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AI Vendor Pulse

An advisory briefing on AI vendors selling into pharma & biotech

ISSUE 18 THE PLANT FLOOR GOES AGENTIC — AI IN CMC, PROCESS DEVELOPMENT & GMP MANUFACTURING

Apprentice.io	Aizon	QbDVision	Basetwo	Katalyze AI
Pharma MES + agentic AI	GxP AI + AI batch records	Digital CMC + lifecycle	Physics-informed process AI	Agentic plant-floor operations

Companies featured in this issue may include current or prospective advisory relationships of Avery & Riley. All data is publicly sourced unless otherwise noted; company-stated claims are labeled as such throughout.

WHY THIS ISSUE EXISTS

The plant floor is going agentic — AI moves into the batch record and the CMC file

CMC and manufacturing are the quiet critical path of drug development: nothing is filed, launched or supplied without a process that is characterized, transferred and run under GMP — much of it still on paper batch records, spreadsheets and siloed lab systems. In 2025–26 the rules started to form. FDA's January 2025 draft guidance put a risk-based credibility framework around AI that informs product quality, with manufacturing in scope,[1] and the European Commission opened consultation on Annex 22, the first GMP annex dedicated to AI.[2] This issue maps five vendors bringing AI to the plant and the CMC record.

WHAT SENIOR LEADERS SHOULD WATCH

01

The batch record becomes the AI surface. Vendors are embedding agents where GMP data is created — agentic features in a pharma MES[3] and AI-built electronic batch records.[4]

02

Credibility is the new validation conversation. Regulators frame AI by context of use and model risk; vendors are answering with credibility frameworks of their own.[5] Ask for the evidence pack, not the demo.

03

Capital and consolidation move together. AI-native challengers raised fresh rounds — $11.5M[6] and $10.5M[7] — while an MES player bought a lab-data platform to span R&D to commercial.[8]

The Avery & Riley 10-stage clinical-development taxonomy

Coverage bars throughout this issue map each vendor against the ten trial-lifecycle stages below — a **directional, point-in-time read** of where a vendor appears to operate. Each lit stage is colored by **source class** — **teal** where coverage is publicly documented (named customers or third-party sources), **gold** where coverage is company-stated. This cohort sits largely outside trial operations: we light **P06** where a vendor supports clinical-supply and development-scale manufacturing, and **P10** where it carries a product into commercial scale-up and lifecycle CMC. Sparse footprints are the finding, not a gap.

P01 Portfolio / indication strategy	**P02** Protocol design / feasibility	**P03** Site identification / selection	**P04** Study startup	**P05** Recruitment / enrollment
P06 Study conduct / execution	**P07** Monitoring / oversight	**P08** Data management / cleaning / DBL	**P09** Close-out / TMF / inspection readiness	**P10** Post-trial insights / evidence



Directional reads from public materials & directory review — a snapshot, not vendor-reported metrics.

LIFECYCLE FOOTPRINT SNAPSHOT

Where each CMC vendor touches the trial lifecycle

VENDOR	P01	P02	P03	P04	P05	P06	P07	P08	P09	P10	FOOTPRINT
Apprentice.io Pharma MES + agentic AI						■				■	2/10
Aizon GxP AI + AI batch records						■				■	2/10
QbDVision Digital CMC + lifecycle						■				■	2/10
Basetwo Physics-informed process AI						■				■	2/10
Katalyze AI Agentic plant-floor operations						■				■	2/10

■ Publicly documented (named customer / third-party) ■ Company-stated positioning

The cohort clusters where manufacturing meets development: clinical-supply and development-scale production (P06) and commercial scale-up and lifecycle CMC (P10); teal at P10 reflects a named commercial customer. Footprint counts the stages a vendor is positioned to touch; a directional, point-in-time read, not a ranking.

Executive market map

VENDOR	PRIMARY CATEGORY	PROBLEM(S) TARGETED	PUBLIC EVIDENCE SIGNAL
Apprentice.io	Pharma MES + agentic AI	Tech transfer, batch execution and release from R&D to commercial scale.	**Scaled challenger.** Agentic Tempo release (2025);[3] Ganymede acquired Jan 2026;[8] 15 of top-20 pharma (co-stated).[9]
Aizon	GxP AI + AI batch records	Paper batch records, yield loss and deviation drag in GMP plants.	**Documented customer.** EUROAPI launch customer;[10] $20M Series C (Feb 2024);[11] Sequence partnership (Jun 2025).[12]
QbDVision	Digital CMC + product lifecycle	CMC knowledge locked in documents; slow tech transfer and CMC change.	**Documented funding.** $13M (May 2025);[13] 3 of top-6 pharma/biotech customers (co-stated);[14] CAMP AI-credibility framework.[5]
Basetwo	Physics-informed process AI	Cycle time, raw-material waste and scale-up in process manufacturing.	**Early-stage.** $11.5M Series A, AVP-led (Jan 2025);[6] up to 40% cycle-time gains (co-stated).[15]
Katalyze AI	Agentic plant-floor operations	Deviation investigations and root cause across MES, QMS and LIMS.	**Newest entrant.** Katalyst agent (Jan 2026);[16] $10.5M seed (Jul 2026);[17] 5 of top-20 pharma (co-stated).[18]

Signals summarize public materials as of the cited profiles that follow; company-stated claims are labeled as such (co-stated).

Apprentice.io

PHARMA MES + AGENTIC AI

Targets: *Data silos that slow tech transfer from R&D into GMP production and stretch batch review and release across disconnected systems.*

WHAT THEY DO

- Tempo Manufacturing Cloud is a GxP SaaS manufacturing execution system — recipe authoring, sampling and lab execution, batch-data aggregation for release, and multi-site production planning (company-stated).[19]
- Agentic AI for Tempo was unveiled in April 2025;[20] analyst firm Axendia reported agents in a customer beta, with general release targeted for Tempo v7.6.1 in late 2025.[3]

COMPANY & BACKING

- Jersey City, NJ; raised $65M in March 2023.[21] On Jan 21, 2026 it acquired lab and process-data platform Ganymede to span R&D through commercial manufacturing (terms undisclosed).[8]
- Named customers include cell- and gene-therapy CDMO Minaris Regenerative Medicine, which selected Tempo to scale commercial production;[22] Aprecia partnership on 3D-printed drug manufacturing (Sep 2025, company-stated).[23]

LIFECYCLE FOOTPRINT — MANUFACTURING EXECUTION, CLINICAL-TO-COMMERCIAL

P06 · P10

P01	P02	P03	P04	P05	**P06**	P07	P08	P09	**P10**

15 of 20[9]
Top-20 pharma companies using its technology (company-stated)

$65M[21]
Financing round, March 2023

Jan 2026[8]
Ganymede acquired — lab data joins the MES

SENIOR-LEADER READOUT

The most enterprise-scaled challenger in the cohort: the MES is where GMP data is born, and Apprentice is putting agents inside it.

Engage when a tech transfer or new facility forces an MES decision — and ask how agent actions are bounded, validated and audit-trailed.

Company-stated claims summarized from public materials; not a buying recommendation.

Aizon

GXP AI + AI BATCH RECORDS

Targets: *Paper batch records and fragmented plant data that slow batch release and hide the drivers of yield loss and deviations.*

WHAT THEY DO

- Aizon Execute is an AI-powered electronic batch record for small-scale, flexible plants such as API CDMOs; AI converts existing paper recipes into digital form — EUROAPI used it on recipes in five languages (company-stated).[4]
- Its 2026 messaging centers on agentic AI for batch release and deviation investigation, published as Aizon-sponsored trade content (company-stated).[24]

COMPANY & BACKING

- San Francisco-based; renamed from Bigfinite in October 2020.[25] Raised a $20M Series C (Feb 2024) led by NewVale Capital, with Atlantic Bridge, Crosslink and Uncork participating.[11]
- EUROAPI was the launch customer for Execute (Sep 2024).[10] A June 2025 partnership with engineering firm Sequence targets digitalization in about six weeks and faster facility start-up (company-stated).[12]

LIFECYCLE FOOTPRINT — GMP BATCH EXECUTION & PLANT ANALYTICS

P06 · P10

P01	P02	P03	P04	P05	**P06**	P07	P08	P09	**P10**

$20M[11]
Series C led by NewVale Capital, Feb 2024

5 languages[4]
Paper recipes digitized with AI at EUROAPI (company-stated)

~6 weeks[12]
Targeted time to digitalization with Sequence (company-stated)

SENIOR-LEADER READOUT

A GMP-native AI specialist that began in plant analytics and now enters through the batch record — the document that gates every release.

Fit for a contained single-site eBR or yield-analytics pilot; ask for validation evidence from the EUROAPI rollout.

Company-stated claims summarized from public materials; not a buying recommendation.

QbDVision

DIGITAL CMC + PRODUCT LIFECYCLE MANAGEMENT

Targets: *CMC knowledge trapped in documents and spreadsheets — which slows tech transfer, regulatory CMC authoring and post-approval change.*

WHAT THEY DO

- A digital CMC and product-lifecycle-management platform purpose-built for biopharma, structuring process and product knowledge for tech transfer and CMC agility (company-stated).[14]
- Its AI layer runs on Amazon Bedrock,[26] and its published "AI for CMC" approach adds CAMP, a credibility framework for governing AI features in regulated CMC work (company-stated).[5]

COMPANY & BACKING

- Founded in 2016 in Austin, TX (formerly CherryCircle Software);[27] raised a $15M Series A in February 2022.[28]
- Raised $13M in May 2025, led by existing investors Northpond Ventures and S3 Ventures;[13] says its customers include three of the top six pharma and biotech companies (company-stated).[14]

LIFECYCLE FOOTPRINT — CMC KNOWLEDGE, DEVELOPMENT TO LIFECYCLE

P06 · P10

P01	P02	P03	P04	P05	**P06**	P07	P08	P09	**P10**

$13M[13]
Financing led by Northpond and S3 Ventures, May 2025

3 of top 6[14]
Pharma/biotech companies as customers (company-stated)

$15M[28]
Series A, February 2022

SENIOR-LEADER READOUT

The cohort's knowledge-layer bet: AI in CMC is only as credible as the structured data beneath it.

Engage ahead of a tech-transfer or filing wave — and ask how every AI output traces back to a controlled CMC record.

Company-stated claims summarized from public materials; not a buying recommendation.

Basetwo

LIFECYCLE FOOTPRINT **2**/10

PHYSICS-INFORMED PROCESS AI

Targets: *Cycle time, raw-material waste and slow scale-up in pharma and chemical processes still tuned by empirical trial and error.*

WHAT THEY DO

- A “Physics AI” platform that combines chemical-engineering first principles with machine learning to model and optimize pharma and chemical production processes (company-stated).[29]
- Its roadmap includes AutoPilot for autonomous, real-time control of plant operations; the company reports up to 40% improvement in cycle times and raw-material usage (company-stated).[15]

COMPANY & BACKING

- Toronto-based; raised a $3.8M seed round in May 2022 led by Glasswing Ventures and Argon Ventures.[30]
- Raised an $11.5M Series A (Jan 2025) led by AVP, with Glasswing, Deloitte Ventures, Global Brain, Shimadzu and Chiyoda;[6] selected for Canada’s AI Compute Access Fund (May 2026, company-stated).[31]

LIFECYCLE FOOTPRINT — PROCESS DEVELOPMENT & SCALE-UP

P06 · P10

P01	P02	P03	P04	P05	**P06**	P07	P08	P09	**P10**

$11.5M[6]
Series A led by AVP, January 2025

up to 40%[15]
Cycle-time and raw-material improvement (company-stated)

$3.8M[30]
Seed round led by Glasswing and Argon, May 2022

SENIOR-LEADER READOUT

The most engineering-led bet here — process physics plus machine learning, aimed at the process-development and scale-up bench.

No named pharma customers surfaced publicly; treat it as a design-partner conversation with clear success metrics.

Company-stated claims summarized from public materials; not a buying recommendation.

Katalyze AI

AGENTIC PLANT-FLOOR OPERATIONS

Targets: *Deviation investigations and root-cause analysis that stall batch release while experts stitch together MES, QMS and LIMS data by hand.*

WHAT THEY DO

- Katalyst (launched Jan 20, 2026) is an AI agent for GxP plants that connects to MES, QMS and LIMS and analyzes shop-floor production data, with traceable, reproducible outputs (company-stated).[16]
- Positioned as an agentic operating platform for pharma operations — teams of agents for deviation investigation, data digitization and parametric release (company-stated).[7]

COMPANY & BACKING

- Co-founded by CEO Reza Farahani and COO Shreyas Becker, formerly head of AI and data products for manufacturing and supply at Sanofi.[7]
- Raised a $10.5M seed (Jul 2026) led by Bonfire Ventures, with Inovia Capital and Ripple Ventures;[17] reports deployments at five of the world's 20 largest pharma companies (company-stated).[18]

LIFECYCLE FOOTPRINT — DEVIATIONS, ROOT CAUSE & RELEASE

P06 · P10

P01	P02	P03	P04	P05	**P06**	P07	P08	P09	**P10**

$10.5M[17]
Seed round led by Bonfire Ventures, July 2026

5 of top 20[18]
Pharma companies deploying Katalyze (company-stated)

Jan 2026[16]
Katalyst plant-floor agent launched

SENIOR-LEADER READOUT

The newest entrant here and the purest agentic play — agents that sit across existing MES, QMS and LIMS rather than replacing them. Customers are not yet publicly named; engage through a bounded deviation-investigation pilot with human sign-off on every conclusion.

Company-stated claims summarized from public materials; not a buying recommendation.

Three patterns to carry into your diligence

01

Agents enter where GMP data is born

MES and batch-record platforms and plant-floor investigation agents put AI into the workflows that gate release — batch review, deviations and root cause — not into a separate analytics dashboard.

02

Credibility beats capability

FDA's credibility framework[1] and draft Annex 22[2] make context of use, performance monitoring and human review the real buying criteria. Ask every vendor for a credibility plan before a pilot.

03

Platforms and point tools converge

Execution platforms are buying data layers to span R&D to commercial,[8] while AI-native startups sit on top of existing MES, QMS and LIMS. Integration posture — replace or overlay — is the real decision.

THE BOTTOM LINE FOR ADOPTION

"Manufacturing AI will be won at the batch record, not the dashboard. CMC and quality leaders who define context of use, credibility evidence and human sign-off now will decide how agents enter the plant — before the rules finalize around them."

From market read to executive diligence

EXECUTIVE DILIGENCE QUESTIONS

- Which CMC workflow needs leverage first — tech transfer, batch-record review and release, deviation investigation, or process optimization?
- What is each model's context of use, and what credibility evidence can the vendor hand your QA team under FDA's draft framework and draft Annex 22?
- Does the tool overlay your existing MES, QMS and LIMS or replace them — and who owns the validated state after every model update?
- Can the vendor show a named, referenceable GMP deployment at your scale and modality — not only company-stated metrics?

SUGGESTED CATEGORIES FOR FUTURE ISSUES

- Clinical trial finance, budgeting & site payments
- AI medical information & call-center (MICC)
- Biostatistics & statistical-programming automation
- Lab informatics & scientific data platforms (ELN / LIMS)
- Commercial, launch & omnichannel AI

Source standard. All data is publicly sourced unless otherwise noted. Company-stated claims are labeled as such and summarized from public materials; they are not independently validated performance guarantees.

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