AVERY & RILEY

Prepared for market education · not a buying recommendation

AI Vendor Pulse

An advisory briefing on AI vendors selling into pharma & biotech

ISSUE 02 BEYOND THE TRIAL: THE GXP BACKBONE

Glean
Enterprise AI search / Work AI

Adlib
Document & content intelligence

Ketryx
Validated software / compliance automation

TrackWise
Enterprise quality management (Honeywell)

MasterControl
Quality + manufacturing (eQMS + MES)

Some companies referenced may be current, former, or prospective advisory relationships of Avery & Riley; others are included independently for informational purposes. All data is publicly sourced unless otherwise noted.

WHY THIS ISSUE EXISTS

Issue 01 looked at the trial. This issue looks at the systems that keep the company compliant.

After the clinical trial comes the **GxP backbone** — the quality, compliance, document, and knowledge systems every regulated company runs on. AI is now moving into these **systems of record**: quality events, validation, batch records, controlled documents, and institutional knowledge. The stakes are different here — this is controlled, inspected, Part-11 territory.

WHAT SENIOR LEADERS SHOULD WATCH

01

AI is moving from the trial **into the systems of record** — QMS, validation, batch records, controlled documents, and enterprise knowledge.

02

In GxP, **the compliance bar now applies to the AI itself**: look for human-in-the-loop, audit trails, permission-aware access, and validation — not just capability.

03

The strongest plays tie a concrete compliance workflow — CAPA, change control, batch release, document control, CSV — to **measurable cycle-time or effort reduction** they can prove under inspection.

THE MEASURING STICK

The Avery & Riley GxP quality, compliance & knowledge stack

Coverage bars throughout this issue map each vendor against the ten domains below — a **directional, point-in-time read** of where a vendor appears to operate, based on the latest publicly known data. These are not vendor-reported metrics and not a buying recommendation.

Q01 Knowledge & enterprise search

Q02 Document rendering & extraction

Q03 Controlled-document management

Q04 Quality events (deviation / CAPA / complaint)

Q05 Change control & risk management

Q06 Audit & inspection readiness

Q07 Training & competency

Q08 Manufacturing & batch records

Q09 Software & system validation (CSV/CSA)

Q10 AI/ML governance & validation



GXP-STACK COVERAGE SNAPSHOT

Where each vendor appears to play across the stack

Vendor	Q01	Q02	Q03	Q04	Q05	Q06	Q07	Q08	Q09	Q10	Coverage
Glean Enterprise AI search / Work AI	■					■				■	3 /10
Adlib Document & content intelligence		■	■			■		■			4 /10
Ketryx Validated software / compliance automation					■	■			■	■	4 /10
TrackWise Enterprise QMS · Honeywell			■	■	■	■	■				5 /10
MasterControl Quality + manufacturing (eQMS + MES)			■	■	■	■	■	■			6 /10

Coverage reads change as vendors add modules, expand partnerships, publish new customer evidence, or reposition products. ■ Q10 AI/ML governance shown in gold — the issue's defining theme. This is a snapshot of the latest publicly known data and Avery & Riley database records available during preparation.

THE SENIOR-LEADER VIEW

Executive market map

VENDOR	PRIMARY CATEGORY	PROBLEM(S) TARGETED	PUBLIC OUTCOME SIGNAL
Glean	**Enterprise AI search / Work AI**	Knowledge fragmented across quality, regulatory, clinical & manufacturing systems; time lost finding SOPs and answers; slow onboarding.	**141%** ROI, <6-month payback; **60 hrs/user/yr** saved on search; **15,000+ hrs/mo** saved (Confluent).
Adlib	**Document & content intelligence (IDP)**	Unstructured regulatory & quality content; eCTD submission prep; document-of-record fidelity across TMF/RIM/QMS/MES; AI-ready extraction.	**50%** less submission prep; **30%** faster trial startup & close-out; **25%** faster batch-release cycles.
Ketryx	**Validated software dev / compliance automation**	Software & CSV validation burden; live requirements-to-code-to-test traceability; change-impact bottlenecks; releasing compliant software & AI.	**70%** less change-impact time (90% AI accuracy); **up to 90%** less documentation time / 10× faster; **60%** shorter doc cycle.
TrackWise	**Enterprise quality management (eQMS) · Honeywell**	Slow deviation / CAPA handling; complaint triage; audit & inspection readiness; change and document control across global sites.	**53%** faster CAPA closure; **9%** shorter change lead time; **25,000+** docs digitized / 400+ audits-yr / 17 sites (SGS).
MasterControl	**Quality + manufacturing (eQMS + MES)**	Paper document control & batch records; deviations / CAPA; training; slow post-production review; audit readiness.	**80%** faster post-production review; **21%** fewer deviations; review **10–15 days → 72 hrs** (Wellington Foods).

Outcome signals are public claims summarized from the cited vendor profiles that follow — not independently validated performance guarantees.

Glean

GXP-STACK COVERAGE
3/10

ENTERPRISE AI SEARCH / WORK AI

Targets: *Knowledge fragmented across regulated systems; time lost finding controlled documents and answers; slow onboarding.*

WHAT THEY DO

- Work AI platform unifying permission-aware enterprise search, an AI assistant, and AI agents over a company-wide knowledge graph with 100+ connectors.[1]
- Healthcare / life-sciences offering with HIPAA and SOC 2, plus a GxP validation path via USDM Life Sciences.[2]

OPERATIONAL PROBLEMS ADDRESSED

- Knowledge siloed across quality, regulatory, clinical, manufacturing, and IT systems.
- Time lost searching for SOPs, study documents, and answers across apps.
- Slow onboarding and time-to-effectiveness in complex regulated orgs.
- Permission-aware, traceable access so AI answers respect document entitlements.

GXP-STACK COVERAGE — AVERY & RILEY SNAPSHOT

Q01 · Q06 · Q10

Q01	Q02	Q03	Q04	Q05	Q06	Q07	Q08	Q09	Q10
■					■				■

141% ROI[3]
Composite Forrester TEI, with <6-month payback

60 hrs[3]
Per user / year saved on search (Forrester TEI)

15,000+ hrs[4]
Saved per month at Confluent (named customer)

SENIOR-LEADER READOUT

Coverage concentrates in enterprise knowledge & search, with audit-ready access governance and AI/data-governance reporting — three of the ten domains.

Public proof is strong on horizontal ROI (Forrester, named customers); named pharma-customer metrics remain limited, with GxP fit established through validation partners.

Public claims; not independently validated. Not a buying recommendation.

Adlib

GXP-STACK COVERAGE

4 /10

DOCUMENT & CONTENT INTELLIGENCE (IDP)

Targets: *Unstructured regulatory & quality content; submission prep; document-of-record fidelity; AI-ready data extraction.*

WHAT THEY DO

- Advanced rendering engine converting 400+ file types into compliant, archive-ready PDFs, plus Transform for OCR, classification, and data extraction.[5]
- AI document intelligence — bring-your-own-LLM (AiLink), Model Context Protocol support, AI redaction, and a multi-LLM accuracy score.[6]

OPERATIONAL PROBLEMS ADDRESSED

- Standardizing regulatory documents into eCTD for health-authority submissions.
- Taming unstructured clinical-trial and quality content into inspection-ready records.
- Document-of-record fidelity across TMF, RIM, QMS, and MES.
- Producing structured, AI-ready data from messy source documents.

GXP-STACK COVERAGE — AVERY & RILEY SNAPSHOT

Q02 · Q03 · Q06 · Q08

Q01	**Q02**	**Q03**	Q04	Q05	**Q06**	Q07	**Q08**	Q09	Q10

50%[5]

Less manual submission prep (vendor claim)

30%[5]

Faster clinical-trial startup & close-out (vendor)

25%[5]

Faster batch-release cycles (vendor)

SENIOR-LEADER READOUT

Coverage concentrates in the document layer — rendering, extraction, controlled-document feed, and batch-record fidelity — four of the ten domains; it powers the PDF engine behind ~98–99% of MasterControl customers.[7]

Outcome signals are vendor-published percentages; named-customer figures are largely narrative.

Ketryx

GXP-STACK COVERAGE

4 /10

VALIDATED SOFTWARE / COMPLIANCE AUTOMATION

Targets: *Software & CSV validation burden; live traceability; change-impact bottlenecks; releasing compliant software and AI.*

WHAT THEY DO

- AI-native ALM + eQMS bridging dev tools (Jira, GitHub) to regulatory requirements, with real-time traceability and auto-generated design/development files.[8]
- "Validated AI agents" that draft documentation, assess change impact, and flag compliance gaps under Part-11 human-in-the-loop approval.[9]

OPERATIONAL PROBLEMS ADDRESSED

- Crushing software / CSV validation and documentation burden.
- Maintaining live requirements-to-code-to-test traceability as products change.
- Slow, SME-bottlenecked change-impact assessments.
- Releasing compliant software and AI/ML devices fast enough.

GXP-STACK COVERAGE — AVERY & RILEY SNAPSHOT

Q05 · Q06 · Q09 · Q10

Q01	Q02	Q03	Q04	**Q05**	**Q06**	Q07	Q08	**Q09**	**Q10**

70%[10]

Less change-impact time, 90% AI accuracy (Cytovale)

Up to 90%[8]

Less documentation time / 10× faster (vendor)

60%[11]

Shorter documentation cycle (Vektor Medical)

SENIOR-LEADER READOUT

Coverage centers on validation and AI/ML governance, plus change & risk and inspection readiness — four of the ten domains. Uniquely, it exists to **validate** AI and software, not just to apply AI.

Strongest named-customer proof here (Cytovale, Vektor Medical); the headline 90% / 10× figures are vendor claims.

TrackWise

GXP-STACK COVERAGE
5 /10

ENTERPRISE QUALITY MANAGEMENT (EQMS) · HONEYWELL

Targets: *Slow deviation / CAPA handling; complaint triage; audit & inspection readiness; change and document control across global sites.*

WHAT THEY DO

- TrackWise Digital cloud eQMS spanning deviations, CAPA, complaints, audits, change control, and document / training management.[12]
- TrackWise AI (QualityWise.ai): auto-categorization, generative summarization, and a Root Cause Advisor, kept human-in-the-loop.[13]

OPERATIONAL PROBLEMS ADDRESSED

- Slow quality-event / deviation handling and investigations.
- Long CAPA cycle times and manual workflow routing.
- Complaint intake, triage, and categorization at scale.
- Audit and inspection readiness across global, multi-site operations.

GXP-STACK COVERAGE — AVERY & RILEY SNAPSHOT

Q03 · Q04 · Q05 · Q06 · Q07

Q01	Q02	**Q03**	**Q04**	**Q05**	**Q06**	**Q07**	Q08	Q09	Q10

53%[14]
Faster CAPA closure cycle (Orion, named customer)

9%[14]
Shorter change-management lead time (Orion)

25,000+[12]
Documents digitized; 400+ audits/yr; 17 sites (SGS)

SENIOR-LEADER READOUT

Coverage spans controlled documents, quality events, change & risk, audit readiness, and training — five of the ten domains; one of the most entrenched eQMS platforms in pharma.[15]

Outcome metrics are named-customer cases; the AI features are recent and explicitly human-in-the-loop.

MasterControl

GXP-STACK COVERAGE
6 /10

QUALITY + MANUFACTURING (EQMS + MES)

Targets: *Paper document control & batch records; deviations / CAPA; training; slow post-production review; audit readiness.*

WHAT THEY DO

- Quality Excellence (document control, change, training, deviations / CAPA, audits) plus Manufacturing Excellence for electronic batch records and paperless production.[16]
- GxPAssist generative-AI suite — document summarizer, translator, and training-exam generator, on customized LLMs.[17]

OPERATIONAL PROBLEMS ADDRESSED

- Manual / paper document control, versioning, and e-signatures.
- Training assignment and comprehension tracking tied to procedures.
- Deviation, CAPA, and quality-event management.
- Paper batch records and slow post-production review.

GXP-STACK COVERAGE — AVERY & RILEY SNAPSHOT

Q03 · Q04 · Q05 · Q06 · Q07 · Q08

Q01	Q02	**Q03**	**Q04**	**Q05**	**Q06**	**Q07**	**Q08**	Q09	Q10

80%[16]
Faster post-production review (vendor, Mfg. Excellence)

21%[16]
Fewer deviations (vendor aggregate claim)

10–15d → 72h[18]
Post-production review time (Wellington Foods)

SENIOR-LEADER READOUT

Broadest footprint here — six of the ten domains — spanning both quality (eQMS) and manufacturing (EBR / MES); a connected-quality play, not a point tool.

Aggregate percentages are vendor claims; Wellington Foods and Fagron provide named-customer proof.[19]

CROSS-VENDOR PATTERNS FOR SENIOR LEADERS

Three patterns to carry into your diligence

01

AI is entering the system of record

Not just productivity tools — AI is moving into the QMS, MES, validation, and controlled-document systems that inspections actually examine.

02

Governance is the product

Permission-aware access, human-in-the-loop, audit trails, and validation are table stakes — and one vendor, Ketryx, exists to validate AI itself.

03

The layers are converging

Knowledge → documents → quality / manufacturing → validation increasingly interconnect; coverage bars are a snapshot, not a fixed boundary.

THE BOTTOM LINE FOR ADOPTION

"Which compliance bottleneck is costly, measurable, and governable enough that an AI-assisted system can earn a place inside your validated environment?" — that question, not vendor novelty, should drive the next conversation.

HOW TO USE THIS ISSUE

From market read to executive diligence

EXECUTIVE DILIGENCE QUESTIONS

- Which compliance or knowledge bottleneck is being solved — and what does it cost today in cycle time, headcount, or inspection risk?
- Is the evidence a named customer case, a vendor claim, or a commissioned study?
- What is the validation and Part-11 story — audit trail, human-in-the-loop, access control, and data integrity?
- How does the AI itself get governed and validated for use in a GxP environment?

SUGGESTED CATEGORIES FOR FUTURE ISSUES

- Regulatory information management (RIM) & submissions
- Pharmacovigilance & safety
- Manufacturing intelligence & MES
- Computer system validation (CSV / CSA) automation
- Enterprise knowledge & agentic workflows

Source standard. *All data is publicly sourced unless otherwise noted. Public claims are summarized from vendor websites, customer stories, announcements, commissioned studies, or industry-publication summaries and should not be treated as independently validated performance guarantees.*

REFERENCES & SOURCES

References

Reference numbers are assigned by first appearance in the body and shown as sequential superscripts throughout this issue.

1 Glean, "Work AI platform / product overview," company website.

2 Glean, "Healthcare & Life Sciences," and USDM Life Sciences GxP partnership materials.

3 Forrester, "The Total Economic Impact of Glean" (Glean-commissioned study).

4 Glean customer story, "Confluent."

5 Adlib, "Life Sciences," company website (submission, trial, and batch-release claims).

6 Adlib, document-automation / Transform materials describing AI, MCP, and AiLink.

7 Adlib–MasterControl case study, "Staying compliant and increasing speed to market."

8 Ketryx, company website / product (documentation-time and 10× claims).

9 Ketryx / PR Newswire, "Ketryx launches first validated AI agents," launch announcement.

10 Ketryx, Cytovale change-impact case study.

11 Ketryx, Vektor Medical case study.

12 Honeywell / Sparta Systems, "TrackWise," product page (incl. SGS deployment).

13 Sparta Systems, "QualityWise.ai / TrackWise AI" materials.

14 Sparta Systems, Orion case study (CAPA and change-management claims).

15 Honeywell, Sparta Systems acquisition press release, December 2020.

16 MasterControl, "Manufacturing Excellence," company website.

17 MasterControl, "GxPAssist AI generally available," announcement.

18 MasterControl, Wellington Foods case study.

19 MasterControl, Fagron case study / Quality (QMS) overview.

Disclosure: Some companies referenced may be current, former, or prospective advisory relationships of Avery & Riley; others are included independently for informational purposes. GxP-stack coverage reads use Avery & Riley's vendor framework compiled from public materials and directory review; they are a snapshot as of the latest publicly known data and may change as vendors add, discontinue, or reposition capabilities.