KAELOX

FDA-REGULATED MANUFACTURING · PHARMA & MEDTECH

Deterministic AI Governance. Built for the Regulator You Actually Answer To.

Pharma & Medtech · FDA-Regulated Manufacturing

WHY NOW

In April 2026, FDA issued its first warning letter explicitly citing AI misuse inside a controlled cGMP record. A manufacturer had used AI agents to draft specifications, procedures, and master production records — and never verified whether the output was accurate before it entered the record. FDA's finding was specific and narrow: AI-generated output requires authorized Quality Unit review before it becomes a controlled record. Kaelox's entire architecture exists to make that specific failure structurally impossible, not merely procedurally discouraged.

757
SECOM Catches
1,567 real wafers · 590 sensors · UCI dataset, DOI-cited

49%
Honest Disclosure
Escalation rate on failed AND all wafers — no lift claimed

308/308
Suite Checks Passing
Every governed capability re-verified before each release

Real case study: 757 catches replayed against a real semiconductor fabrication dataset (1,567 wafers, 590 sensors, UCI SECOM) — published with an honest disclosure that the dataset carries no per-row ground truth, so no detection-power claim is made on it. We show you the win and the limit in the same breath, because a platform that only shows wins isn't one you can trust with a regulated decision.

PROOF, NOT A PROMISE — HOW A DECISION ACTUALLY GETS MADE

1
Configure
You declare your regulatory floor, parameters, and thresholds. At SEAL, that configuration is hashed and chain-logged — frozen, not editable by anyone without a new, logged event.

2
Input
Your real process data — sensor readings, lot identity, SOPs — is what the Gate runs against, on your infrastructure. Nothing leaves the facility to make a decision.

3
Process
Every reading is evaluated by a deterministic trajectory calculation — physics, not prediction — cross-checked in parallel by two independent language models watching for disagreement. The math decides; the models never do.

4
Output
A chain-logged verdict, a plain-language explanation of what governed it, and a document set your inspector or auditor can pull directly — generated from the run that just happened, not written after the fact.

HOW THE PLATFORM STAYS TRUSTWORTHY

Fault-Tolerant AI, By Design

Kaelox never asks a single model to be right. Two independently-trained small language models (SLMs) evaluate the same input in parallel and are cross-checked for disagreement — a technique called divergence scoring. By policy,...

Deterministic Decisions, Not Predictions

The Gate that actually decides is a pure mathematical function — no model inference, no database call, in its evaluation path. It applies deterministic trajectory mathematics of the same certifiable class used to bound the beha...

Zero-Egress Architecture

Every deployment runs through a CONFIGURE→SEAL lifecycle. During CONFIGURE, your facility's parameters, thresholds, and jurisdiction floor are set. At SEAL, that configuration is cryptographically frozen — hashed, chain-logged,...

Built Toward the Right Cybersecurity Standard

Kaelox has identified IEC 62443 SL2 (SDLA and CSA) as its target cybersecurity standard — the category built for cyber-physical governance systems, not a generic software certification borrowed from an unrelated one. Formal thi...

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Patent Pending — U.S. Prov. No. 64/050,006 (April 26, 2026) · No. 64/081,396 (June 26, 2026)

SIX CAPABILITIES, ONE DETERMINISTIC ENGINE

Every facility gets access to all six. Which ones are front-and-center for you is a configuration decision, not a sales tier.

Shadow Audit

The real Gate runs against your real facility data — producing real, chain-logged verdicts — before you change a single thing about how your line runs today. You see exactly what Kaelox would have caught, with an honest account of what it didn't prove, before you commit to anything further. Delivered today as a practitioner-led engagement, with a self-serve version underway.

R&D / Cpk Improvement Sandbox

A Digital Twin Bench for your own process data. Upload your own readings, run Cpk experiments, and watch the same deterministic engine that governs production catch a drift toward a limit while the batch is still in spec — isolated from your live systems, nothing shared.

Yield (X-Matrix)

Hoshin-style strategy deployment tied to live plant metrics — not a quarterly slide deck. Yield, OEE, and quality metrics roll up from the same chain-logged data your compliance record is built from, so the operations view and the audit trail are never telling two different stories.

Micro-Kaizens (Improvement Ledger)

Floor-level fixes and CAPA outcomes roll into one Improvement Ledger, cross-referenced against yield — not a spreadsheet a continuous-improvement lead has to remember to update by hand.

TTE — Trust Transfer Envelope

A three-layer (process / governance / evidence) envelope for transferring trust between two parties — a contract manufacturer handing a batch to a brand owner, one site handing a lot to another — with a named Quality Person sign-off attached, not an email and a PDF.

Quality Improvements

A CAPA Register that closes only on logged evidence, never on a status field someone flipped, plus a plant-risk score computed from real chain data — named factors, not a hand-maintained heat map.

HOW YOU SELECT WHAT'S ACTIVE FOR YOUR FACILITY

1

Declare Your Floor

At CONFIGURE, declare US_PCCP / FDA QMSR as your regulatory floor.

2

Set Parameters

Enter your validated envelopes, thresholds, and role assignments.

3

SEAL Freezes It

Configuration is hashed, chain-logged, and immutable from that point on.

Declare your facility as FDA-regulated at CONFIGURE and the platform activates the PCCP-aligned change-control workflow, Part 820/QMSR-structured documentation, and device-identity traceability — the HACCP-specific critical-control-point workflow built for food manufacturers stays off, because it isn't relevant to what your inspector asks for.

WHAT YOU WALK AWAY WITH — OUTPUTS FOR FDA

Everything Kaelox produces is generated from the same chain-logged record your inspector would pull — never a summary reconstructed after the fact.

Validation Passport	GAMP 5–structured IQ/OQ/PQ record, generated from real, executed verification, not a template filled in by hand.
FDA Inspection Readiness	483 response support, CAPA linkage, and MDR/E2B reference fields, organized the way an inspector actually asks for them.

PCCP Change-Control Documentation	FDA's own three-section Predetermined Change Control Plan structure — Description of Modifications, Modification Protocol, Impact Assessment — not a generic single-field change log.
Trust Envelope Explanation (KTE)	A plain-language explanation of everything that governed a decision — all 14 governed elements, in real sentences — for an inspector who should never have to read source code to understand a verdict.
ALCOA+ Audit Export	A hash-chained, tamper-evident export of the full decision record, sequence-numbered and independently verifiable.

Next on the roadmap: a single report mapping a full replay against GAMP 5, Part 11, and Annex 11 side by side — everything above ships today.

See it catch something on your own data.

Request a Shadow Audit briefing — the Gate runs against your real facility data, no changes to your line required to see the result.

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MVP ALPHA