

verixa

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GMP Design Partner Sprint

One facility. One workflow. 90 days. Measured outcome.

GMP deviation-to-CAPA evidence burden, reviewer rework, and audit-preparation friction — baselined, measured, and resolved or not — in a 90-day founder-led sprint.

India Edition

Implemented codebase. Validation package in progress. Customer validation required before production use.

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23 June 2026 · Confidential — for prospective Design Partners

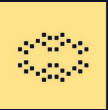
GMP quality teams don't lack forms. They lose time reconstructing defensible evidence.

Deviation · RCA · CAPA · audit prep — work breaks down at the evidence layer

WHAT BREAKS · TODAY

- 1 Investigations take too long to structure.
- 2 RCA quality varies investigator-to-investigator.
- 3 CAPA evidence is hard to link back to risk + root cause.
- 4 Audit prep becomes reconstruction.
- 5 Lean QA teams carry too much manual coordination.

The cost is not just time. It is rework, delayed closure, weak RCA-to-CAPA linkage, and audit-prep scramble.



Before Verixa. After a 90-day GMP sprint.

AI assists. Human decides. Audit trail records. No black-box content generation.

BEFORE · TODAY

- Deviation triage scattered across email, Excel, SOP folders, and investigator memory
- RCA quality depends on investigator skill
- CAPA linkage to risk and root cause is manually reconstructed
- QA reviewers send work back for missing rationale or weak linkage
- Audit-prep evidence is assembled late
- AI use, if any, is ungoverned and hard to explain

AFTER · 90-DAY SPRINT

- One bounded GMP deviation-to-CAPA workflow configured
- Evidence chain captured deviation → risk → RCA → CAPA
- Reviewer trail and AI rationale captured (governed AI · human decides)
- Baseline-to-outcome burden measured
- Governed evidence pack reviewed by QA
- Customer has a clear convert / extend / pause / stop decision

Phase 1 scope: GMP quality events only.

Deliberately narrow. One workflow. One facility. Measured outcome.

INCLUDED

- GMP deviation intake
- Risk assessment support
- RCA structuring
- CAPA evidence pack
- Human review gates
- Audit-preparation evidence
- Traceable AI rationale

EXCLUDED

- Full eQMS replacement
- Autonomous GxP decisions
- Batch release / disposition
- OOS disposition automation
- Validated system-of-record claim
- Broad GCP / GLP / GDP / GVP rollout
- Customer-validated production go-live in Phase 1

SUCCESS MEANS

- Workflow completed end-to-end
- ROI readout delivered
- Evidence pack reviewed by QA
- Validation-support pack reviewed
- Open gaps documented
- Convert / extend / pause / stop decision made

Production go-live is NOT a success criterion.



What you receive in 90 days

Five concrete deliverables tied to measurable burden reduction.

1

Configured workflow One bounded GMP deviation-to-CAPA evidence workflow, set up on your tenant with your roles and approvals.

2

Governed evidence pack Deviation narrative · risk rationale · RCA structure · CAPA linkage · reviewer trail · AI rationale. Built from partner-approved historical, redacted, sample, or controlled cases.

3

Measured ROI readout Baseline-to-outcome comparison for deviation triage effort, RCA structuring effort, CAPA evidence-pack effort, QA rework, evidence completeness, and audit-prep retrieval.

4

Validation-support package URS · risk assessment · RTM · test-script examples · Part 11 / Annex 11 support matrix · AI governance evidence.

5

Open gaps log Documented gaps · proposed closure path · convert / extend / pause / stop recommendation for Day 90.

90-day plan

Baseline → Run → Outcome → Decision.

DAYS 0–15

Baseline + Config

Measure current workflow · define intended use · configure one GMP workflow. Capture baseline metrics across triage, RCA, CAPA, audit-prep, rework, and evidence gaps.

DAYS 15–60

Workflow Run

Run selected GMP cases using partner-approved historical, redacted, sample, or controlled cases. Weekly check-ins · gap log · reviewer + AI rationale captured.

DAYS 60–80

Evidence + ROI Readout

Compare baseline vs sprint-end metrics · produce governed evidence pack · produce ROI readout · gap closure proposals.

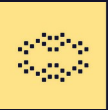
DAYS 80–90

Decision

Convert · extend · pause · stop. Clean handoff regardless. Workflow-fit and burden-reduction evidence delivered.

CUSTOMER COMMITMENT (estimated)

- 1 named Head of Quality or VP Quality as workflow owner · ~3–5 hrs/week
- 1 SME for the bounded workflow · ~5–8 hrs/week during Days 15–60
- Partner-approved historical, redacted, sample, or controlled cases for baseline + run
- QA reviewer time for Day 60–80 evidence-pack review



A measured decision. Not a guaranteed savings claim.

Time · rework · evidence gaps · reviewer acceptance — measured. Then convert · extend · pause · stop.

TIME

- Deviation triage
- RCA drafting
- CAPA evidence-pack prep
- Audit-prep retrieval

REWORK

- Reviewer rework cycles
- Investigation handoff cycles
- Missing-info loops

EVIDENCE GAPS

- Missing evidence per case
- RCA → CAPA linkage gaps
- Risk-rationale completeness

REVIEWER ACCEPTANCE

- QA reviewer accept rate
- Inspection-prep readiness
- Documentation completeness

DAY-90 DECISION RULE

Convert only if measured burden reduction, evidence-quality improvement, and workflow fit justify Year-1 evaluation. **Extend · pause · stop** all remain valid Day-90 outcomes.

The sprint pays for a measured decision, not a demo. Illustrative economics only · partner baseline required · savings are measured during the sprint, not assumed.

Commercial offer

Founding-partner rates · first 2 partners by 31 Dec 2026 · 100% Phase 0 credit · no forced conversion

This is not a demo fee. It funds workflow configuration, baseline measurement, governed evidence-pack production, validation-support documentation, ROI readout, and founder-led adaptation for one GMP workflow.

OPTION 1

Evidence Mapping Sprint

10 business days · ₹3 lakh

Output:

- Workflow scoping memo
- Sample evidence pack template
- Architecture fit assessment
- Phase 1 SoW draft

100% credited to Phase 1 if you convert within 30 days. No forced conversion.

OPTION 2 · RECOMMENDED

GMP Design Partner Sprint

90 days · ₹9 lakh

Includes:

- 1 facility · 1 bounded GMP deviation-to-CAPA workflow
- Configured workflow · governed evidence pack · ROI readout · validation-support pack · gap log
- 12-month controlled evaluation access — subject to customer validation before production use
- Acceptance criteria written into SoW

Expansion path: six GMP evidence packs

After Phase 1 proof. Each pack is bounded, measured, and customer-validation-gated.

1 Inspection prep

Mock-inspection evidence assembly · USFDA / EU-GMP / CDSCO readiness narratives.

2 APQR / PQR

Annual Product Quality Review evidence pack · trend rollup · CAPA tie-back.

3 OOS / OOT investigation

Out-of-spec / out-of-trend evidence chain · 2-step investigation governance.

4 Change control

Change-request evidence · impact assessment · approval trail · CAPA linkage.

5 Supplier quality

Supplier evaluation evidence · qualification trail · ongoing performance review.

6 Training / document evidence

Training-record evidence · controlled-document review · effectiveness check.

Clear responsibility boundary. Built by a GMP QA operator.

Verixa provides workflow controls and evidence. Customer QA owns validation, approval, and production release.

VERIXA PROVIDES

- Implemented workflow controls
- Validation-support documentation
- AI governance evidence
- Traceable workflow output
- Technical support during sprint
- Founder-led configuration guidance

CUSTOMER OWNS

- Intended use
- Validation execution
- QA approval
- SOP approval
- Training records
- Production release decision

FOUNDER

Vimal Veereshwarayya
PhD · RAC

20+ years pharma & biotech. 16+ years QA and Regulatory.

Built by someone who has lived GMP deviation, CAPA, inspection, CSV/CSA, and data-integrity pressure.

No certification claim. No "validated" claim.

Customer validation always required before production use.

Next step

20-minute workflow-fit call. If fit, Phase 0. If no fit, stop.

20-MINUTE WORKFLOW-FIT CALL

One question we answer together:

"Do you have a GMP deviation, RCA, CAPA, or audit-prep workflow where evidence assembly or QA reviewer rework is consuming measurable time?"

If yes → Phase 0 Evidence Mapping Sprint (₹3 lakh · 10 business days · 100% credited to Phase 1).

If no → Stop. We don't push. We re-check in 60–90 days only if you ask.

CONTACT

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Reply to schedule the 20-minute call.

How we compare

Show only if asked. Verixa vs a broad, established eQMS suite.

VERIXA

- Governed, AI-native GxP eQMS
- Architected to EU Annex 22 (draft) / EU AI Act
- Tamper-evident, hash-chained audit trail
- Validation-ready — you own validation
- One bounded workflow, proven in 90 days

BROAD INCUMBENT SUITE

- Mature, many modules incl. LIMS / MES
- AI added on top of a pre-AI core
- Validated, with established references
- Strong on breadth and consolidation
- Heavier, suite-wide deployment

Where they fit: consolidating an existing stack. **Where we fit: a governed AI evidence workflow you can prove in 90 days — built to the AI rules every QMS will face.**