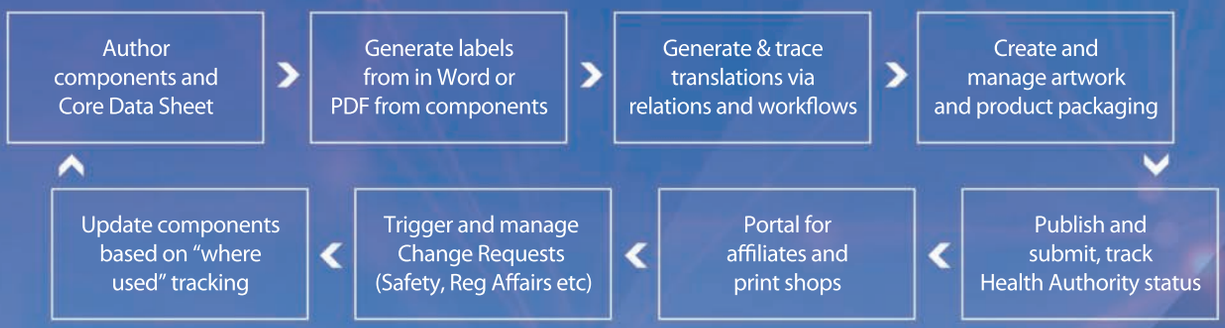
Pharmaceutical Labeling

How CARA can provide the full end to end lifecycle of a label and associated content



Structured content authoring

Manage labelling content in components (content or meta-data) and generate Word or PDF from the components with where-used traceability

Production/packaging management

Manage packaging processes includ-ing print shop portal (FTP) through CARA, including Change Requests and CAPA (using CARA or through integrations)

Master Data Management

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 ver-sion of each label has been created from, submitted and approved during which date period

Translations

Automatic generation of related translations including options to trigger workflow to external translation agencies via a portal or use AI translations

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 on Health Authority approval status – including integration with registration tracking
- Trace where labels are generated from, and impact of changes to e.g. CCDS
- CARA Dashboards allow reporting across documents, products, markets
- Manage packaging including the Change Request process in CARA or via integrations

Use Cases

Top 3 global Life Science company using CARA to create and manage labellingcontent, 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.