Life sciences and pharma agents on Katonic

35 agents across nine areas

A life sciences company's work runs through its quality, manufacturing, laboratory, regulatory, safety and clinical systems and the controlled documents around them. Every agent reaches them in one of four ways, all through the same tool gateway and the same approval rules:

	HOW EACH AGENT CONNECTS
01	**A file the user uploads** in the conversation: a batch record, a deviation report, a source document for an adverse event, a site visit report.
02	**A knowledge source.** Standard operating procedures, specifications, validated methods, the approved product information, the protocol and regulatory guidance are indexed in the Knowledge Engine, with each reader's permissions kept.
03	**An imported API.** The company gives Katonic the description of an API it already runs, and the operations it chooses become tools. This is the route to systems of record: quality events, documents, laboratory results, submissions, safety cases, trial documents.
04	**An MCP server from the catalogue,** deployed inside the company's own cluster. This is the route to the data warehouse, reporting databases and web search of the published literature.

System names are left out on purpose. The company supplies the address and the sign-in. Nothing here is a tested integration with a named product.

THE NINE AREAS

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AREA 01

Manufacturing

AGENT	WHAT IT DOES	READS FROM	WHERE IT STOPS FOR A PERSON
Batch Record Review Agent	Reads a completed batch record against the master record and lists every missing entry, value outside its limit and step without a second check	The batch record as an uploaded file or through an imported API, read only; the master record as a knowledge source	The quality reviewer still reviews the record as the procedure requires and decides on every item. The agent releases nothing and signs nothing
GMP Procedures Q&A Agent	Answers an operator's question from the site's own procedures, cites the document, version and step, and says when they are silent	Procedures as a knowledge source	It informs. Anything the procedures do not cover goes to the supervisor
Shift Handover Summary Agent	Drafts the handover summary from the shift's log: batches in progress, holds, open events, what to do first	The log as an uploaded file or from a reporting database, read only	The outgoing shift lead checks and signs the summary
Cleaning and Line Clearance Record Check Agent	Checks a cleaning or line clearance record against the procedure and lists every missing step, check or signature	The record as an uploaded file; the procedure as a knowledge source	The supervisor and quality accept or return the record

AREA 02

Quality assurance

AGENT	WHAT IT DOES	READS FROM	WHERE IT STOPS FOR A PERSON
Deviation Report Agent	Turns the first account of a deviation into the site's report form: what happened, the batches touched, the procedure it departed from, and similar past events	The account as an uploaded file; past events through an imported API; procedures as a knowledge source	The quality owner classifies the deviation, decides the root cause and closes it
Corrective Action Tracking Agent	Lists open corrective and preventive actions with owner, due date, age and the evidence still missing for the effectiveness check	Action records through an imported API or a reporting database	The quality lead decides priorities and closes every action
Change Control Impact Agent	Reads a proposed change and lists the documents, validations, filings and training it may touch, with the reason for each	The change request as an uploaded file; the document list through an imported API; procedures as a knowledge source	The change board decides the assessment and approves the change
Product Quality Review Agent	Drafts sections of the yearly product quality review from the year's batches, deviations, complaints and changes, with each figure traced to its source	A reporting database, read only; the review template as a knowledge source	Quality assurance checks and approves the review

AREA 03

Quality control laboratory

AGENT	WHAT IT DOES	READS FROM	WHERE IT STOPS FOR A PERSON
Out-of-Specification Investigation Agent	Sets out an out-of-specification result against the investigation procedure: the checks done, the ones still open, and the records behind each	The result and the laboratory records as uploaded files or through an imported API, read only; the procedure as a knowledge source	The laboratory head and quality decide the cause and the batch
Analytical Record Review Agent	Reads an analytical record against the method and lists missing entries, values outside the system suitability limits and calculations that do not agree	The record as an uploaded file; the method as a knowledge source	The second analyst reviews and signs the record
Methods and Specifications Q&A Agent	Answers an analyst's question from the company's methods, specifications and the pharmacopoeia it holds, with the clause cited	Methods and specifications as a knowledge source	It informs. The analyst follows the approved method
Stability Data Summary Agent	Summarises a study's results by time point and condition, and lists results that are outside the specification or moving towards its limit	Stability results from a reporting database, read only	The stability lead judges every trend and decides what to report

AREA 04

Regulatory affairs

AGENT	WHAT IT DOES	READS FROM	WHERE IT STOPS FOR A PERSON
Submission Document Check Agent	Checks a submission's documents against the content plan and the authority's published requirements, and lists what is missing, inconsistent or out of date	The documents as uploaded files or through an imported API, read only; the requirements as a knowledge source	The regulatory lead decides what goes in. The agent submits nothing
Labelling Change Comparison Agent	Compares two versions of product information, or a local label against the company's core text, and lists every difference with its place	The texts as uploaded files or as a knowledge source	The labelling manager decides every change
Authority Question Response Agent	Drafts a response to a health authority's question from the filed dossier, with each statement tied to the section it rests on	The question as an uploaded file; the dossier as a knowledge source	Regulatory affairs and the subject experts approve and send every response
Regulatory Change Summary Agent	Summarises a new guideline, consultation or rule change and lists the products and procedures it touches	The document as an uploaded file or through web search	The regulatory intelligence lead decides the response

AREA 05

Pharmacovigilance

AGENT	WHAT IT DOES	READS FROM	WHERE IT STOPS FOR A PERSON
Adverse Event Case Intake Agent	Reads an incoming report, sets out the reporter, the patient, the product and the event, flags what is missing for a valid case, and prepares the case entry	The source document as an uploaded file; the product list as a knowledge source	A safety officer decides whether the case is valid, serious and expected, and whether the product caused the event. The agent decides none of these
Literature Screening Agent	Screens the results of the company's literature search and sets aside articles that may hold a case or safety information, with the passage for each	Published literature through web search or an imported API; the search strategy as a knowledge source	A safety reviewer reads every article set aside and samples the rest
Case Narrative Agent	Drafts the case narrative from the fields of a case already entered, in the company's format	The case through an imported API, read only	The case processor edits and approves the narrative
Safety Report Section Agent	Drafts tables and descriptive sections of a periodic safety report from the period's cases, with every count traced to its query	The safety data through a reporting database, read only; the report template as a knowledge source	The safety physician writes the assessment and signs the report

AREA 06

Clinical operations

AGENT	WHAT IT DOES	READS FROM	WHERE IT STOPS FOR A PERSON
Trial Master File Check Agent	Checks a study's or a site's file against the expected document list and lists what is missing, expired or unsigned	The file index through an imported API, read only; the document list as a knowledge source	The study manager decides what to chase and files nothing on the agent's word
Site Visit Report Agent	Turns a clinical research associate's visit notes into the visit report form, and lists the findings that need a follow-up letter	The notes as an uploaded file; the report template and the monitoring plan as a knowledge source	The clinical research associate checks and signs the report
Protocol Q&A Agent	Answers a study team or site question from the protocol, its amendments and the study manuals, with the section cited	The protocol and manuals as a knowledge source	It informs. Eligibility and medical questions go to the medical lead; the investigator decides about every patient
Protocol Deviation Summary Agent	Groups a period's protocol deviations by site, type and importance, and lists the ones still open	Deviation records through an imported API or a reporting database	The study team classifies every deviation and decides the action

AREA 07

Medical information

AGENT	WHAT IT DOES	READS FROM	WHERE IT STOPS FOR A PERSON
Medical Information Response Agent	Drafts a reply to a question from a health professional from the approved product information and the company's standard responses, with each statement referenced	The question as an uploaded file; approved responses and product information as a knowledge source	A medical information specialist approves and sends every reply. A report of a side effect goes to the safety team
Promotional Material Check Agent	Checks a draft piece against the approved product information and the references it cites, and lists claims without support	The piece and its references as uploaded files; product information as a knowledge source	The medical, legal and regulatory reviewers approve or reject the piece
Scientific Literature Summary Agent	Summarises published papers on a question, with the source of every statement and the limits of each study	Published literature through web search or an imported API	The medical affairs scientist checks the summary against the papers

AREA 08

Validation and engineering

AGENT	WHAT IT DOES	READS FROM	WHERE IT STOPS FOR A PERSON
Validation Document Agent	Drafts a test protocol or a summary report from the requirements and the company's validation procedure, in the company's format	Requirements as an uploaded file; the procedure and templates as a knowledge source	The validation lead and quality approve every document before it is run
Requirements Traceability Check Agent	Checks that every requirement has a test and every test a result, and lists the gaps	The requirements, tests and results as uploaded files or through an imported API	The validation lead decides how each gap is closed
Calibration and Maintenance Record Agent	Lists instruments and equipment whose calibration or maintenance is due or overdue, and the batches made since an out-of-tolerance finding	Records through an imported API or a reporting database	The engineer and quality decide the impact and the action
Periodic Review Agent	Gathers what a periodic review of a system needs: changes, incidents, access reviews and open actions since the last review	Records through an imported API; the review procedure as a knowledge source	The system owner writes the conclusion and signs the review

AREA 09

Supply, finance and people

AGENT	WHAT IT DOES	READS FROM	WHERE IT STOPS FOR A PERSON
Supplier Qualification Check Agent	Checks a supplier's certificates, questionnaire and audit report against the company's requirements and lists what is missing or expired	Documents as uploaded files; requirements as a knowledge source	Quality decides whether the supplier is approved
Temperature Excursion Summary Agent	Sets a shipment's temperature record against the product's allowed range and time, and prepares the summary for assessment	The record as an uploaded file; the product's limits as a knowledge source	Quality decides whether the product may be used
Invoice Matching Agent	Matches a supplier invoice to the order and the goods receipt, and lists every difference	The invoice as an uploaded file; the order and receipt through an imported API	Accounts payable approves every payment
Training Content Agent	Drafts a short training note or quiz from a procedure, in the company's format, and lists who is due the training	The procedure as a knowledge source; training records through an imported API	The training lead approves the content. The agent assesses no one

WHAT EVERY AGENT HAS IN COMMON

01 **It runs on the company's own infrastructure or private cloud,** with a model the company serves. Batch, patient, safety and unpublished product data stay there.

02 **Every tool call passes the company's policy.** A policy can allow a tool, record its use, hold it for a person's approval, or block it, for the whole organisation or for one team.

03 **A tool that changes something waits for approval** unless the company has decided otherwise for that tool. That is how no record, case, reply or filing changes unapproved.

04 **No agent signs.** Review, approval and release signatures are made by the person, in the system of record, under the company's own procedure.

05 **The agent acts as the person using it.** Where the company's API checks the caller, Katonic passes the signed-in user's identity, and the agent cannot claim another.

06 **Every call is recorded,** with who asked, which tool, and what was decided, and an agent, a tool or a whole server can be switched off at once.

WHERE TO START

Pick work where reading is slow, the decision stays with a person, and no patient or batch waits on the agent.

THREE PLACES THAT FIT

GMP Procedures Q&A

Operators ask what the site's own procedures say and get the answer with the document and step cited. No system of record is touched, so it can run on day one.

Batch Record Review

The agent lists every missing entry and value outside its limit. The quality reviewer decides.

Literature Screening

The agent sets aside the articles that may hold a case. A safety reviewer reads them and samples the rest.

One product, one site, invented data first. Then beside the manual process, measured against it.

Each one prepares the work. A named person decides.

About Katonic AI

Katonic AI builds the platform that organisations use to build, run and govern AI agents on their own infrastructure: in their own data centre, in a private or sovereign cloud, or with no connection to the internet at all. The platform is in production with governments, banks, telecom operators and utilities. Katonic is certified to ISO 27001.

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