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DESIGN PARTNER BRIEF · INDIA · MAY 2026

AI-governed GMP evidence sprint

for Schedule M and export-quality readiness.

One low-risk GMP workflow. One inspection-oriented evidence package.

INR pricing · India delivery · No incumbent QMS displacement.

Built foundation · Domain hardening required · GMP-first launch.

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

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India's GMP bar is rising.

Your evidence burden is rising with it.

Three forces converging across export-oriented Indian sites: tighter domestic GMP regulation, sustained USFDA inspection scrutiny, and a new evidence gap created by AI used inside quality work.

Jan 2026

Revised Schedule M deadline

India ordered drugmakers to meet global GMP standards by January 1, 2026. State regulators directed to inspect and act against non-compliant units.

200+

USFDA inspections of India sites (2023)

FDA conducted more than 200 inspections in India in 2023 and signalled intent to increase activity. Export licences ride on inspection outcomes.

NEW

AI in quality work — the audit-trail gap

What AI suggested · what data it used · what the human accepted or rejected · where that evidence lives. Legacy QMS does not capture this.

VERIXA STARTS WITH ONE LOW-RISK WORKFLOW — not full QMS replacement. Evidence first. Software conversion later.

Sources: Reuters — India orders drugmakers to meet global standards by Jan 2026 (Nov 2025) · Reuters — US FDA to boost inspections of drug manufacturing units in India (Feb 2024).

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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 QMS / DOCUMENT STACK

AmpleLogic, Caliber, TrackWise, MasterControl, Veeva, SharePoint, Excel, local DMS / QMS.

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, analyst-written summaries.

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 GMP evidence layer.

Does not replace your incumbent in Phase 1. 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.

Verixa is not a chatbot, Copilot wrapper, or custom-GPT deployment. It is a schema-level AI-governance layer with model + prompt + evidence audit, human authority gates, e-signature, and controlled refusal. AI outputs never auto-finalize regulated decisions.

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Five commitments — built in, not added.

AI governance as a first-class GxP object.

01	**Advisory-only AI**	AI proposes. Named humans decide. Autonomous AI decisions prohibited in critical quality paths.
02	**Human-in-the-loop gates**	Authority profiles, segregation of duties, e-signature on every regulated decision.
03	**Immutable audit trail**	Model version, prompt, evidence, output, human accept / reject / override — first-class GxP objects.
04	**Evidence pack generator**	Inspection-oriented PDF + JSON of the full AI-governance audit chain. For internal QA / validation review.
05	**Phase-gated modules**	Built foundation across GMP / GxP. Customer use requires domain hardening, workflow evidence, and an agreed validation boundary.

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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 Plant QA Head + one QC analyst. One low-risk GMP workflow scoped: Document Control, deviation documentation review, or CAPA effectiveness-review support.

WEEK 3-6

Module configuration

Configured to your SOP language, authority profiles, audit-trail conventions. Dataset options: synthetic, de-identified historical, or low-risk scoped records approved by QA. Existing QMS remains source of truth.

WEEK 7-10

Parallel / sandbox run

Existing QMS + Verixa side-by-side on the selected dataset. AI agents draft. Named QA reviewer decides. We log AI input, AI output, human decision, evidence-pack entry.

WEEK 11-12

Evidence review

Inspection-oriented evidence package for internal QA / validation review. Go / no-go on extending into Phase 2 Year-1 Governed Software Evaluation.

OUT OF SPRINT SCOPE: OOS final disposition · batch release · recalls · product release decisions. *Existing QMS remains source of truth throughout.*

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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 INSPECTION-ORIENTED EVIDENCE PACK

PDF + JSON showing how AI governance was applied to one GMP workflow. For internal QA / validation review.

02 AI GOVERNANCE GAP MEMO

4–6 pages. Gaps in your current AI-governance posture, severity ranking, recommended controls.

03 CONFIGURED WORKFLOW TEMPLATE

Your SOP logic translated into a governed workflow structure (advisory layer · HITL gates · e-sig binding · audit-trail spec).

04 FOUNDER-LED QA REVIEW

60–90 days of direct quality / regulatory input from Vimal — 20+ years pharma & biotech, 16+ years QA & Regulatory (Genentech, BMS, Arcellx, Alumis).

05 SOFTWARE CONVERSION MEMO

Workflow value · controls demonstrated · validation work remaining · recommended Year-1 governed software scope.

06 INTRODUCTORY PRICING LOCK

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

07 OPTIONAL CASE STUDY

Only with prior written approval. Full content veto. Anonymization allowed. No automatic logo or reference rights.

BOUNDED. NOT OPEN-ENDED.

Comparable external QA, CSV, or digital-quality consulting engagements can become open-ended.

Verixa keeps the first engagement bounded: one workflow, one evidence package, one fee.

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 — *phase-gated for domain hardening.*

Built foundation across GMP / GxP. Phase 1 India scope is GMP-only. All agents are advisory.

IN SCOPE · INDIA PHASE 1 · GMP

- **Document Control / SOP Agent**
- **Deviation / RCA Agent**
- **CAPA Evidence Agent**
- **AI Governance Evidence Agent**
- **Inspection Evidence Pack Agent**

BUILT · NOT DEFAULT SPRINT SCOPE

OOS / OOT · Change Control · Complaints

Supplier Quality · Training

APQR · Batch Records · Stability · EM

GDP / Cold Chain

GCP / GVP / CRO workflows

Dashboards / mock inspection

All agents are advisory. Customer use requires domain hardening, workflow evidence, OQ evidence, and an agreed validation boundary.

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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, Caliber, AmpleLogic, or MasterControl replacement in Phase 1.

If your incumbent QMS 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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Phase-gated. Bounded. INR + GST.

Production license is a separate decision.

Each phase has a defined deliverable, a defined fee, and a decision gate to the next. Phase 3 production software is separate and requires customer-approved validation boundary, vendor qualification, and final commercial agreement.

PHASE 0 · EVIDENCE MAPPING SPRINT

10 business days · workflow scoping

Sprint Fee

₹6–8L *+ GST*

Deliverable

Workflow map · AI governance gap memo · data-boundary plan · Phase 1 scope

PHASE 1 · CONTROLLED GMP EVIDENCE SPRINT

45–60 days · 1 low-risk GMP workflow

Sprint Fee

₹22–35L *+ GST*

Deliverable

Configured workflow · controlled dataset run · evidence pack · validation-gap memo · conversion memo

PHASE 2 · YEAR-1 GOVERNED SOFTWARE EVAL

12 months · controlled access · quarterly review

Evaluation Fee

₹55–90L *+ GST*

Deliverable

Controlled software evaluation · quarterly evidence review · limited workflow scope

PHASE 3 · PRODUCTION SOFTWARE LICENSE — quoted after validation boundary. Expected enterprise annual license starts at **₹1 Cr+ + GST.** *Requires customer-approved validation boundary, vendor qualification, security/legal review, intended-use documentation, defined production scope.*

FOUNDING-PARTNER TERMS — limited to the first two paid design partners signed by 31 Dec 2026. Conditional on Phase 0 → Phase 1 conversion within 30 calendar days and prior written approval of mutually agreed reference rights.

Pricing scales by in-scope site count, workflow count, dataset complexity, and named-reviewer count. Indicative ranges assume one site and one workflow in Phase 1.

NON-NEGOTIABLES · EVERY DESIGN PARTNER MSA

1 · No validated GMP system claim · advisory AI only · named-human e-signature

2 · Verixa (Navira) owns platform IP · sprint data not used to train shared models

3 · Data boundary agreed before sprint (AWS Mumbai default) · customer owns data

4 · No logo / case study / reference without prior written approval, on each use

WHO YOU'RE WORKING WITH

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Founder-led. Direct accountability.

No middlemen during the sprint.

CO-FOUNDER & CEO · NAVIRA REGULATORY TECHNOLOGIES

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. Trained where global regulators inspect.

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

INDIA ENGAGEMENT PATH:
Contracting / invoicing: Navira Regulatory Technologies Pvt Ltd (India contracting path subject to CA / legal confirmation).
Delivery: India-led with founder oversight. **Data boundary:** AWS Mumbai unless otherwise agreed.
Data use: sprint data does not train shared models. **Privacy posture:** DPDP-aware data minimisation, purpose limitation, access control, and breach-notification commitments if personal data is processed.

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One conversation. One scoping call.

Decision in two weeks.

01	**Discovery call**	60 minutes with Vimal + your Head of Quality / Plant QA. Workflow shortlist. Dataset boundary. NDA executed if needed.
02	**Sprint proposal**	3-page proposal within 5 business days: workflow, dataset option, roles, timeline, fee.
03	**Phase 0 sign-off**	₹6–8L + GST Evidence Mapping Sprint signed. 10 business days. Workflow map + AI governance gap memo + data-boundary plan + Phase 1 scope.
04	**Phase 1 decision**	Proceed only if the workflow map, data boundary, and evidence plan are clear. If Phase 0 converts into Phase 1 within 30 days, Phase 0 fee may be credited under agreed terms.
05	**Conversion to Phase 2**	If the Phase 1 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 10 business days, you will know:

- where AI governance gaps exist in one GMP workflow;
- what evidence your QA team can show;
- what data boundary is safe;
- whether Verixa deserves a controlled evidence sprint;
- whether a Year-1 governed software evaluation makes sense.

NEXT STEP: **60-minute discovery call.** Decision after that: **₹6–8L + GST Evidence Mapping Sprint.**

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