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DESIGN PARTNER BRIEF · MAY 2026

Become an evidence partner *for the AI-governed pharma QMS*

built for the regulated AI world starting Aug 2, 2026.

A 60–90 day controlled GMP evidence sprint that can convert into governed software evaluation if the evidence proves value. One workflow. Founder-led.

Vimal Veereshwarayya, PhD., RAC · Co-Founder & CEO
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When the inspector asks how AI touched

your GMP quality record — what evidence do you show?

The question is no longer who approved the record. It is what AI suggested, what data it used, what the human accepted or rejected, and where that evidence lives in the audit trail.

5

Regulatory events in 12 months

Annex 22 draft (Jul 2025) · EU AI Act GPAI (Aug 2025) · FDA+EMA AI Principles (Jan 2026) · FDA CSA updated (Feb 2026) · First AI WL (Apr 2026)

1st

WL 722591 — Purolea Cosmetics Lab

FDA's first WL with a dedicated 'Inappropriate Use of AI' section. §211.22(c). Drug products under FD&C Act 501(a)(2)(A). April 2 2026.

Aug 2, 2026

EU AI Act high-risk applies

Pharma manufacturing AI classified high-risk. Fines up to €35M or 7% of global turnover for non-compliance.

Sources: EC Health Annex 22 consultation · EU AI Act timeline · fda.gov/.../purolea-cosmetics-lab-722591-04022026.

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Your eQMS logs the WHAT.

Your AI tools do the WHY — and don't log it.

Most pharma quality teams now operate two parallel systems. Neither one closes the regulator's loop.

TODAY: YOUR eQMS

Veeva, MasterControl, TrackWise, Qualio.

Logs WHO did WHAT, WHEN. Workflow-level audit trail. Mature, but blind to AI.

Cannot answer:
which AI produced this recommendation?
what model version?
what input data?

TODAY: YOUR AI TOOLS

ChatGPT, Copilot, internal LLMs.

Does the WHY — drafts deviations, summarizes investigations, suggests CAPAs. Productive, but ungoverned.

No audit log.
No model versioning.
No human-approval gate.
No refusal when evidence missing.

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AI-governed pharma QMS.

Logs the WHO + the WHAT + the AI's WHY — and refuses to act when governance evidence is insufficient.

When the regulator asks:
who approved this AI output?
you point at the audit trail. Not at a slide.

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Five commitments — built in, not added.

AI governance as a first-class GxP object.

01	**Advisory-only AI**	Autonomous AI decisions prohibited in critical quality paths. AI proposes, human disposes.
02	**Human-in-the-loop gates**	Authority profiles, segregation of duties, e-signature for every regulated decision.
03	**Immutable audit trail**	Model version, prompt, retrieved evidence, AI output, human acceptance/rejection — first-class GxP objects.
04	**Evidence pack generator**	Built-in: inspection-oriented PDF + JSON export of the full AI-governance audit chain. For internal QA / validation review.
05	**Phase-gated GxP modules**	Core eQMS → OOS/OOT, deviations, CAPA, complaints, inspections → batch records, stability, EM, APQR → GMP/GDP/MIRA.

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From workflow-mapping to inspection-oriented *evidence in one GMP quality cycle.*

One facility. One low-risk workflow. One end-to-end evidence package. A scope you can defend to your CFO and your inspector.

WEEK 1-2

Workflow mapping

Joint session with your QA Head + one QC analyst. We map a single low-risk GMP workflow — Document Control, deviation (DR-only), or CAPA closure — end to end. OOS, batch release, and recalls are explicitly out of sprint scope.

WEEK 3-6

Module configuration

Verixa modules configured to your SOP language, your authority profiles, your audit-trail conventions. Partner-selected dataset: synthetic OR de-identified historical low-risk events.

WEEK 7-10

Parallel run

Your existing eQMS + Verixa side-by-side on the selected dataset. Mira drafts. Your named QA signer reviews. We log AI input, AI output, human decision, evidence-pack entry.

WEEK 11-12

Audit-readiness review

Structured evidence package for one complete quality-event cycle. Go / no-go decision on extending into a paid evaluation period.

Deliverable: one inspection-oriented GMP evidence package for internal QA / validation review. No incumbent QMS displacement during sprint.

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You are not being asked to buy *production software today.*

Software access during the sprint is controlled evaluation. Production use comes only after your validation boundary, vendor review, and internal approval. The deliverables below are what you keep regardless.

01 EVIDENCE PACK

PDF + JSON artifact showing AI-governance applied to one GMP workflow. Use it to prepare your QA, validation, and inspection-response teams. Yours forever.

02 AI-GOVERNANCE GAP ANALYSIS

4–6 page document. Named gaps in your current AI-governance posture, ranked by inspection risk, with remediation recommendations.

03 CONFIGURED WORKFLOW TEMPLATES

Your SOPs encoded in AI-governable form (advisory layer · HITL gates · e-sig binding · audit-trail spec). Portable to any future system.

04 FOUNDER-LED CONSULTING

60–90 days with Vimal directly — 20+ years pharma & biotech, 16+ years QA & Regulatory at Genentech, BMS, Arcellx, Alumis. Director-level QA brain.

05 CO-AUTHORED CASE STUDY

Documentation that you were an early adopter of AI-governed quality workflows. Full content veto + right to anonymise. You control publication.

06 INTRODUCTORY PRICING LOCK

Documented introductory commercial terms when Verixa converts to Year-1 software evaluation. First-mover protection on the renewal window.

07 SOFTWARE CONVERSION MEMO

Short conversion memo: workflow value · evidence gaps closed · controls demonstrated · validation work remaining · recommended software scope · Year-1 commercial path.

AS STANDALONE CONSULTING:

Big 4 digital quality **$80–200K**
CSV consultancy **$30–80K**
Sr QA/Reg consultant **$50–150K**

Verixa sprint: *$25K–$75K*

THE CONVERSION LADDER: Phase 0 Evidence Mapping → Phase 1 Controlled Evidence Sprint → Phase 2 Year-1 Governed Software Evaluation → Phase 3 Production License. *Each step gates the next.*

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A catalog of governed AI agents — *not a monolithic AI feature.*

Phase 1 GMP scope. Each agent: HITL approval, redlines, full audit trail of model + prompt + evidence.

Deviation Agent

Drafts investigation, classifies severity, suggests RCA hypothesis

CAPA Agent

Tracks effectiveness, flags overdue actions, recommends closure

Change Control Agent

Analyzes change impact across docs, validation, regulatory commitments

Complaint Agent

Triages complaints, classifies criticality, flags MDR/AE signals

OOS/OOT Agent

Detects out-of-spec/out-of-trend patterns; drafts initial investigation

APQR Agent

Auto-assembles APQR from batch records, deviations, complaints, stability

Inspection Readiness

Generates inspection evidence pack on demand with full traceability

Regulatory Intelligence

Monitors CDSCO/FDA/EMA changes, flags impact on SOPs

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Four things we will not claim.

Said directly, before you ask.

Most QMS vendors overclaim validation, parity, scope, and product framing. We will not.

We are NOT selling production software use in this sprint.

The sprint uses Verixa in a controlled evaluation mode. The paid deliverable is the evidence pack, gap analysis, configured workflow template, and conversion memo. Production software use requires a separate agreement, customer-approved validation boundary, and vendor qualification path.

We are NOT yet a validated 21 CFR Part 11 / EU Annex 11 commercial system.

Verixa is in design-partner phase. The sprint produces validation inputs and evidence — it does not validate Verixa for production GMP use. Partner remains responsible for their regulatory submissions.

We are NOT a Veeva or MasterControl replacement.

If your incumbent eQMS is working, keep it. Verixa attaches alongside — AI-governed agent workflows, audit-trail layer, evidence packaging. Phase 1 is augmentation. Replacement is a Year-3 conversation.

We are NOT going to replace your QA Head's judgment.

AI agents draft. Your QA Head decides. The system refuses to write to a GMP record field without a named human e-signature. We instrument the human authority your regulator already trusts.

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Commercial terms for limited-scope *GMP evaluation.*

Phase-gated commercial structure. Each phase has a defined deliverable, a defined fee, and a decision gate to the next phase. Production software (Phase 3) is a separate decision after extended evaluation, validation boundary approval, and vendor qualification.

PHASE 0 · EVIDENCE MAPPING SPRINT

10 business days · workflow scoping

Sprint Fee

$5K–$10K

Services

₹4–8 lakh · workflow map

PHASE 1 · CONTROLLED EVIDENCE SPRINT

45–60 days · 1 GMP workflow

Sprint Fee

$20K–$40K

Services

₹18–35 lakh · evidence pack

PHASE 2 · YEAR-1 SOFTWARE EVALUATION

12 months · controlled access · quarterly review

Evaluation Fee

$40K–$90K

Services

₹35–75 lakh · governed eval

PHASE 3 · PRODUCTION SOFTWARE LICENSE — separate decision after Phase 2. Requires customer-approved validation boundary, vendor qualification, security/legal review, intended-use documentation, and defined production scope. *Phase 0 and Phase 1 fees may be credited against Phase 2 or Phase 3 at Verixa's discretion if signed within agreed timelines.*

EVERY DESIGN PARTNER MSA INCLUDES · NON-NEGOTIABLE

1. No validated GMP system claim · Verixa is not represented as production-validated today
2. AI agents advisory only · all outputs require named-human review and e-signature
3. Data boundary agreed before sprint · India → AWS Mumbai, US → AWS US-East
4. Customer owns its data · clean exit · 30-day data export obligation
5. Verixa (Navira) owns platform IP · de-identified aggregate metadata retained only
6. No logo, case study, or reference participation without prior written approval, on each use
7. Production use requires customer-approved validation boundary

WHO YOU'RE WORKING WITH

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Founder-led. Direct accountability.

No middlemen during the sprint.

CO-FOUNDER & CEO · NAVIRA TECHNOLOGIES, INC.

Vimal Veereshwarayya, PhD., RAC

RAC-certified · 20+ years in pharma & biotech · 16+ years in QA and Regulatory

Career: Sr. Director GCP/PV at Alumis · Director Clinical Quality at Arcellx (cell therapy) · Director Clinical Quality at MyoKardia/BMS · Strategy Lead, Clinical QA & Risk at Genentech · Clinical Scientist / Regulatory PM at Northwestern Feinberg.

Domain expertise: 21 CFR Part 11, EU Annex 11, ICH Q9, CAPA, RCA, FMEA, audit-readiness simulation, ATMPs.

Entity: Navira Regulatory Technologies, Inc. (US Delaware C-corp) · Navira Regulatory Technologies Pvt Ltd (India). Verixa is the platform.
Sprint engagement counterpart — not a substitute for your QA Authority on your records.

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One conversation. One scoping call.

Decision in two weeks.

01	**Discovery call**	60 minutes with Vimal + your Head of Quality. Workflow shortlist. Scope sketch. Data-boundary confirmation. NDA executed if needed.
02	**Sprint proposal**	3-page proposal within 5 business days: workflow chosen, dataset option (synthetic / historical), 60–90 day plan, commercial terms.
03	**Phase 0 sign-off**	Phase 0 Evidence Mapping Sprint signed: $5K–$10K, 10 business days, single workflow map deliverable.
04	**Phase 1 sprint launch**	Configuration → parallel run → audit-readiness review. Single GMP workflow. Inspection-oriented evidence package + conversion memo at week 12.
05	**Conversion decision**	If the evidence package proves value, we jointly decide whether to move into Phase 2 — Year-1 Governed Software Evaluation.

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THE DECISION

Do not buy production software today.

Buy a bounded evidence sprint.

In 60–90 days, you will know:

- whether AI-governed evidence improves one GMP workflow;
- whether your QA team trusts the audit trail;
- whether Mira's advisory role is acceptable;
- what validation work remains;
- whether Verixa deserves a Year-1 Governed Software Evaluation.

NEXT STEP: **60-minute discovery call.** Decision after that: **$5K–$10K Evidence Mapping Sprint.**

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