CARA AI for Regulatory

Natively integrated into the CARA Life Sciences Platform, CARA AI understands regulatory intent rather than relying on simple keyword matching. It continuously connects content across submissions, markets, and domains, turning regulatory information into a single, traceable lifecycle asset.

By automatically linking related activities and identifying cross-domain impacts, such as manufacturing or stability changes, CARA AI helps Regulatory teams detect required variations and lifecycle updates earlier, supporting continuous compliance with greater confidence.

The result? Proactive lifecycle management, faster submissions, and more confident Health Authority interactions. Your regulatory content becomes a strategic asset that keeps your organisation globally aligned and inspection-ready.

Operational result

70% reduction in authoring time for module 2 summary documents

Operational result

Faster submissions, fewer rework cycles, and continuous global alignment across the regulatory lifecycle.

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The Intelligence Layer You've Been Missing

Understand Meaning, Not Just Keywords
Search "hepatic impairment" and actually find "liver dysfunction." CARA understands regulatory synonyms and context, no more missed content because someone worded it differently.

Monitor Intelligence Automatically
CARA reads regulatory updates so you don't have to. Flags what's relevant to your portfolio and tells you what it means for your submissions.

Map Dependencies Automatically
This variation affects those three filings, CARA maps the relationships for you. Detects when scientific meaning changes between versions and shows the web of dependencies.

Extract Data from Documents
No more copy-pasting substance names and dosages from PDFs. CARA extracts structured data and populates your RIM system automatically.

Compare Markets in Seconds
Does the German label match the UK version? CARA compares labels across countries and languages, showing you differences in wording and intent instantly.

Enforce Controlled Terminology
Wrong MedDRA term in 12 documents? CARA applies controlled vocabularies automatically and catches inconsistencies before they become xEVMPD problems.

Alert on Cross-Domain Changes
Quality updated manufacturing last week? CARA alerts you when changes in other departments create regulatory impacts, before you miss a deadline.

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Operational ROI for Regulatory Teams

Summarise

When You Need Clarity Fast

- Someone needs a Module 2 summary in 2 hours

CARA AI: Generates regulatory summaries automatically. Assesses literature impact. Consolidates history across variations and labels. Decision-ready insight, not manual synthesis.

Predict

When You Need to Stay Ahead

- "When will we hear back from EMA?" You have no idea. Neither does anyone else
- You have 10 years of legacy documents. IDMP compliance is coming. Good luck

CARA AI: Identifies related changes and required activities before you miss them. Predicts review timelines and likely queries. Extracts IDMP attributes from legacy docs. You're proactive, not reactive.

Translate

When You Need to Go Global

- Japan wants it in Japanese. EMA wants British English. FDA wants American English

CARA AI: Adapts eCTD content to regional requirements, translates with regulatory intelligence, enforces controlled terminology. You go global without losing accuracy.

Compare

When Markets Drift Apart

- You updated wording in one market 6 months ago. Did the others follow?
- Health Authorities are asking overlapping questions. Are your answers consistent?

CARA AI: Compares labels and submissions across all markets. Highlights meaning changes, catches contradictions, tracks what's approved vs. what's submitted. No more market drift.

Generate

When You're Writing. Again.

- Quality changed the manufacturing process. You need a variation narrative. From scratch
- Renewal time. Time to populate the same dossier template. Again

CARA AI: Creates variation narratives from QMS/CMC data. Auto-populates renewals. Drafts responses using prior submissions. Built-in consistency. Built-in traceability. Built-in speed.

Ready to Stop Firefighting?

Your team is brilliant. Imagine what they could do if they weren't buried in document and data manual cross-checks. Let's talk about what regulatory could look like when intelligence works for you.

REQUEST A DEMONSTRATION

There’s a better way, and it starts with CARA

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