verixa

Pricing Strategy — US / Global + India

Inspection-ready, AI-native quality.

AI-native **USFDA-credible** **Bundled validation accelerator** **India-HQ**

Board / Investor Pricing Review · June 2026

Verixa Regulatory Technologies — AI-native eQMS for pharma, biotech & CDMO

EXECUTIVE SUMMARY

Six decisions that define Verixa's pricing posture

1 Vendor-managed AI is the default — no meter

AI is bundled into every tier. No token meter, no $/1K overage. Verixa owns the qualified model, version & change control. The credit/overage engine is deleted from scope.

2 Advisory / HITL = Annex 22 inspection-ready

All Verixa AI is advisory and human-approved — it never approves, closes or releases a GxP record. Marketed as a strength, not a limit.

3 Bundled validation accelerator is the moat

Reduces ~30–60% of the customer's $50K–$150K Year-1 CSV. India-delivered + productized → validation COGS ~1–3% of ACV at mid/enterprise.

4 Three clear segment ACV bands

Emerging biotech $15K–$60K · Mid-market & CDMO $110K–$350K · Enterprise $350K–$1.5M+ — site-anchored, unlimited users in band.

5 India is home market & largest opportunity

396 USFDA-approved facilities. INR-denominated bands (₹10L–₹8Cr) + FX hedging — a differentiator no global vendor offers.

6 Structured paid pilots convert 60-90%

Credit-toward-license pilots (10–20% of ACV, 100% credited) vs. 20–30% for free pilots. AI bundled & advisory in pilot.

Source: CloudTheApp · CareEdge · SaaStr · RegASK (Annex 22)

MARKET CONTEXT

A $9.5B market by 2033 — with no published price architecture

$3.27B → $9.47B

Life-sciences QMS software market, 2024 → 2033

12.65%

CAGR 2024–2033

77%

cloud / SaaS share of revenue

Price bands span $12K–$500K+ ACV — every meaningful vendor is quote-only.

THE UNPUBLISHED PRICE ARCHITECTURE

Enterprise / Legacy

Veeva, TrackWise, ETQ, MasterControl

$200K – $1M+

Mid-Market

MasterControl SMB, Ideagen, Dot Compliance, AmpleLogic

$50K – $250K

Growth / SMB

Qualio, Greenlight Guru, SimplerQMS, ZenQMS, Scilife

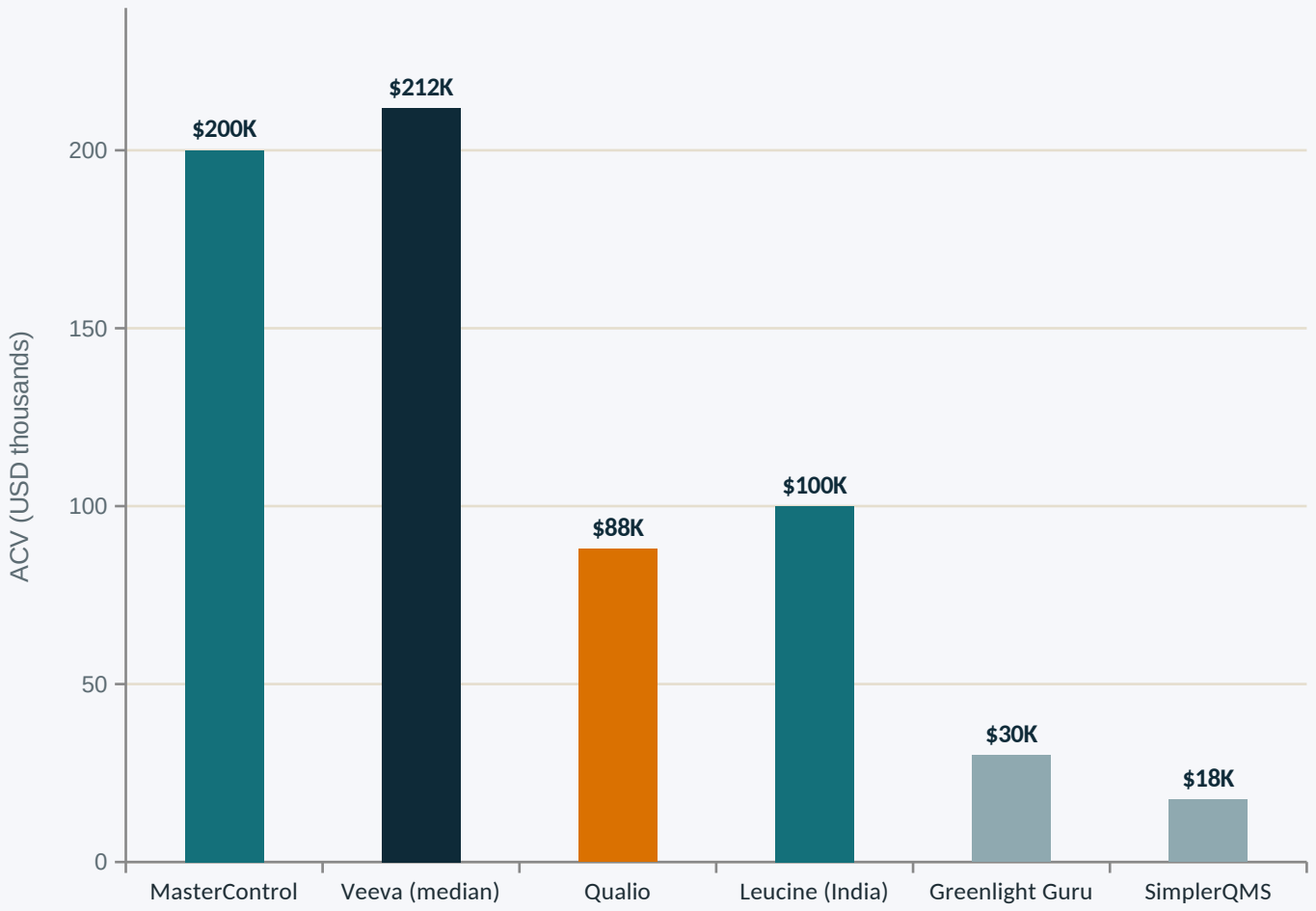
$12K – $80K

Cloud/SaaS = 77% of revenue · Pharma = 57% of end-use spend · North America ≈ 40%.

Source: Grand View Research · SimplerQMS · Capterra

COMPETITIVE LANDSCAPE

We don't price AI by the token either — we bundle it and win on validation



The white space

No competitor publishes a standalone AI price increment. AI is bundled, tier-gated, or announced-but-unpriced everywhere.

Verixa's answer: bundle AI (no meter), and compete on managed validation + workflow.

Published anchors to beat

- MasterControl ~$200K avg ACV ($25K Basic published)
- Veeva median ACV $211,872 (range $113K–$501K)
- SimplerQMS $17,500/yr — validation included
- Caliber LIMS (India) ₹1.5L/user/yr (~$1,807)

Source: Vendr (Veeva) · GetLatka (MasterControl) · MasterControl · SimplerQMS · Economic Times (Leucine)

THE VALIDATION MOAT

Bundled validation accelerator: invisible to buyers, lethal to incumbents

WHAT THE BUYER SEES vs. WHAT THEY ACTUALLY PAY

Subscription line item
(the visible tip)

waterline

$50K – $150K

Year-1 CSV (IQ/OQ/PQ) — non-waivable GxP cost
(up to $250K+ for complex enterprise)

+ $15K – $60K / yr ongoing revalidation

"Never appears in a vendor's pricing sheet."

Productized + India-delivered = the margin engine

Verixa bundles it

Pre-built, continuously-maintained IQ/OQ/PQ evidence reduces ~30–60% of the customer's biggest hidden cost — the highest switching cost in the category.

~1–3% of ACV

Productized + India-cost delivery drives validation COGS to ~1–3% of ACV at mid-market & enterprise — the structural margin engine.

~24–55 person-day floor

Verify-not-validate: the customer keeps an irreducible PQ/UAT, URS, SOP & sign-off floor no accelerator removes. Verixa accelerates; it does not validate for the customer.

Source: CloudTheApp

WILLINGNESS TO PAY

Buyers pay for cost-of-failure, not efficiency — the FDA "15% Rule"

≥ 15%

of a business unit's revenue is the minimum cost to remediate an FDA Warning Letter

→

$200M co.

facing a Warning Letter →

→

$30M+

exposure to remediation cost

→

0.3–0.5%

a $100K–$150K eQMS is a trivial fraction of that risk

Why this reframes every tier

- Validated in practice: LifeScan ~17% of $750M; Cordis 13–17% of $3–4B.
- Single-facility 483 remediation can run $1.5M+ over 9+ months; CDER warning letters rose 59% in FY2025.
- Lead pricing narrative with inspection-outcome & warning-letter avoidance — not productivity.
- Budget owner shifts by tier: Head of Quality → VP Quality + IT → CQO + CIO + CFO.

Source: Compliance Architects · CloudTheApp

VALUE METRIC

Price the manufacturing site — not the seat

Site / facility is the primary value metric.

Unlimited users inside the band.

Site-count maps to procurement authority, scales with operational complexity, and speaks pharma/CDMO vocabulary — without taxing the small QA team.

WHY NOT PER-SEAT?

Pharma QA teams are small (5–50 users)

but compliance value spans the whole operation — per-seat caps growth on a narrow base.

Per-seat triggers the "AI tax" problem

Charging per user for AI-heavy work penalizes adoption exactly where Verixa wants it to spread.

Site-count = the procurement unit

It aligns to how pharma & CDMO buyers budget, and scales naturally with sites, modules & risk.

Recommended structure: site-anchored base + modular expansion + bundled managed validation + bundled (un-metered) AI.

Emerging / Clinical-Stage Biotech

TARGET ACV

$15K – $60K

PROFILE

- <100 employees
- 1–2 sites
- Series A–C funding
- Buyer: Head of Quality

PACKAGING & TIERS

Starter

$15–25K

≤10 users · Doc Control + CAPA + Deviations · bundled validation accelerator + bundled AI

Growth

$35–60K

≤25 users · adds Supplier Quality, Audit, Training & Change Control

Validation: Bundled validation accelerator included; managed execution is a paid add-on; guard the Starter floor.

Commit: Annual prepay preferred; resist bespoke validation at the low end.

Source: CloudTheApp · SimplerQMS

Mid-Market Pharma & CDMO

TARGET ACV

$110K – $350K

PROFILE

- $50M–$500M revenue
- 2–5 sites
- Buyer: VP Quality + IT co-approver
- ROI-literate

PACKAGING & TIERS

Per-site base

Unlimited users · core QMS · bundled validation accelerator + bundled AI

$30–60K /site

Module add-ons

Per module, per site — expand scope as the operation grows

$8–20K /module

Multi-site discount

10% for 2–5 sites · 15% for 6+ sites

10% / 15%

Validation: Bundled validation accelerator (managed execution add-on); COGS ~1–3% of ACV at this scale.

Commit: Multi-year deals; per-site expansion is the growth path.

Source: Vendr (Veeva) · GetLatka (MasterControl) · CloudTheApp

Enterprise Pharma

TARGET ACV

$350K – $1.5M+

PROFILE

- Top-50 pharma
- 5+ global sites
- $500M+ revenue
- Buyer: CQO + CIO + CFO

PACKAGING & TIERS

5–10 sites

Site-count band · unlimited users · global managed validation + bundled AI

$300–500K

11–25 sites

Multi-region rollout, harmonized SOPs & evidence libraries

$500–800K

26–50 sites

50+ sites: negotiated enterprise agreement

$800K–1.2M

Validation: Global managed validation across sites; the highest switching cost.

Commit: 3–5 yr deals with CPI escalators; enter ~10–30% below incumbents.

Source: Vendr (Veeva) · MasterControl · CloudTheApp

INDIA OPPORTUNITY

Home market and single largest opportunity — priced in INR

396

USFDA-approved facilities — more than any country outside the US (342)

+73%

surge in USFDA warning letters, H2 2025, as unannounced inspections began

Schedule M

Revised Schedule M now mandates eBMR, ALCOA+ and digital CAPA — a near-term spend trigger

CDMO = the India beachhead

- Dual CDSCO + global-client compliance pressure
- Mid-market sweet spot with ROI-literate buyers
- India CDMO market $7.9B–$23.3B, 13.2% CAGR — a favorable 2024–2027 window

The INR-contract differentiator

- INR-denominated contracts with built-in FX hedging — no global vendor matches this
- Revised Schedule M is a direct, near-term spend trigger for domestic manufacturers
- India-HQ must NOT signal a discount in export/US markets — price at value parity there

Source: CareEdge · Reed Smith · iFactory (Schedule M)

INDIA PRICING DETAIL

Three INR / USD bands — premium to India tools, below global incumbents

India Segment	Verixa India ACV	Positioning
Emerging biotech / early CDMO 1–3 sites, <50 users	**₹10–30 lakh ($12K–$36K)**	Entry; monthly option; Revised Schedule M trigger
Mid-market pharma / CDMO 3–10 sites, 50–200 users	**₹30–150 lakh ($36K–$181K)**	Core segment; vs AmpleLogic & Leucine
Enterprise pharma 10+ sites, 200+ users, USFDA-reg	**₹1.5–8 crore ($180K–$960K)**	~40–50% savings vs Veeva / MasterControl

Positioning vs peers

AmpleLogic (India)

claims 30–40% cheaper than US/EU — we sit above, on AI-native value

Leucine (India, AI-native)

~$100K ACV, rising toward $300–400K

Caliber LIMS (India)

₹1.5 lakh/user/yr (~$1,807) — seat-priced; we price per site

Pricing principle: premium to India-only vendors, meaningfully below Veeva/MasterControl — not a price war with AmpleLogic. INR contracts + FX hedging are the wedge no global vendor offers.

Source: Economic Times (Leucine) · Capterra (Caliber LIMS) · Vendr (Veeva)

THE CORE POSITION

AI & Governance: inspection-ready by design

1 Vendor-managed AI — the default

AI is bundled into every tier. NO token meter, NO $/1K overage. Verixa owns the qualified model + version, change control and audit trail. The credit/overage engine is deleted from scope.

2 Advisory / human-in-the-loop only

Verixa AI never approves, closes or releases a GxP record. "Inspection-ready by design — advisory, human-approved, version-controlled." This is Annex 22 compliance AND the strongest selling point.

3 One upsell: AI premium-capability tier

Investigation autopilot, CAPA-draft depth, predictive analytics — priced on CAPABILITY DEPTH, not tokens, not outcomes. Treat as a pilot willingness-to-pay HYPOTHESIS — not committed ARR.

4 BYOK — benched to P2, demand-gated

Built only against a signed enterprise procurement condition: large-enterprise only (>$500M, own provider account + AI-governance function), HITL/non-critical use, NO discount, 9-condition attestation. Not a current offering.

PIC/S Annex 22 (AI), 7 Jul 2025: restricts CRITICAL GMP apps to static/deterministic models (LLMs excluded from critical use); enforcement ~2027–28. **FDA CSA, final 3 Feb 2026:** validated state must be maintained across vendor/model changes — vendor supplies the change docs.

Source: RegASK · Qualifyze · FDA CSA Guidance · NSF

PILOT → PAID

Credit-toward-license pilots convert at 60–90%

The credit-toward-license offer

$25K – $50K pilot

= 10–20% of target ACV

100% credited

to the Year-1 contract on conversion

90 – 120 days

duration; run CSV & security review in parallel

AI: vendor-managed

bundled, advisory/HITL only — spend cap on Verixa's provider account

CONVERSION BENCHMARKS

Validation = verify-not-validate

Validation is OUT of the pilot. Verixa verifies the build; the customer validates for intended use. Do NOT claim full IQ/OQ in scope. No BYOK in pilot.

Source: SaaStr · Pulse RevOps

RECOMMENDATIONS

What to commit now — and what to validate

COMMIT NOW

- Ship vendor-managed, bundled AI as the default — no meter, no overage, across all segments.
- Lead every pitch with advisory/HITL = Annex 22 inspection-ready positioning.
- Make the bundled validation accelerator the headline moat; guard the Starter floor.
- Adopt the three US ACV bands and the three India INR bands; price India in INR with FX hedging.
- Make CDMO the India beachhead; hold value parity in export/US markets (no India discount).
- Run structured, credit-toward-license paid pilots (90–120 days), validation verify-not-validate.

VALIDATE (NOT COMMIT)

AI premium-capability tier WTP

Treat the premium AI tier price as a pilot willingness-to-pay HYPOTHESIS — measured in pilots, never booked as committed ARR until validated.

BYOK demand signal

Keep BYOK benched to P2 — build only against a signed enterprise procurement condition with the 9-condition attestation.

Starter-tier margin

Watch validation COGS as a share of ACV while the install base is still small.

Inspection-ready, AI-native quality.