



CARA AI

Trust. Control. Confidence.

CARA AI is the most secure, compliance-first AI solution for regulated content in the life sciences industry.

Natively built into the unified CARA Life Sciences Platform, it governs every document and data point, ensuring full auditability and enterprise-grade privacy while delivering AI-driven productivity.

Because the AI operates inside the platform itself, every action remains accurate, traceable, and compliant by design.



Delivers measurable ROI across regulatory, quality, safety, and clinical functions, **reducing manual effort by over 90%.**



Validated for Life Sciences

Proven across , regulatory, quality, CLinical and safety environments.



Traceability & Auditability

Every AI-generated output includes source trace links and a full audit log.



Massive Time & Cost Savings

Automate complex workflows, reducing weeks of work to seconds. across RIM, Quality, Safety and Clinical.



Built-in Security & Privacy

Fully secure, compliant AI that meets GxP, FDA, EMA, ISO, and data residency requirements.



Flexible Intelligence

Choose or combine LLMs, with governance and configuration handled inside CARA.



Finding the Right Info, Fast

Searching through countless documents, CARA's AI understands context, not just keywords, ensuring faster and more accurate document retrieval across sectors.

CORE AI Capabilities



Labeling comparison

Compare product labels across languages to identify compliance gaps (e.g., Japan, EU, US).



Medical Inquiries & Complaints

Ingest and analyse end-customer inquiries, generating contextual draft responses.



Generate Submission Documents from Data

Create eCTD-format documents (Module 2/3) from structured data.



Regulatory Intelligence Applicability

Parse global updates and assess their impact on your portfolio.



Health Authority Q&A

Auto-analyse and draft responses to regulatory questions by functional area.



PSMF Annexes & Log Book

Automatically generate and update PSMF Annexes and change logs for submissions.



SOP's

Detect and summarise SOP version changes, generating local variants from global masters.



Literature Surveillance

Scan literature to extract relevant insights and product indications.

Use Case Time Savings



USE CASE

Without AI

With CARA AI

Labeling Comparison

1–2 days manual comparison

1 minute automated analysis

Health Authority QA

2–5 days drafting

5–20 minutes

Medical Inquiries & Complaints

1–2 days per query

5–20 minutes

PSMF Annexes & Log Book

1–2 days manual update

1–2 days manual update

Submission Docs from Data

50–1000 hours expert time

1 minute auto-generation

Submission Readiness

Submission Readiness

1–3 minutes

Submission Docs from Data

1–2 hours

1 minute

SubmissionRegulatory
Intelligence ApplicabilityDocs
from Data

1–2 days

5–10 minutes

Literature Surveillance

1–2 days

5–10 minutes

CARA AI

Trust. Control. Confidence.

CARA's AI layer is engineered for trust, combining embedded security, governed LLM access, and full traceability to ensure data is never compromised and always compliant.

In life sciences, every decision depends on trust, trust in data, in process, and in compliance. CARA AI safeguards that trust by embedding intelligence within the same secure, governed platform used for your most critical content & data.

The result:

Automation that
accelerates outcomes
without ever
compromising control.



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

sales@generiscorp.com



Copyright © 2025 Generis Enterprise Technology Limited, all rights reserved

www.caralifesciences.generiscorp.com