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LIFE SCIENCES SUITE

Enhancing Labeling Management

Reduce risk, improve efficiency, and enable end-to-end management with a standardized and connected approach to Labeling.

Failure to respond quickly to changing product information or market requirements can result in delays to market or rejected product registrations, resulting in an impact on sales, revenues and market profile as well as posing an unnecessary risk to patients. That's why an effective approach to labelling is critically important.

However, more often than not, label status tracking still happens in spreadsheets or home-grown systems, with content updated on a country-by-country basis using isolated labeling solutions embedded into disintegrated processes. These are rarely connected to companies' registration and submission planning and management tools, preventing a clear line of sight and management capability across all labeling activities.

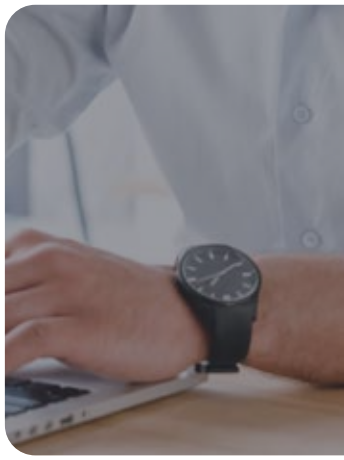
That's why Amplexor has developed LabelExpert™, an end-to-end labeling management solution, which addresses change process and activities, such as the assessment, revision, approval, tracking and implementation of labeling changes. Amplexor also offers best-in-class after sales service, as well as strong domain expertise, to guarantee successful deployments and operations.

Amplexor LabelExpert™ delivers:

- Labeling Process Management: support of local and global labeling processes, change management and compliance tracking.
- Labeling Content Management: support of local and global/ core labels/product information, including translations.
- Automated notifications to process stakeholders and powerful search capabilities.
- Workflow automations (process triggers, cross-references and data exchange) with backend or frontend processes, departments and systems (i.e. Regulatory, Safety, and Manufacturing).
- Labeling deviation and dependency management.
- Interactive Labeling Management dashboards for actionable insights and easy access to key information.
- Seamless process and data connectivity with regulatory submission planning and tracking activities to connect labeling management with regulatory variation management.

It equips businesses with the tools to:

- Record an event which triggered a label change.
- Manage label change requests and related label changes.
- Track all information related to a label change request and label change by placing all data and documents in one place.
- Notify stakeholders involved in the end-to-end process.
- Manage labeling content in one place.
- Control labeling change management activities.
- Collaborate on global and local levels.
- Trigger and connect to regulatory actions, from impact assessment to variation approval.



LabelExpert™ enables users to oversee and govern labeling changes, while increasing inspection readiness and supporting regulatory requirements through a validated solution. It also increases operational efficiency through a consistent and user-friendly enterprise collaborative environment regardless of the user's physical location.

This means companies can harmonize and standardize labeling management processes; achieve control of the labeling process to minimize the risks of regulatory non-compliance; reduce rework and facilitate reporting in the labeling area to minimize efforts and increase productivity; and manage, reuse and control labeling data and documents throughout their entire life cycle.

LabelExpert™ operates as part of Amplexor's wider RIM suite, which encompasses:

Product Information Management

ProductExpert™ addresses the planning, collection, management and submission of structured product data throughout the submission lifecycle, post-submission, and post-approval, following the IDMP target operating model according to stringent compliance and quality standards. Product information management is a seamless part of the end-to-end RIM experience.

Regulatory Planning & Tracking

RIMExpert™ is a powerful planning, tracking and reporting solution designed to standardize the data management process across your entire company. It provides a new, intuitive compliance structure with no double data entry, no extra effort and no time wasted, enabling a clearer picture for planning and scheduling, while seamlessly connecting to IDMP, eCTD and EDMS solutions for faster time to market.

Regulatory Content Management

R&DExpert™ promotes cross-functional collaboration and establishes a single authoritative document asset repository, covering all document management functionalities, including template management, collaborative editing, annotations and hyperlinking, flexible workflows, electronic signature and audit trail, advanced rendering, compound documents and role based security.

Submission Management & Publishing

SubmissionExpert™ consolidates submission management and publishing capabilities within one unique solution. It covers regulatory intelligence and product information driven global and local submission content planning, submission pre-validation and publishing according to regional standards in eCTD, NeeS, PDF or EAEU format as well as versatile submission archive.

Life Sciences Analytics

RIMAnalytics™, ProductAnalytics™, SubmissionAnalytics™ and **LabelAnalytics™** consist of a preconfigured set of standard dashboards and reports as well as self-service analytics, meeting business tracking, reporting and analytical needs.

LabelExpert™ provides a user-friendly Labeling Management interface, combining both search and browsing functionalities as well as inbox capabilities for overview and processing of user's tasks alongside the business processes.

Please get in touch to find out more or visit us online.

solutions@amplexor.com → **amplexorlifesciences.com/rim/labeling-management**

ABOUT AMPLEXOR LIFE SCIENCES

Amplexor Life Sciences is a global provider of regulatory, quality and safety software solutions, serving and trusted by pharmaceutical, biotechnology and medical device companies for over 25 years. Its holistic Life Sciences Suite solution helps life sciences organizations to be efficient with launching products and breaking into new markets quickly while ensuring quality, efficiacy and safety through end-to-end support to product lifecycle processes, data and content management.

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