AI IN HEALTHCARE AND PHARMA SUMMIT · BOSTON · 18 NOVEMBER 2026

Why AI Stalls at 1% in Pharma, and How We Got to 20%

Dalbir Bains, CEO · Galaxy Pharmaceuticals

Galaxy is a 503B outsourcing facility: we sell sterile manufacturing as a service

WHO WE ARE

1. A 503B outsourcing facility in Albany, New York
2. Sterile drugs that hospitals need
3. Manufacturing as a service
4. FDA Registered

WHAT WE MUST GET RIGHT

Quality	**Get quality right.**
Delivery	**Deliver when promised.**
Economics	**Make money doing it.**

All three, at once.

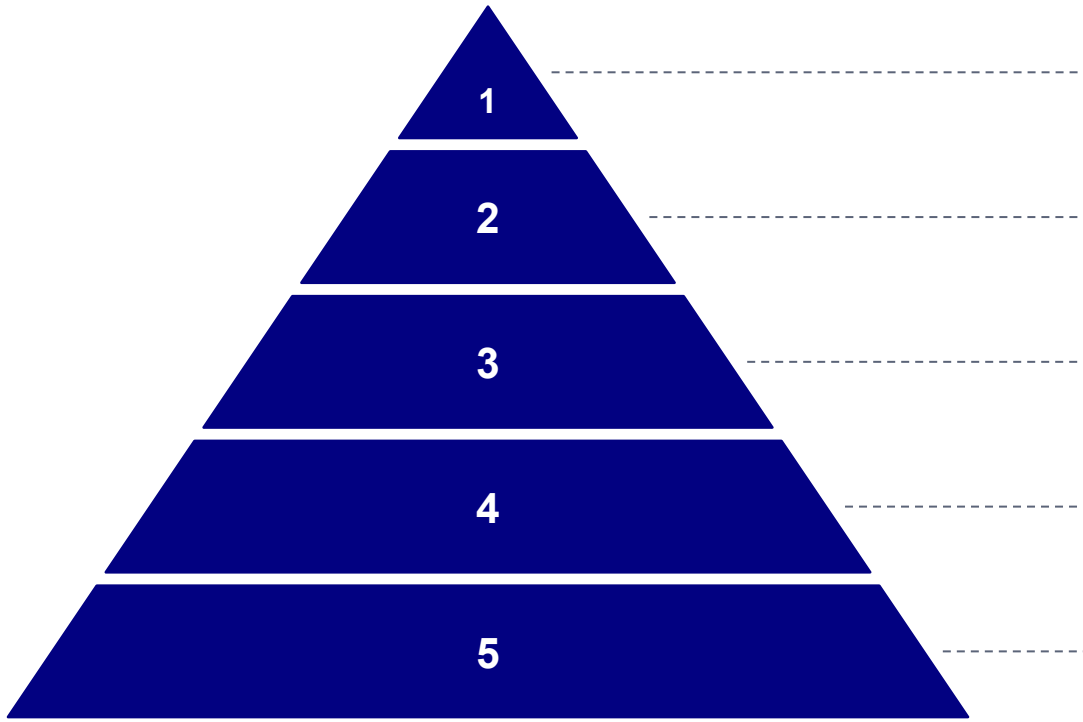
AI stalls at 1% for three reasons, and none of them is the model

WHY AI STALLS	WHAT WE SAW AT GALAXY	WHAT IT TAKES
1 **The data is not connected.**	March: Quality had a gown plate above its alert limit. Facilities had the gowning room in alarm for four days. The information was there. It just wasn't connected.	→ **An AI layer in the middle, on our systems of truth.**
2 **The work cannot be traced.**	Our March deviation took 103 days from opening to signature, on paper.	→ **One model of the work, with every action recorded.**
3 **Nobody designed the gate.**	October: agents put twenty decisions in front of me. I answered all twenty before eleven.	→ **The machine prepares. A person signs.**

The model was never the bottleneck.

1% is where we started: our own experience, not an industry statistic. 103 days: one deviation, from opening to signature, on paper.

Our answer is one operating model in five levels, built around an AI layer in the middle of the company



VISION
One screen for the whole company: Atlas.

PRINCIPLES
Eight drivers. Three rules that do not bend.

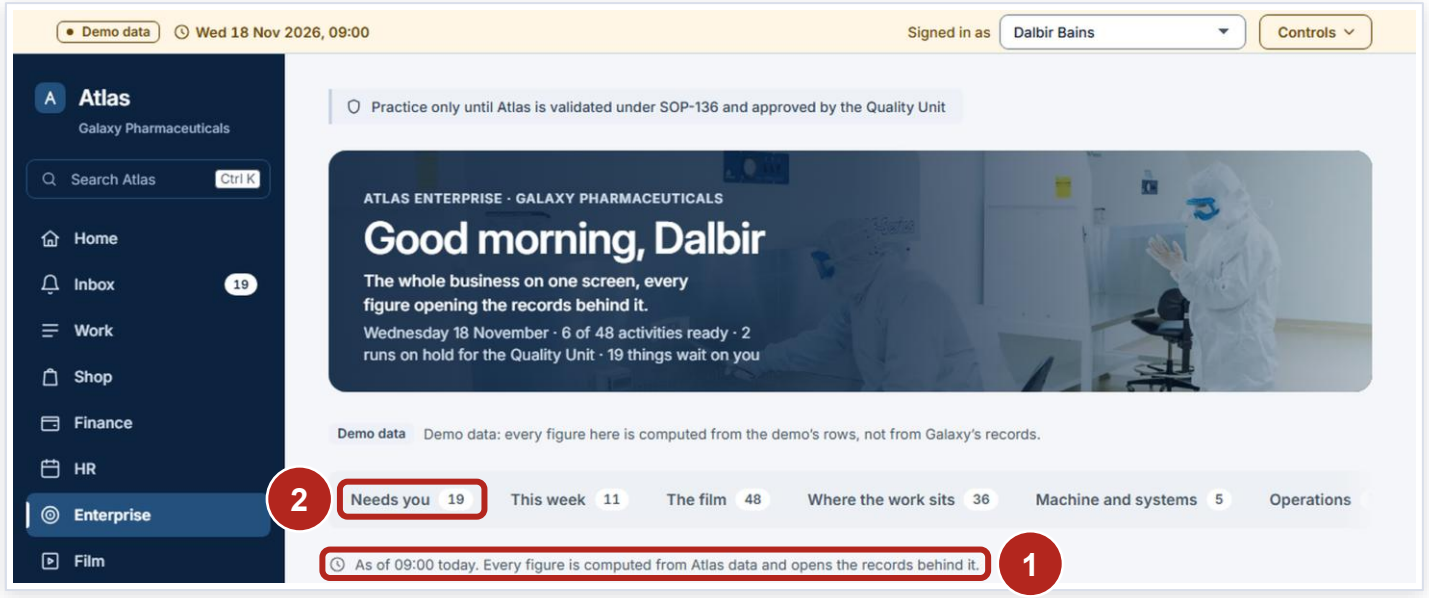
OPERATING MODEL
Orchestrate with tools. A person signs.

THE AI LAYER
Eight layers, one model, in the middle.

WORKFLOWS
One cGMP workflow, with agents at work.

Each slide that follows goes one level deeper.

At the top is Atlas: the whole business on one screen, with every figure traceable to its records



ATLAS · THE CEO'S VIEW

1. **Every figure is computed, and opens its records.**
2. **What needs me comes first.**

Every figure is computed. None is typed in.

Atlas as it stands on 15 November 2026.

Eight drivers took us from 1% to 20%; they come down to three moves



2 PRINCIPLES

Connect the work

1. Connect the information
7. Make it visible

Govern the gate

3. The machine prepares, a person signs
6. The CEO makes the decisions
8. Design the human gate

Learn from every version

2. Reject the first answer
4. Let it tell you the truth first
5. Measure honestly, and restart

Connect the work. Govern the gate. Learn from every version.

20% is my estimate of the share of our work done with AI; 1% is where we started. The numbers are the order I tell the drivers in.

I built the first version myself, because asking and waiting was the slowest step



2 PRINCIPLES

WHAT I TYPED

“I am sick and tired of handing this off and getting nowhere. Not anymore.”



THE LEADER SETS THE BAR

EXPERTS AND THE TEAM MAKE IT REAL

Vision first. Then experts, tests and roll-out.

Three rules are not negotiable: live data, one source of truth, best in class



2 PRINCIPLES

1 Real-time data, through APIs

IN MY WORDS

“I want real time integrated all the time.”

IN PRACTICE

Every tool reads the live system, or says that it does not.

2 One source of truth

IN MY WORDS

“Make sure it’s being read from that system of truth.”

IN PRACTICE

Every data point has one system that owns it.

3 Best in class, benchmarked

IN MY WORDS

“Always benchmark what you are doing with what’s in the market.”

IN PRACTICE

Benchmark first. Adopt what exists. Build the rest.

If it does not read the real systems, it is fake.

We automate by orchestrating each process with tools, and we stop at a person’s gate

THE AGENT ORCHESTRATES

Find	Check	Order	Prepare	Route	Record
Reads the systems, so you don’t open ten.	Each value against its limit.	This step first. Then the next.	The record, ready to confirm.	To the role that must sign.	Every action, in the audit trail.

A PERSON’S GATE

Confirm. Attest. Sign.

The machine prepares. A person signs.

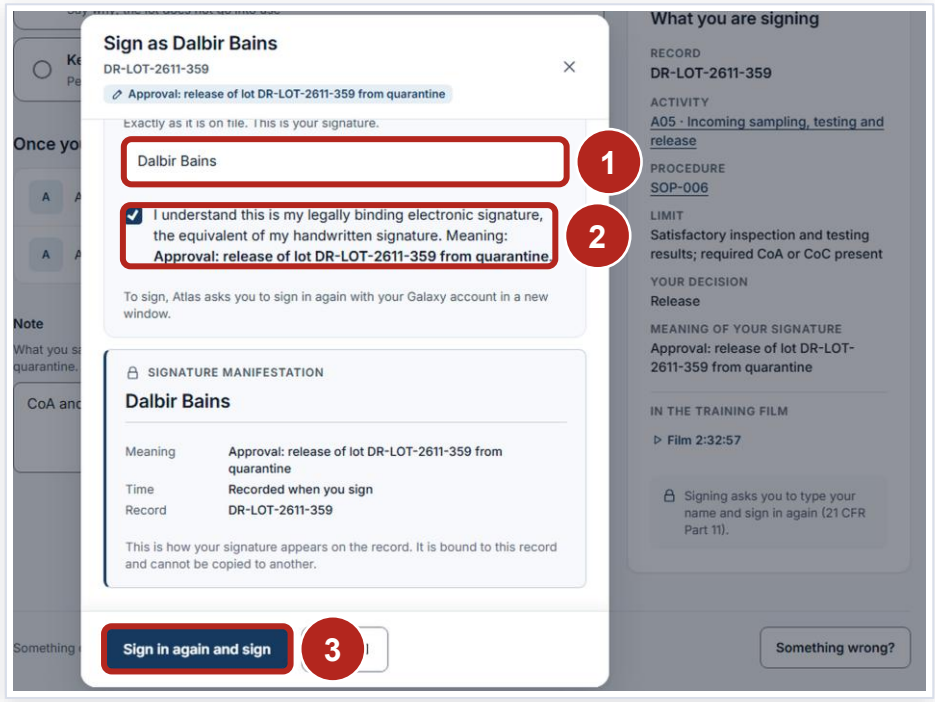
The gate is designed in: four decisions always stay with a person



MACHINE PREPARES	MACHINE PREPARES	MACHINE PREPARES	MACHINE PREPARES
A digital record, from each document.	A change to the ontology.	Work, only on a published agent version.	An audit trail entry for every access decision.
▼	▼	▼	▼
A PERSON **Approves or rejects each record.**	**A PERSON** **Approves each change request.**	**A PERSON** **Publishes each locked version.**	**A PERSON** **Can audit every decision.**

The machine prepares. A person signs.

The gate holds in practice: I told an agent to approve a purchase order, and it refused



8 NOVEMBER, ON A TEST COPY

I told our AI agent to approve a purchase order.
It refused.
The click had to be mine.

THE SAME GATE, BUILT INTO THE SCREEN

1. **Typed name.**
2. **Its meaning.**
3. **A fresh sign-in. Every time.**

The machine prepares. A person signs.

The signature step in Atlas.

People sign on top, seven launched systems of truth plug in below, and AI sits in the middle



4 THE AI LAYER

PEOPLE

Confirm. Attest. Sign.

▲ prepared for a person ▼ signed by a person

AI IN THE MIDDLE

Data hub
Every feed in one place

Ontology
One model of the work, tested with questions

Agents
Orchestrate each process, with tools

▲ reads through connectors and uploads ▼ writes back only after a person confirms

SYSTEMS OF TRUTH

Galaxy database	Controlled documents	Quality system	ERP	MES	Environmental monitoring	Security
LAUNCHED	LAUNCHED	LAUNCHED	LAUNCHED	LAUNCHED	LAUNCHED	LAUNCHED
Feeds the AI layer	Feeds the AI layer	Feeds the AI layer	Next to connect	Next to connect	Next to connect	Next to connect

All seven systems are launched. Three already feed the AI layer (66 document libraries, about 1,326 files); four are next to connect. As at 16 November 2026.

Inside the AI layer, our documents become records, then a knowledge graph, then the work of agents



4 THE AI LAYER

THE STORY: FROM A DOCUMENT TO AN AGENT

Documents → **Digitization** → **Ontology** → **Agents**

Our SOPs, forms, logs and records, in document libraries. The hub.

Each document becomes a digital record.

AI extracts the things and the links between them: a knowledge graph.

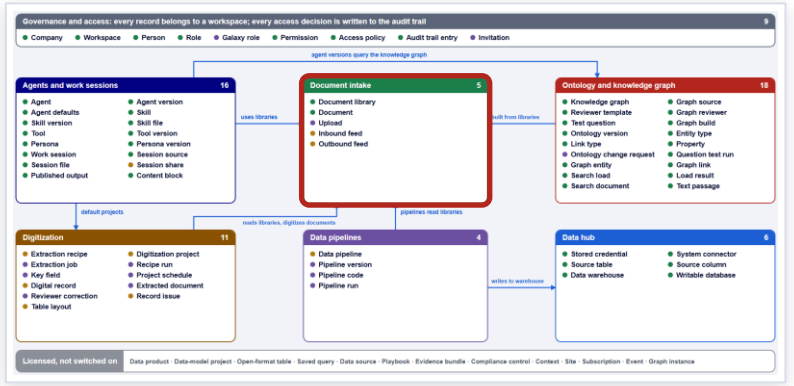
Query the graph. Work from the libraries.

↺ **Every build is scored against test questions, then rebuilt.**

A PERSON'S GATE

A person approves each record, and each change to the model.

THE FULL MODEL BEHIND IT



8 layers

82 building blocks

98 links

In red: document libraries, the hub.

Our documents are the hub. Everything else reads from them.

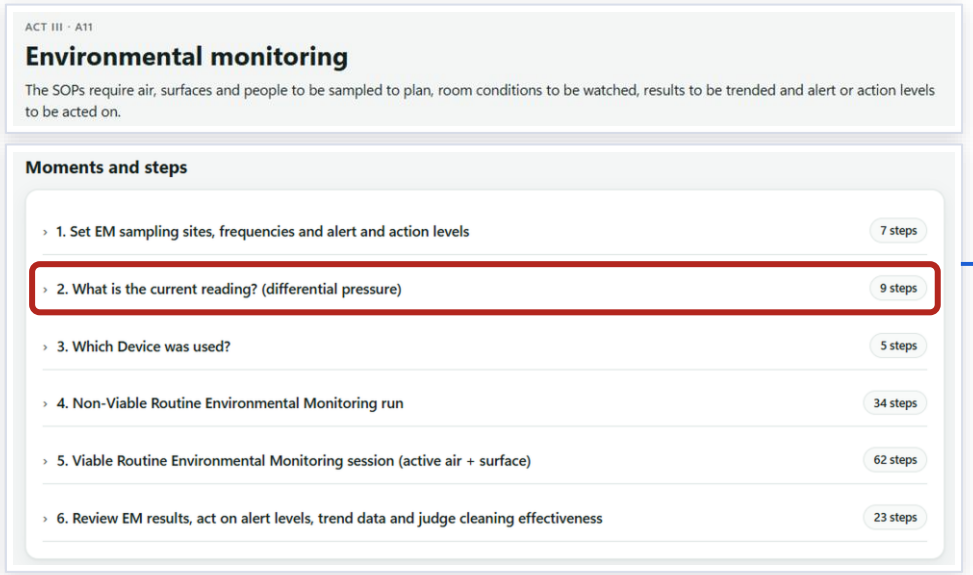
The AI layer, read from our live workspace on 16 November 2026. The full-size model is in the appendix.

From ontology to screen: one question, modelled once, is answered by an agent and shown to a person



4 THE AI LAYER

1 THE ONTOLOGY LAYER



2 THE AGENT ORCHESTRATES

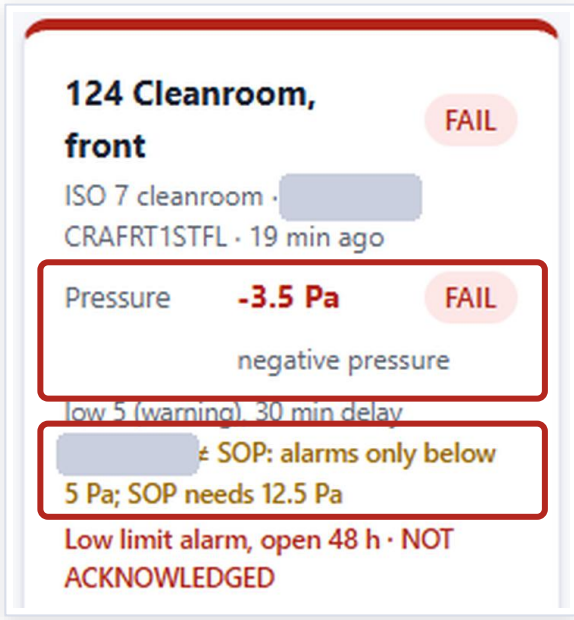
Finds every logger, about every 30 seconds.

Checks each reading against the SOP limit.

Records one answer, with the reason.

Routes the alarm to a person.

3 THE SCREEN WE BUILT



Modelled once. Applied by the agent. Shown to the person who decides.

Ontology: Atlas pilot, activity A11 (6 moments, 140 steps), read 16 November 2026. Screen: live monitoring, 16 November. The limits are those our SOPs state.

The same model runs at every stage of one cGMP workflow, with tools and agents already at work on it



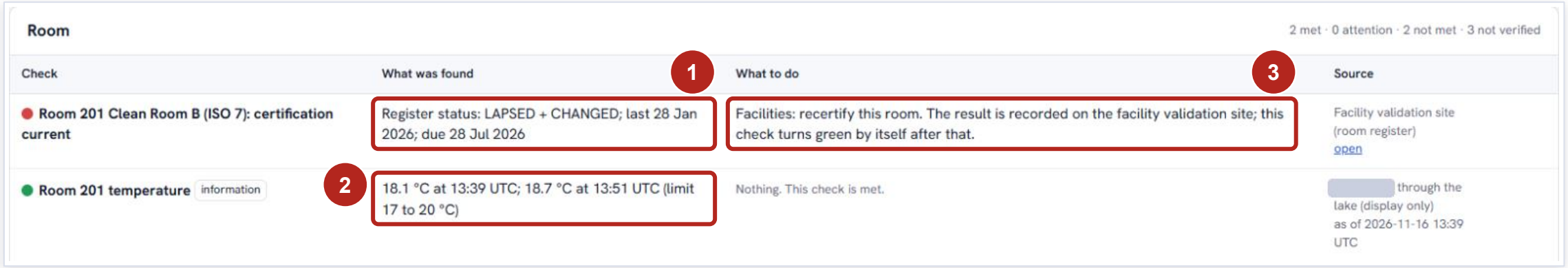
Purchasing	Receiving	Production	Quality	Testing
Requisitions and ordering	Receipt and quarantine	Daily huddle and routines	Verify and release the run	Environmental monitoring
		Readiness gate	Deviation drafting	Lab results
		Gowning check		
Purchasing watch		Huddle Conductor · Gowning coach		Monitoring watch

Under all of it: equipment validation · facility validation

Read the source. Prepare. A person signs. Write it back.

Solid: running today. Dashed: being built. Blue: an agent at work on that stage today.

Before a run, the readiness gate answers 28 of 39 checks from our systems; people verify only the rest



Room

2 met · 0 attention · 2 not met · 3 not verified

Check	What was found	What to do	Source
Room 201 Clean Room B (ISO 7): certification current	Register status: LAPSED + CHANGED; last 28 Jan 2026; due 28 Jul 2026	Facilities: recertify this room. The result is recorded on the facility validation site; this check turns green by itself after that.	Facility validation site (room register) open
Room 201 temperature information	18.1 °C at 13:39 UTC; 18.7 °C at 13:51 UTC (limit 17 to 20 °C)	Nothing. This check is met.	through the lake (display only) as of 2026-11-16 13:39 UTC

BY HAND

Open the quality system for 11 documents. Open the ERP for 18 lines of material. Check 10 pieces of equipment, the room and the people.

THE AGENT

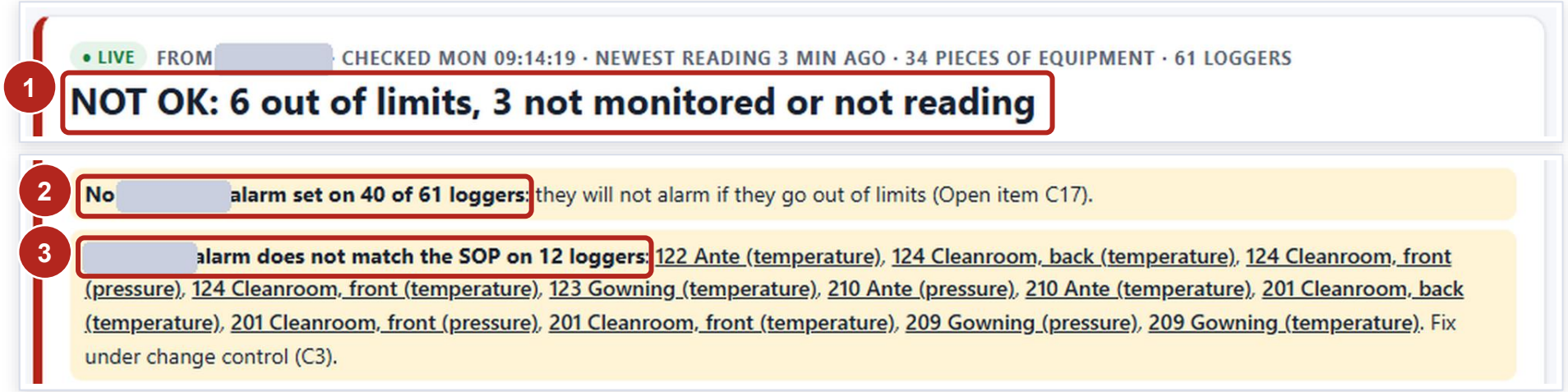
Reads each system. Shows what it found, when it read it and who must fix what. Puts the steps in order.

THE RESULT

28 of 39 checks answered by the systems. A lapsed room certification shown before the run. No release until every required check is green.

Our Production site, 16 November 2026. One supplier name covered.

The monitoring watch reads 61 loggers about every 30 seconds, and it found 40 with no alarm set



BY HAND

Open the monitoring system. Read 61 loggers, one by one. Look up each limit in the SOP.

THE AGENT

Reads every logger. Checks each against our own SOP limit. Gives one answer: OK, or not OK and why.

THE RESULT

40 of 61 loggers had no alarm set. 12 alarm settings did not match our SOP. A person must acknowledge every alarm.

Two parts of our live screen, Monday 16 November 2026, 09:14. One supplier name covered.

At 7:40 every weekday the Huddle Conductor reads five systems and lays out the day for each person



THIS WEEK

Mon 16 Nov Board and printed pack ready before the huddle.

Thu 12 Nov 41 updates written to the board.

Every day 102 routine tasks for 7 people.

BY HAND

Build the day from the plan, the logs and email. Ask who is blocked. Chase yesterday's actions.

THE AGENT

Reads five systems and the mail. Proposes each item. Lays out every person's day, hour by hour.

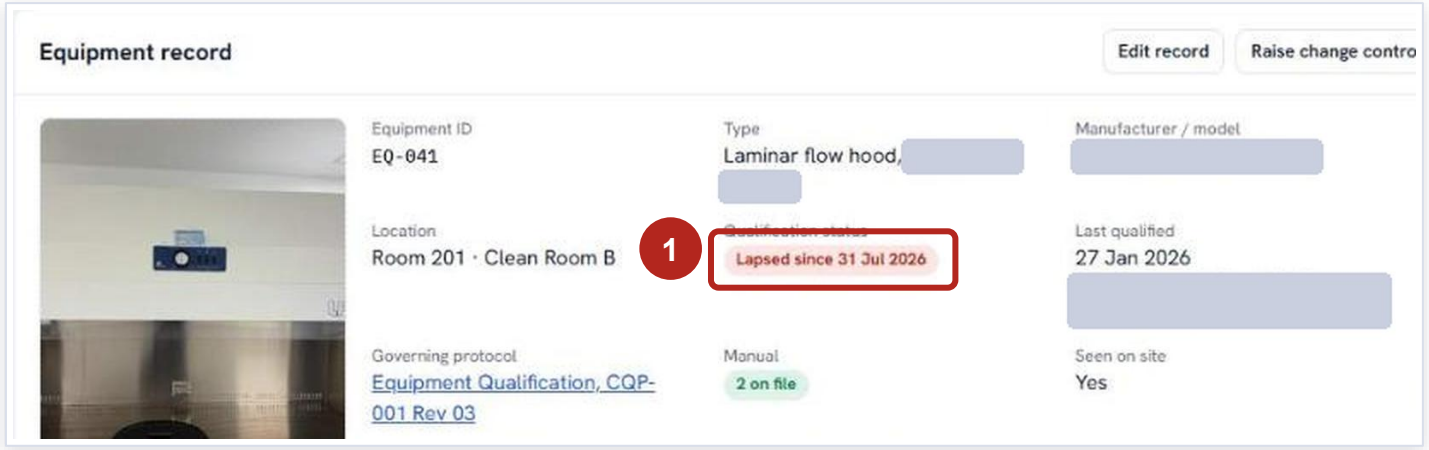
THE RESULT

Each task names its log and its checker. Owners accept or decline every item. The tick is not the record.

Staff tool, one operator's morning (13 November); runs of 12 and 16 November 2026 read from the scheduler.

The validation sheets check each result as it is typed, and showed a hood whose qualification had lapsed

5 WORKFLOWS



ALSO FOUND: PRESSURE REVERSED

+7.7 Pa
January 2026

−9.4 Pa
12 November 2026

Required: at least +12.5 pascals.

BY HAND

Find the protocol and the limit. Judge each result yourself. Chase a second person, then Quality.

THE WORKFLOW

The limit is on the sheet. Pass or fail as you type. A lapsed instrument is refused. Nobody reviews their own test.

THE RESULT

A hood lapsed since 31 July. A cleanroom whose pressure had reversed. Nobody had to go looking.

Equipment and facility validation sites, 15 November 2026. Maker, model and serial covered.

The gowning coach checks each video against 28 points, and found our own documents disagree in seven places



THE PERSON → AI → AI → QUALITY

Gown on camera → **AI checks the video** → **Feedback to the person** → **QA decides**

Next: real-time feedback before the door opens, and an alert to QA.

WHAT IT FOUND

One SOP: at least **30 s**

Another SOP: **60 s**

THE PERSON

Gowns on camera, in one take. Can ask QA to look at any step they dispute.

THE AGENT

Checks the video against our SOPs and a reference video. Names the clause and the second to watch.

THE RESULT

Two people followed two different SOPs. Our gowning documents disagree in seven places. QA decides which rule stands.

The gowning check on the staff tool: a coaching check only. Qualification stays with the observer, the contact plates and Quality.

One story, five levels: each level makes the next one possible

LEVEL	WHAT WE DECIDED	WHERE IT STANDS TODAY
1 Vision	**One screen for the whole company**	Atlas: built
2 Principles	**Three rules. A person signs.**	Four gates designed into the AI layer
3 Operating model	**Orchestrate each process, with tools**	Readiness gate: 28 of 39 checks answered by the systems
4 The AI layer	**Eight layers, one model, in the middle**	47 of 82 building blocks running on live records
5 Workflows	**One cGMP workflow, role by role**	Agents at work on the floor; seven document conflicts found

The machine prepares. A person signs.

Counts read from the running systems on 16 November 2026. 20% is my estimate.