientific, medical, and administrative information across all labels globally

## Streamline Tracking and Reporting

Ensuring traceability of historic changes globally at the content level (not only at the document level)



SAFETY  
SIGNAL LOG



DCDS & CCDS  
MANAGEMENT



RPI  
MANAGEMENT



TRACKING



PROOF  
READING



COMPARISON



USER  
MANAGEMENT



DOCUMENTS  
LIBRARY



INBOX



★ **FEATURED FUNCTIONALITY**

## Label Comparison and Alignment

The ability to compare labels and manage content from version to version or label to label

★ **FEATURED FUNCTIONALITY**

## Management of Simultaneous Labels in Review

The ability to track and manage simultaneous label updates, ensuring compliance with the latest approved version

★ **FEATURED FUNCTIONALITY**

## Track and Monitor Label Compliance

The ability to track and monitor label compliance from source label to local labels

# DirectusPRO



### CORE FUNCTIONALITY

- Structured content authoring
- MS Word-like document editor with an XML-like backbone
- SPL conversion
- Structured document templates
- Redlined and annotated label management
- Label history and health authority correspondence management
- Management of label summary of changes and label dissemination
- Document content indexing and search
- Automated naming and versioning convention (no manual entries)
- Configurable workflows
- Searchable document repository
- Single-view/click document associations
- Intuitive user interface and experience
- Notifications within system and to external emails
- Visual cues and reminders



### INFORMATION MANAGEMENT

- Core data sheet
- Regional product information
- Drug listing
- Labeler code
- Establishment
- Translations



### TRACKING AND REPORTING

- Core data sheet dissemination and actions
- Regional product information dissemination and actions
- Regional product information health authority submissions and interactions
- Compliance of label to both source label and to supporting information
- Workflow status (including internal and health authority approvals)
- Simultaneous variations and versioning



### TECHNICAL CONSIDERATIONS

- Robust configurable access and permissions
- Validated
- Client audited
- API-enabled integrations (SSO and other systems)
- Dedicated virtual private cloud
- Complete data isolation for tenants
- 21 CFR Part 11 compliance
- Audit trail
- Encrypted data at rest and in-transit



#### ABOUT RED NUCLEUS

Red Nucleus is the premier provider of system, process, and learning 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 450+ global full-time employees whose commitment to creativity, quality, and on-time delivery is unrivaled in our space.

LEARN MORE AT → [REDNUCLEUS.COM](https://rednucleus.com)