AI agents for the regulated work behind a medicine

Agents that read your procedures, your batch records and your safety reports, prepare the work, and stop for a named person. On infrastructure you control.

THE PROBLEM

A template we opened triggers a regulatory submission from an adverse event report with no step where a person approves, and we found none for a batch record or a deviation. Of 2,719 operations in 31 public life sciences interfaces, 1,214 are sent as changes, and the method alone cannot tell which only read.

HOW IT WORKS, IN THREE STEPS

STEP 01

Connect what the agent may read.

Procedures, specifications and methods become knowledge sources, with each reader's permissions kept. Quality events, laboratory results and safety cases are reached through the description of an interface you already run; batch and stability history through a reporting database, read only.

STEP 02

Decide where it stops.

Every tool call passes your policy. A tool that changes a record, a case or a filing waits for a named person.

STEP 03

Run it where the data lives.

In your data centre or your private cloud, on a model you serve.

THE RULE EVERY AGENT FOLLOWS

It prepares. A named person decides.

Thirty-five agents in nine areas

Manufacturing	Batch Record Review. GMP Procedures Q&A. Shift Handover Summary. Cleaning and Line Clearance Record Check
Quality assurance	Deviation Report. Corrective Action Tracking. Change Control Impact. Product Quality Review
Quality control laboratory	Out-of-Specification Investigation. Analytical Record Review. Methods and Specifications Q&A. Stability Data Summary
Regulatory affairs	Submission Document Check. Labelling Change Comparison. Authority Question Response. Regulatory Change Summary
Pharmacovigilance	Adverse Event Case Intake. Literature Screening. Case Narrative. Safety Report Section
Clinical operations	Trial Master File Check. Site Visit Report. Protocol Q&A. Protocol Deviation Summary
Medical information	Medical Information Response. Promotional Material Check. Scientific Literature Summary
Validation and engineering	Validation Document. Requirements Traceability Check. Calibration and Maintenance Record. Periodic Review
Supply, finance and people	Supplier Qualification Check. Temperature Excursion Summary. Invoice Matching. Training Content

Also in the pack: the full list with what each agent reads and where it stops, and the white paper “AI agents inside the drug maker”, with its sources.

Seven questions to ask before an agent touches a regulated record

01 Where does it run, and where is the model?

02 Does it keep each person’s permissions?

03 Which tools change a record, a case or a filing, and does each wait for a person?

04 Where is the step at which a named person approves?

05 Can it sign or release anything, and what does it do when it does not know?

06 What is recorded, and for how long?

07 Can we stop one agent, one tool, or all of them, at once?

WHERE THE PLATFORM RUNS TODAY

In production at a top-tier bank in Asia, air-gapped, inside the bank’s own perimeter.

It has run in production for about 1,100 staff of a life insurer in Asia, on the insurer’s own cluster, inside its network.

Where to start

One product, one site, invented data first. A GMP procedures assistant can run on the first day, because no system of record is touched.

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