

KAELOX

FSMA-REGULATED MANUFACTURING · FOOD & BEVERAGE

Deterministic AI Governance. Catches the Drift Before the Critical Limit, Not After the File Review.

Food & Beverage · FSMA-Regulated Manufacturing

WHY NOW

21 CFR 117 already requires you to prove your preventive controls are being monitored — not just documented after a deviation is found. Across FDA's own 2025–26 enforcement data, inadequate corrective-action systems and documentation gaps remain the most common root causes cited in warning letters, food included. Kaelox's Gate doesn't wait for a file review to catch a critical-limit breach — it catches the trajectory toward one while the batch is still in spec, and logs the reasoning as provable arithmetic, not a reviewer's best guess weeks later.

392

In-Spec Trajectory Catches

36 months of real gas-sensor drift,
UCI dataset, DOI-cited

83,464

Evaluations Replayed

Real telemetry at 344,000 rows/sec
on a single laptop

308/308

Suite Checks Passing

Every governed capability re-verified
before each release

Real case study: 392 in-spec trajectory catches across 36 months of real sensor drift (UCI gas-sensor array dataset), replaying 83,464 real evaluations at 344,000 rows per second on a single laptop — every catch was still inside its band when flagged; the trajectory said it would breach.

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,...

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,...

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...

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...

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_FSMA_PC 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 FSMA-regulated at CONFIGURE and the platform activates the HACCP-aligned preventive-controls workflow and lot/batch traceability — the PCCP AI-change-control workflow built for device makers stays off, because it isn't relevant to what your auditor asks for.

WHAT YOU WALK AWAY WITH — OUTPUTS FOR FSMA

Everything Kaelox produces for a food-safety review comes from the same chain-logged record your auditor would pull — never a summary reconstructed after the fact.

HACCP-Aligned Preventive-Controls Trail

A continuous audit trail structured around your declared critical control points — 21 CFR 117, implemented as an enforced floor, not a policy binder.

Lot & Batch Traceability Export

The exact unit a recall investigation actually asks about, exportable on demand — not reconstructed from three separate systems under time pressure.

CAPA Register Export	Corrective and preventive actions that close only on logged evidence, never on a status field someone flipped.
Trust Envelope Explanation (KTE)	A plain-language explanation of everything that governed a decision — all 14 governed elements, in real sentences — for an auditor 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 your preventive-controls plan — 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.