Verixa — Marketing Outreach: Claim-Cleaned Synthesis

Issue 01 newsletter + 4 personalized founder emails · prepared 2026-06-25 · surgical claim-discipline edits only

STATUS — this is a proposed claim-cleaned version, NOT a cleared one.
Banned-term fixes applied per the locked lexicon (see change-log). Your formal claim-review gate still applies before any send: Droupathy first-pass, then Contractor formal review, then Vimal voice approval. Two items still need human confirmation: (1) the FDA CSA Feb-2026 vs 24-Sep-2025 nuance, and (2) registered address + unsubscribe URL in the newsletter footer.

Verification — FDA CSA date

The FDA final guidance “Computer Software Assurance for Production and Quality System Software” was issued 24 September 2025 (verified, fda.gov). A CDRH/CBER version appears in February 2026; the newsletter has been corrected to the 24 Sep 2025 finalization date. Confirm against fda.gov before send if you intend to cite the Feb-2026 version specifically.

Change log — every edit (surgical)

#	Location	Original	Corrected	Reason
N1	Newsletter · Sec 2	FDA CSA — Final Guidance, February 2026	FDA CSA — Final Guidance, issued 24 September 2025	Factual accuracy. FDA finalized the guidance 24 Sep 2025 (verified, fda.gov). A CDRH/CBER version appears Feb 2026 — confirm which the team cites.
N1b	Newsletter · Sec 2	For SaaS QMS platforms specifically	For SaaS QMS software specifically	Remove 'platform' (locked lexicon) even in generic use; no meaning change.
N2	Newsletter · Sec 3	Audit trail export generating an inspector-readable record	Audit trail export generating a complete, exportable record	'inspector-readable' edges toward banned 'inspection-ready'; neutral wording, same meaning.
N3	Newsletter · sign-off	vimal@verixa.ai	vimalv@verixa.ai	Standing sender rule (vimalv@verixa.ai).
E1	Email 1 (Cronus)	we build AI-governed quality management platforms	we build AI-governed quality management systems	'platform' is banned buyer-facing; 'systems' preserves meaning.
E2	Email 1 (Cronus)	Our platform — verified under our SDLC	Our system — verified under our SDLC	'platform' → 'system'.
E3	Email 2 (Zenara)	Verixa is an AI-governed QMS platform	Verixa is an AI-governed QMS	Drop 'platform'.
E3b	Email 2 (Zenara)	companies that want to co-shape the platform	companies that want to co-shape the product	Drop 'platform'.
E4	Email 2 (Zenara)	inspection-ready record export	inspection-preparation evidence export	'inspection-ready' banned; 'inspection-preparation evidence' is the approved term.
E5	Email 3 (Aizant)	most QMS platforms were not built to handle	most quality management systems were not built to handle	Drop 'platform'.
E5b	Email 3 (Aizant)	Our platform gives CDMO quality teams	Our system gives CDMO quality teams	Drop 'platform'.
E6	Email 4 (ScieGen)	Verixa is an AI-governed QMS platform built for exactly this	Verixa is an AI-governed QMS built for exactly this	Drop 'platform'.

#	Location	Original	Corrected	Reason
E4b	Email 4 (ScieGen)	inspection-ready record export	inspection-preparation evidence export	'inspection-ready' banned; approved term substituted.
E7	All 4 emails · sign-off	vimal@verixa.ai	vimalv@verixa.ai	Standing sender rule.

A) Tightened Newsletter — The Verixa Brief, Issue 01

Subject line options (Vimal picks one):

A: What EU GMP Annex 22 actually means for your QMS — and what to do before it becomes law

B: The one question FDA and EMA inspectors will now ask about AI in your quality system

C: AI in GxP: the new rule that changes how your QMS must be designed

Hi [First Name],

The question your management is going to ask you this year is not whether your QMS uses AI. It is whether your AI-assisted quality decisions can survive an inspector's scrutiny. A draft guidance from the EMA just made that question a lot more specific.

Section 1 — Inspection Radar

What is happening in FDA and EMA inspections right now.

Data integrity is now the number one citation category in FDA inspections of Indian pharmaceutical facilities. In 2024 and 2025, facilities across Telangana and Andhra Pradesh received warning letters citing destroyed analytical records, out-of-specification results that were not investigated, and audit trails that did not capture the full decision chain. The pattern is consistent: it is not that the data was always wrong. It is that the system could not prove the data was right.

At the same time, the EMA is signalling a new requirement for facilities using AI or automated decision-support in their quality systems. The message from both regulators is the same: the human decision-maker must be identifiable, traceable, and present in the record at every critical step.

Section 2 — Regulatory Updates

Three updates your QA team needs to know about.

EU GMP Annex 22 — Draft 2025 (AI/ML in GxP) · Still a draft, not yet enforceable law

Annex 22 establishes that AI and machine learning tools used in GMP environments must not make — or be the sole path for — critical GMP decisions. A qualified human must review, approve, and be traceable in the record at every such step. This is what the industry calls Human-in-the-Loop (HITL) governance. What it means for your team: if you are using any AI-assisted deviation triage, RCA suggestion, or CAPA classification tool, you need to be able to show an inspector that a qualified person reviewed and approved every output before it became part of the official record.

FDA Computer Software Assurance (CSA) — Final Guidance, issued 24 September 2025

FDA's final CSA guidance shifts the emphasis from documentation-heavy validation to risk-based assurance of software intended use. For SaaS QMS software specifically, this means the vendor verifies the system works as designed — and your team validates intended use in your own environment. The burden of proof does not disappear. It is redistributed between vendor and user based on risk.

India Schedule M — Revised GMP Standards (2024 onwards)

India's revised Schedule M brings domestic GMP requirements closer to international standards. For mid-tier formulation exporters who operate under both FDA and Schedule M requirements, this means your QMS must now satisfy two regulatory frameworks simultaneously. Deviation management, CAPA traceability, and audit trail requirements are now explicitly mandated under Schedule M, not just implied through international harmonisation.

Section 3 — Verixa Shipped

Scope note: This section describes only what we have demonstrated in a controlled environment. Verixa is verified under our SDLC — the customer validates intended use in their environment.

This month we completed a scripted demonstration of the deviation → RCA → CAPA → audit trail export workflow in a single-tenant environment. The demonstration covered:

- Deviation intake with structured data capture and auto-classification support
- Root cause analysis with MIRA advisory suggestions — each requiring human reviewer sign-off before proceeding
- CAPA creation with traceability back to the originating deviation record
- Audit trail export generating a complete, exportable record with full decision chain, timestamps, and e-signature attribution

MIRA, our AI advisory layer, operates as advisory · human-in-the-loop · not system-of-record. Every MIRA suggestion requires a qualified human to review and approve before it is recorded. This architecture was designed to align with the HITL requirement that EU GMP Annex 22 now makes explicit.

Section 4 — Anonymised Pharma Case

A scenario your team may recognise.

A mid-tier formulation exporter in South India — FDA-registered, actively exporting to the US market — received a Form 483 during a routine inspection. One of the observations cited inadequate investigation of out-of-specification results and failure to trace who approved the CAPA closure and on what basis.

The records existed. The CAPA had been closed. But when the inspector asked: 'Show me who reviewed the root cause, what they concluded, when they approved it, and what evidence they had at the time' — the QA team could not produce a single traceable chain of custody for that decision.

The gap was not in their intent or their process. It was in their system. The system captured the outcome — CAPA closed — but not the decision path that led to closure. Under Annex 22's HITL requirement and FDA's updated data integrity expectations, that gap is the difference between a 483 observation and a clean inspection.

Section 5 — Open Question to Readers

If an FDA inspector asked your QA team to trace the last CAPA your team closed — who approved it, what evidence they reviewed, and when — how long would it take you to produce that record?

Reply to this email. We read every response personally.

Until next issue,

Vimal Veereshwarayya, PhD., RAC

Founder & CEO, Verixa · vimalv@verixa.ai

P.S. If a colleague in your QA or regulatory team would find this useful, forwarding this is the most valuable thing you can do. These issues are rarely solved by one person alone.

B) Personalized Outreach Emails (4) — claim-cleaned

EMAIL 1 of 4 · PRIORITY #1 · CRONUS PHARMA SPECIALITIES INDIA PVT LTD

To: Shravan Kumar Mallisetty · smallisetty@cronuspharma.com · Rangareddy, Hyderabad

Subject line options (Vimal picks one):

1. A question on managing recurrent quality deviations across complex pharma operations
2. How mid-tier Indian exporters are building inspection-resilient quality systems in 2026
3. Verixa — a brief note from the founder on systematic quality control

Dear Shravan,

I am Vimal Veereshwarayya, founder of Verixa — we build AI-governed quality management systems for pharma and biotech teams exporting to regulated markets.

I am reaching out personally because I know the challenge you are navigating. When quality deviations recur across inspection cycles — not as isolated incidents but as a pattern — it usually signals a system problem rather than a people problem. The root cause is rarely the individual event. It is the absence of a connected quality record that makes each deviation and its investigation fully traceable from initial intake through CAPA closure.

Verixa was built to solve exactly this. Our system — verified under our SDLC, with MIRA as an advisory, human-in-the-loop layer — gives QA teams a single connected record across deviation, RCA, CAPA, and audit export, with every human decision timestamped and attributable.

We are opening a small founding design-partner cohort for mid-tier Telangana exporters. If this resonates, I would welcome 20 minutes to share what we have built and understand your current quality infrastructure.

Warm regards,

Vimal Veereshwarayya, PhD., RAC

Founder & CEO, Verixa · vimalv@verixa.ai

P.S. I also sent you our first newsletter on EU GMP Annex 22 and AI governance in quality systems — which I hope is useful independent of any conversation about Verixa.

▸ *Internal angle: recurrent-deviation = system problem. Do NOT reference the 483.*

EMAIL 2 of 4 · PRIORITY #2 · ZENARA PHARMA PRIVATE LIMITED

To: Manik Reddy Pullagurla · manikreddy@biophore.com · Hyderabad

Subject line options (Vimal picks one):

1. Congratulations on the sertraline approval — a question on scaling quality systems with your US portfolio
2. Managing inspection readiness as your FDA ANDA portfolio grows — a note from Verixa
3. Quality infrastructure for a growing US generics pipeline — a brief note

Dear Manik,

Congratulations on the FDA approval for sertraline hydrochloride capsules with 180-day CGT exclusivity — that is a significant milestone and a clear signal that Zenara is serious about building a meaningful US generics presence.

I am Vimal Veereshwarayya, founder of Verixa. I am reaching out because I have seen a pattern across mid-tier Indian generics companies: as the ANDA portfolio grows, the quality system that worked well at a smaller scale starts to show stress — particularly in deviation investigation traceability, CAPA cycle times, and inspection-preparation evidence export. The more ANDAs, the more FDA exposure, the more critical it becomes to have a quality system that can produce a complete evidence trail on demand.

Verixa is an AI-governed QMS — verified under our SDLC, designed specifically for regulated market exporters. Our MIRA advisory layer is human-in-the-loop by design, which aligns with the direction EU GMP Annex 22 is taking AI in pharma quality systems.

We are opening a founding design-partner cohort for mid-tier Telangana exporters — companies that want to co-shape the product and lock in favourable commercial terms early. Would you be open to a 20-minute conversation?

Warm regards,

Vimal Veereshwarayya, PhD., RAC

Founder & CEO, Verixa · vimalv@verixa.ai

P.S. I also sent along our Verixa Brief newsletter — Issue 01 covers EU GMP Annex 22 and what it means for AI-assisted quality decisions. I hope it is useful.

▸ *Internal angle: lead with congratulations; growing portfolio = growing inspection risk. Do NOT reference the 483.*

EMAIL 3 of 4 · PRIORITY #3 · AIZANT DRUG RESEARCH SOLUTIONS PVT LTD

To: Rameshbabu Mattupalli · ramesh.mattupalli@aizant.com · Hyderabad

Subject line options (Vimal picks one):

1. Managing quality traceability across contract pharma clients — a question from Verixa
2. Quality oversight across multi-client CDMO operations — how are you handling it?
3. A note on AI-governed quality management for CDMO operations

Dear Rameshbabu,

I am Vimal Veereshwarayya, founder of Verixa. I am reaching out because contract research and development organisations face a quality management challenge that is genuinely different from single-product manufacturers — and one that most quality management systems were not built to handle well.

When you are running analysis, manufacture, and pack operations across multiple client molecules — each with its own regulatory dossier, its own deviation history, and its own FDA submission trail — the question of how you keep each client's quality evidence intact, traceable, and separable is critical. A single deviation in a shared facility can have implications across multiple client relationships if the record-keeping is not precise.

Verixa was built with this complexity in mind. Our system gives CDMO quality teams a single connected record per workflow — deviation intake, RCA, CAPA, and document export — with every human decision traceable by user, timestamp, and role. Our MIRA advisory layer is human-in-the-loop, not autonomous — which means your QA team stays in control of every quality decision.

We are opening a founding design-partner cohort for mid-tier Telangana operations. I would value 20 minutes to understand your current quality infrastructure and share what we have built.

Warm regards,

Vimal Veereshwarayya, PhD., RAC

Founder & CEO, Verixa · vimalv@verixa.ai

P.S. Our newsletter Issue 01 on EU GMP Annex 22 — the new EMA guidance on AI in pharma quality — is also in your inbox and may be of interest to your team.

▸ *Internal angle: CDMO multi-client complexity. Do NOT reference inspection history.*

EMAIL 4 of 4 · PRIORITY #4 · ScieGen PHARMACEUTICALS INDIA PVT LTD

To: Mayank Sharma · Mayank@sciegenpharm.com · Mahabubnagar, Telangana

Subject line options (Vimal picks one):

1. Building quality traceability for a growing ANDA portfolio — a note from Verixa

2. ANDA portfolio quality management post-recall — how are you structuring your QMS?
3. A conversation on systematic quality documentation for regulated market exporters

Dear Mayank,

I am Vimal Veereshwarayya, founder of Verixa. I am reaching out because ScieGen has built a serious US generics portfolio — gabapentin, rosuvastatin, fluoxetine, irbesartan — and I know that managing quality documentation across an active ANDA pipeline at that scale puts real demands on your quality system.

When a product recall happens — regardless of the root cause — the first thing FDA looks for is whether the quality system detected the issue, documented the investigation, and produced a complete corrective action trail that is traceable from the initial signal all the way through to resolution. That entire chain of evidence needs to be in one place, with every human decision timestamped and attributable.

Verixa is an AI-governed QMS built for exactly this — deviation intake, RCA, CAPA, and inspection-preparation evidence export in a single connected system. Our MIRA advisory layer is human-in-the-loop: it supports your QA team's decisions without replacing human judgement — which is precisely the standard EU GMP Annex 22 is now requiring for AI in pharma quality.

We are opening a founding design-partner cohort for mid-tier Telangana exporters. If you are thinking about your quality infrastructure as your US portfolio continues to grow, I would welcome a 20-minute conversation.

Warm regards,

Vimal Veereshwarayya, PhD., RAC

Founder & CEO, Verixa · vimalv@verixa.ai

P.S. Our newsletter Issue 01 on Annex 22 and AI governance in pharma quality is also in your inbox — relevant reading for any regulated market exporter.

▸ *Internal angle: ANDA portfolio growth. Do NOT reference the recall or OAI.*