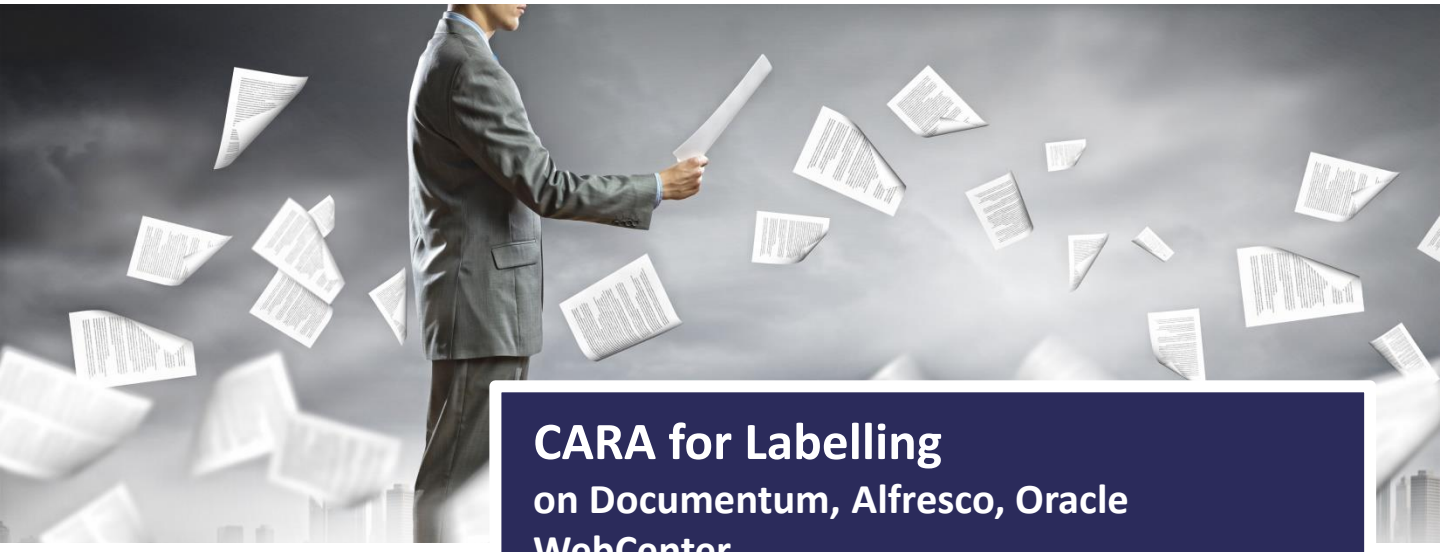
cara



CARA for Labelling

on Documentum, Alfresco, Oracle WebCenter

Structured authoring

Author individual components that are collated to single labels

Submission and production integration

Seamlessly integrate the label documents with both labelling production systems and submission systems

Master Data Management

MDM

Integrate seamlessly with a variety of master data management systems (product information) or manage it in CARA

Where Used

Easily track and trace where each version of each label has been submitted and approved during which date period

Translations

A→α

Manage translations of labels including providing a portal access via CARA to translation companies

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Labelling made simple

Managing Labelling documentation is a complex matter for Life Sciences companies, given not only the variety of the documents (Core Data Sheets through to individual labels for different dosage forms, strengths and markets), but also the need for managing translations, regulatory affairs interactions internally and with authorities, the changing industry regulations for such content, and the need to interact with Product Supply and integrate feedback loops from new safety / efficacy data and regulatory directives. CARA allows this complexity to be handled in a secure and simple way.

Authoring

- Create your content inside Documentum using CARA – fully configurable next generation UI
- Author in small components (paragraphs, sentences) and build a complete document from the these
- Reuse components across documents (from Core Data Sheet to Labels, PI etc)

Regulatory Affairs

- Integrate labelling documents into submissions
- Build labelling documents using data from other disciplines e.g. Clinical, ensuring that updates in the source data flags the requirement to update labelling documentation
- Easily track which versions of which components or compiled labelling documents were submitted where, when, and whether a regulatory change request must be reflected in other markets
- Push labelling information through to Product Supply and artwork production
- Output files in format required by different regulatory authorities

Submit, track, update

- Update information in CARA on Health Authority approval status – seamless integration with registration tracking
- Understand how an update required on one piece of labelling information has to flow to other label documents for other dosages, markets and translations
- CARA Dashboards allow reporting across documents, products, markets

Use Cases

Top 3 global Life Science company using CARA to create and manage labelling content, translations and updates

Global Top 10 Life Science company using CARA in Regulatory Affairs for labelling authoring and submissions

Major global Biotech company using CARA for managing the updates of labelling after safety / efficacy updates

Major Life Science company using CARA to track "where approved" on labels in global markets / health authorities

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Contact us for a demo or evaluation