

PHARMACEUTICALS

From safety signal to submission: regulatory variation management for a global pharma company

A single safety-committee recommendation can ripple into label changes, variation filings across markets, country affiliates, packs and submission evidence. Wexa modelled the whole regulatory chain in a context graph and built an agent that computes the blast radius and routes every change to the right signer.

17

impacted objects found across 4 hops

~1M

packs in the supply chain reached by the change

5 of 9

submission artefacts ready; the blocker identified

6 / 0

human signature gates / autonomous executions

CLIENT

Global pharmaceutical company
(regulatory and medical affairs)

REGION

EU / US

WHEN

2026

ENGAGEMENT

Solution build

WEXA COMPONENTS

Wexa · regulatory ontology · context graph · routing agent · human signature

The challenge

- Safety signals, labels, marketing authorisations and supply data sit in separate systems
- Impact assessment is manual and slow
- Every regulatory action needs a named human signature

What Wexa built

- ✓ Ontology: product, marketing authorisation, country, health authority, core data sheet, label section, safety signal, case, change event, submission, label change
- ✓ Blast-radius analysis from a safety signal to labels, filings, affiliates and packs in the supply chain
- ✓ Evidence readiness check across the submission dossier
- ✓ Routing agent proposing the variation route per market; it rejected a fast-track route when the wording went beyond the committee's core text

How it runs on Wexa

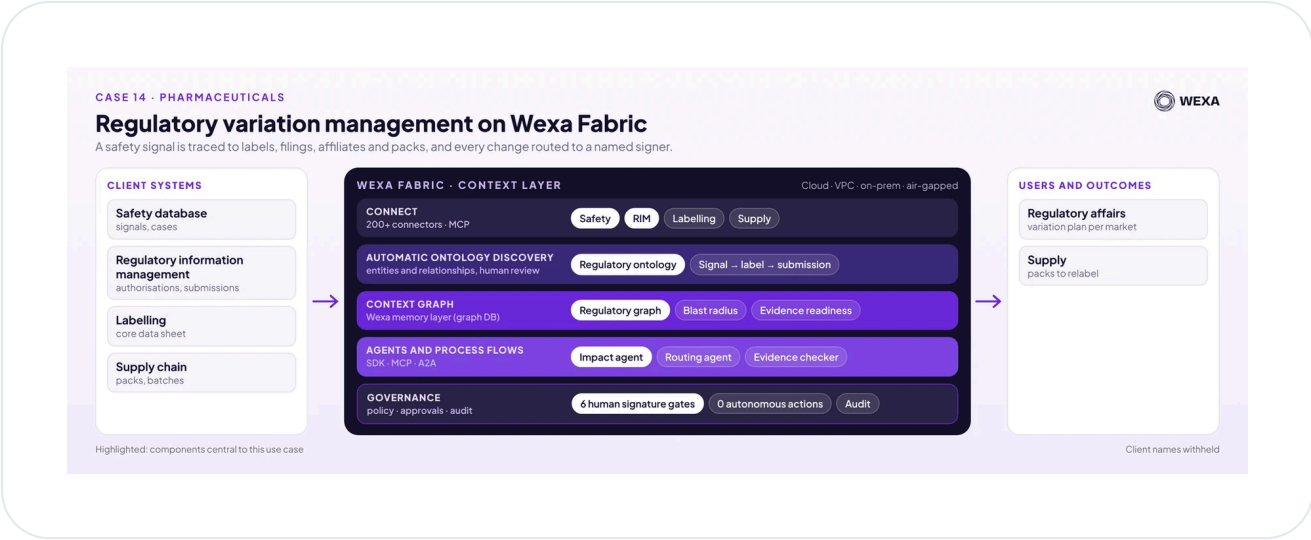


FIGURE How this use case runs on Wexa: client systems connected, ontology discovered, context graph in the Wexa memory layer, agents and process flows, and governance. Highlighted components are central to this use case.

Results

MEASURE	BEFORE / WITHOUT WEXA	WITH WEXA
Impact-assessment hours per variation (150 variations a year)	120 hours	24 hours
Annual cost of the process	\$2.2M	\$432K
Time to implement the AI solution	6 months	6 weeks
AI build cost (one-time)	\$480K	\$44K
AI operating cost per year (models, infrastructure, upkeep, platform)	\$312K	\$166K

MEASURE	BEFORE / WITHOUT WEXA	WITH WEXA
Total AI cost in year 1	\$792K	\$210K

WITH WEXA

\$1.6M

net annual value to the client after Wexa's
own operating cost

4x

faster to implement

47%

lower AI operating cost

\$582K

less AI spend in year 1

- ✓ Six change proposals, each routed to a named signer; nothing executed without a signature
- ✓ Packs still in packaging within the change window identified for relabelling