AI Vendor Pulse

An advisory briefing on AI vendors selling into pharma & biotech

ISSUE 17 THE FILING LAYER GOES AGENTIC — AI IN REGULATORY SUBMISSIONS & RIM

Weave Bio	Peer AI	Generis	LORENZ	Celegence
AI-native submission authoring & review	Agentic regulatory documentation	CARA regulatory content platform + AI	eCTD publishing & validation	AI-assisted CMC & CER dossiers

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 filing layer is going agentic — AI moves into the regulatory dossier itself

The filing is where years of trial work become a dossier a health authority can review — and it is still assembled largely by hand: drafting, publishing, validation and the question-and-answer cycle after submission. In 2025–26 the layer began to move. Venture money flowed to AI-native submission platforms (a $20M Series A for Weave Bio[1] and a $12.1M round for Peer AI[2]), while established content and publishing vendors added AI (CARA 5.13 from Generis[3]; AI-assisted CER authoring from Celegence[4]). This issue maps five vendors in the regulatory submissions and RIM layer.

WHAT SENIOR LEADERS SHOULD WATCH

01

From drafting to dossier. Weave Bio extended from INDs to an NDA workflow with Parexel in Apr 2026, reporting authoring more than 60% faster (company-stated).[5,6] Peer AI cites up to 94% faster drafting (company-stated).[7]

02

Health authorities become a second user. Weave's HAQ Manager targets health-authority question responses[8], and a LORENZ-hosted pilot reportedly automates submission pre-checks for BfArM (secondary report).[9]

03

Platform or point tool? Generis embeds AI inside a governed regulatory content platform (CARA 5.13)[3], while Celegence launched AI-assisted CER authoring as a CAPTIS module in Sep 2026.[4] Where the system of record lives is the diligence question.

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. Regulatory submission work sits at the edges of this taxonomy: filings that open a study (P04) and filings that carry results to health authorities (P10). This issue's cohort clusters there.

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 regulatory-submissions vendor plays across the trial lifecycle

VENDOR	P01	P02	P03	P04	P05	P06	P07	P08	P09	P10	FOOTPRINT
Weave Bio AI-native submission authoring				■						■	2/10
Peer AI Agentic regulatory documentation		■								■	2/10
Generis Regulatory content platform + AI				■						■	2/10
LORENZ eCTD publishing & validation										■	1/10
Celegence AI-assisted CMC & CER dossiers										■	1/10

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

The cohort clusters at the edges of the lifecycle — study startup filings (P04) and submission-to-evidence work (P10). No lit stage this week rests on independent, stage-level documentation, which is itself a finding. 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
Weave Bio	AI-native submission platform	Dossier drafting, review and verification; NDA workflow; health-authority question (HAQ) responses.	**Momentum.** $20M Series A (Oct 2025)[10]; NDA workflow with Parexel (Apr 2026)[5]; HAQ Manager built with Takeda[8].
Peer AI	Agentic regulatory writing	Authoring and quality-checking of CSRs, protocols and Module summaries; pre-filing regulator-question flagging.	**Early-stage.** $12.1M round (Oct 2025)[2]; exhibited at DIA 2026[11]; no named customer found in public sources.
Generis	RIM / regulatory content platform	Governed regulatory documents, correspondence and submission content, with AI summaries and generation inside the platform.	**Documented customers.** Theramex[12] and Kyowa Kirin[13]; CARA 5.13 AI release (Apr 2025)[3].
LORENZ	Submission publishing & validation	eCTD publishing, validation and review; reported GenAI pre-checks of submission content.	**Incumbent.** docuBridge live at the FDA[14]; GenAI validation (verifAI) reported by a secondary source.[15]
Celegence	Regulatory services + AI tools	CER authoring for MDR/IVDR; CMC Module 3 drafting; dossier management.	**Recent launch.** AI-assisted CER authoring in CAPTIS (Sep 2026)[4]; all efficiency figures company-stated.

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

Weave Bio

AI-NATIVE SUBMISSIONS + HA QUESTIONS

Targets: *The manual drafting, review and assembly of regulatory dossiers — and the health-authority questions that follow filing — across IND, NDA and CTA workflows.*

WHAT THEY DO

- **AI across the submission workflow** — extraction, authoring, review and verification; flagship AutoIND targets INDs, with stated ambition to extend to NDA, BLA and post-market (company-stated).[10]
- **Releases:** HAQ Manager, built with Takeda (Nov 2025)[8]; NDA workflow with Parexel (Apr 2026)[5]; dossier structures incl. a preloaded EU CTA template (Jun 2026).[16]

COMPANY & BACKING

- **Funding:** $20M Series A led by USVP (Oct 2025) following a $10M seed (May 2024).[1,10,17]
- **Advisory board (Mar 2026):** executives from Gilead, Takeda and Boehringer Ingelheim plus Stanford's Russ Altman.[18]

LIFECYCLE FOOTPRINT — SUBMISSION DOSSIERS & HEALTH-AUTHORITY QUESTIONS

P04 · P10

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

$20M[1]
Series A led by USVP, Oct 2025

>60%[6]
Faster NDA authoring in the Parexel workflow (company-stated)

5[18]
Advisory-board members named, Mar 2026 (one is an investor)

SENIOR-LEADER READOUT

Venture-backed, with dateable 2025–26 signals in funding, a CRO co-developed workflow and a big-pharma collaborator. The efficiency headline is a joint vendor/CRO claim — ask for a sponsor-measured baseline and traceability into your RIM system of record.

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

Peer AI

AGENTIC REGULATORY DOCUMENTATION

Targets: *The time and quality burden of drafting CSRs, protocols and module summaries — with regulator questions anticipated before filing.*

WHAT THEY DO

- **Domain-specific agents** handle data extraction, authoring, formatting and validation, with medical writers reviewing at human control points (company-stated).[19]
- **Scope:** drafting CSRs, protocols and module summaries, and flagging likely regulator questions before filing (company-stated).[11]

COMPANY & BACKING

- **Founded 2023**, San Francisco; co-founders include CEO Anita Modi.[20]
- **Funding:** $12.1M announced Oct 7, 2025, led by Flare Capital Partners and SignalFire.[2]
- **Customers:** the company says pharma and biotech organizations use the platform; we found no named customer in public sources.

LIFECYCLE FOOTPRINT — PROTOCOL, CSR & MODULE-SUMMARY AUTHORING

P02 · P10

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

$12.1M[2]
Round announced Oct 7, 2025

up to 94%[7]
Faster submission drafting (company-stated, repeated by an investor)

2023[20]
Year founded, per directory profile

SENIOR-LEADER READOUT

A young, venture-backed authoring specialist whose public evidence is funding and positioning rather than named outcomes. Ask for named references and filed submissions, a head-to-head pilot against your current medical-writing process, and how validation and human-review controls are documented.

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

Generis

LIFECYCLE FOOTPRINT **2**/10

CARA RIM PLATFORM + EMBEDDED AI

Targets: *Fragmented regulatory content, correspondence and submission records in regulated life-sciences organizations — governed in one platform instead of many.*

WHAT THEY DO

- **CARA is a content and regulatory information management platform;** Extedo has extended its extedoPULSE RIM software using CARA as the foundation.[21]
- **CARA 5.13 (Apr 2025)** added AI summaries, automated metadata tagging and extraction, and GenAI content generation that respects user permissions and lists the source documents behind AI-generated insights (company-stated).[3]

COMPANY & BACKING

- **London-based** software company.[22]
- **Named customers:** Theramex adopted CARA to consolidate and digitise regulatory processes[12]; Kyowa Kirin selected it for global regulatory correspondence management (2021).[13]
- **Partnerships & roadmap:** Regenold device-regulatory partnership (Apr 2025)[23]; sovereign-cloud hosting planned from early 2027 (company-stated).[24]

LIFECYCLE FOOTPRINT — REGULATORY CONTENT & SUBMISSION RECORDS

P04 · P10

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

5.13[3]
CARA release adding embedded AI, Apr 2025 (company-stated)

3[12,13,21]
Named customer / platform relationships found: Theramex, Kyowa Kirin, Extedo

early 2027[24]
Planned sovereign-cloud availability (company-stated)

SENIOR-LEADER READOUT

A governed-content incumbent embedding AI inside the platform rather than selling it as a separate authoring tool. We found no public ownership or funding disclosure and no 2026 product news beyond the sovereign-cloud plan — ask for production evidence on regulatory content tasks and the roadmap commitments behind the AI features.

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

LORENZ

ECTD PUBLISHING + VALIDATION

Targets: *The compilation, validation and review of eCTD submissions — the mechanical last mile between a finished dossier and a health authority.*

WHAT THEY DO

- **Core software:** docuBridge (eCTD publishing and review), eValidator and Automator; the company announced go-live of these products at the US FDA.[14,25]
- **AI angle (secondary reporting):** a third-party guide dated Oct 2025 describes verifAI, a generative-AI content-validation product[15]; a separate report describes a LORENZ-hosted pilot automating submission pre-checks for Germany's BfArM. We did not confirm either with the vendor.[9]

COMPANY & BACKING

- **Frankfurt am Main, Germany;** directory profiles list it as privately held with no funding on record, and we found no acquisition.[25,26]
- **Installed base (company-stated):** more than 2,000 paid installations in 48 countries, including 19 regulatory authorities.[15]
- **Integrations and customers:** Egnyte integration (May 2024)[27]; NIAID holds a docuBridge license per a federal procurement notice.[28]

LIFECYCLE FOOTPRINT — SUBMISSION PUBLISHING & VALIDATION

P10

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

2,000+[15]
Paid installations (company-stated, via secondary guide)

48[15]
Countries with installations (company-stated)

19[15]
Regulatory authorities using the software (company-stated)

SENIOR-LEADER READOUT

The established publishing layer: scale and regulator familiarity, with AI claims that so far reach us only through secondary reporting. Ask for dated release notes and validation documentation for the AI features, and confirm ownership and roadmap directly.

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

Celegence

SERVICES-LED REGULATORY + CAPTIS AI

Targets: *The manual drafting of clinical evaluation reports (MDR/IVDR) and CMC Module 3 content that slows device and drug filings.*

WHAT THEY DO

- **Regulatory services plus software:** CAPTIS supports MDR/IVDR compliance documentation, including clinical evaluation reports.[29]
- **AI releases:** AI-assisted CER authoring in CAPTIS launched Sep 15, 2026[4]; generative-AI automation of CMC Module 3 drafting announced in 2025.[30]

COMPANY & BACKING

- **Acquisition:** bought Qdossier (Netherlands) on Jul 18, 2022; no outside investor or ownership change surfaced in our review.[31]
- **Positioning (2026):** a RAPS Convergence 2026 write-up stresses human review and traceability in AI regulatory writing.[32]
- **Evidence:** every efficiency figure found is vendor-reported; the CMC pilot customer is not named.[30]

LIFECYCLE FOOTPRINT — CER & CMC DOSSIER AUTHORING

P10

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

up to 80%[4]
Drafting-effort reduction on select CER sections (company-stated)

80–95%[30]
Alignment with approved submissions in a CMC Module 3 pilot (company-stated)

60%[30]
Faster draft turnaround, same CMC pilot (company-stated)

SENIOR-LEADER READOUT

A services-led specialist with the freshest dated launch in the cohort (Sep 2026) and the heaviest device and CMC orientation. Every metric is self-reported, so ask for customer-validated baselines and clarity on how much of the work remains human-reviewed services.

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

Three patterns to carry into your diligence

01

Submissions are the new automation frontier

Funding and launches cluster in this layer — $20M[1], $12.1M[2] and a Sep 2026 CER launch.[4] Every efficiency figure in the cohort (more than 60%, up to 94%, up to 80%) is company-stated, with no independent baseline.[4,6,7]

02

Platform incumbents embed; challengers specialize

Generis and LORENZ sit in governed content and publishing, with AI added inside[3,15]; Weave, Peer AI and Celegence lead with authoring. The question is where the system of record, audit trail and source-data traceability live.

03

Health authorities are the second user

HAQ responses[8], pre-filing regulator-question flagging[11] and reported agency-side pre-check pilots[9] show AI entering the review conversation, not just the authoring step.

THE BOTTOM LINE FOR ADOPTION

"The dossier is becoming software-assembled. Leaders who demand sponsor-measured baselines and traceability to source data now will define what "inspection-ready" AI authoring means — before the vendors do."

From market read to executive diligence

EXECUTIVE DILIGENCE QUESTIONS

- Which filing steps most need leverage first — dossier drafting, publishing and validation, or the health-authority question cycle?
- What baseline proves the gain — a sponsor-measured before/after on your own documents, not a vendor or partner-reported percentage?
- How is AI output governed for GxP and 21 CFR Part 11 — validation, audit trail, source-data traceability and documented human review?
- Does the tool integrate with your RIM system of record and publishing stack, or ask you to replace them?

SUGGESTED CATEGORIES FOR FUTURE ISSUES

- Site payments, budgeting & contracts
- CTMS & study-operations copilots
- Medical imaging & central reads
- Labeling, translation & artwork
- Manufacturing, CMC & quality (Pharma 4.0)

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. Where a reference is a vendor press release or secondary coverage of one, the reference says so.

References

Reference numbers are assigned by first appearance in the body and shown as sequential superscripts throughout this issue. Each entry links to its source.

1 **HIT Consultant (Oct 16, 2025)** — Weave Bio raises $20M to scale AI-native regulatory automation platform (trade press).

2 **Venture Capital Access Online (Oct 7, 2025)** — Peer AI raises $12.1M to accelerate drug approvals with an intelligent regulatory workflow; led by Flare Capital Partners and SignalFire.

3 **PRLog / Mammoth Times (Apr 7, 2025)** — Generis introduces AI capabilities in CARA 5.13: AI summaries, automated metadata tagging, GenAI content generation (company press release).

4 **Celegence (Sep 15, 2026)** — Celegence launches AI-assisted CER authoring in CAPTIS — up to 80% drafting-effort reduction on select sections (company-stated).

5 **Parexel newsroom (Apr 29, 2026)** — Weave Bio launches NDA workflow designed in partnership with Parexel (company press release).

6 **Bioxconomy** — AI tech can cut NDA submission timelines by 60%, says Weave Bio — authoring >60% faster (company-stated).

7 **SignalFire — Why we invested in Peer AI** — Investor post: draft submissions up to 94% faster (company-stated, investor-repeated).

8 **NewsQuantified (Nov 6, 2025)** — Weave Bio launches HAQ Manager, built with Takeda, for health-authority question responses (syndicated company release).

9 **Bioxconomy (undated)** — AI streamlines pharma regulatory reviews as BfArM pilot tackles ~19,000 annual submissions — LORENZ-hosted VerifAI pilot reported (secondary source).

10 **Business Wire (Oct 16, 2025)** — Weave Bio secures $20M Series A led by USVP — AI-native regulatory platform; AutoIND; IND-to-NDA/BLA/post-market ambition (company press release).

11 **DIA 2026 Global Annual Meeting — exhibitor listing** — Peer AI: drafting of CSRs, protocols and module summaries (company-stated).

12 **Scientific Computing** — Theramex adopts life sciences platform to consolidate and digitise regulatory processes (CARA; trade press).

13 **PharmiWeb (Oct 8, 2021)** — Kyowa Kirin selects the Generis CARA platform for global regulatory correspondence management (company press release).

14 **PR Newswire** — LORENZ docuBridge, eValidator and Automator go live at the US FDA (company press release; undated in our review).

15 **IntuitionLabs (Oct 23, 2025)** — LORENZ docuBridge eCTD guide — verifAI; 2,000+ paid installations in 48 countries; 19 regulatory authorities (secondary source; company-stated figures).

16 **Business Wire (Jun 15, 2026)** — Weave Bio enables global submissions from a single source of truth — customizable dossier structures incl. preloaded EU CTA template (company press release).

17 **Business Wire (May 30, 2024)** — Weave Bio announces $10M in new funding and launch of its AI-powered platform (company press release).

18 **Business Wire (Mar 25, 2026)** — Weave Bio establishes inaugural Strategic Advisory Board (company press release).

19 **Pulse 2.0 (Oct 2025)** — Peer AI: $12.1M raised to advance drug approvals with an intelligent agentic platform (trade press).

20 **CB Insights — Peer AI profile** — Founded 2023; San Francisco; co-founders incl. CEO Anita Modi (directory).

21 **Extedo blog** — Extedo to extend its extedoPULSE RIM software using Generis's CARA platform (company blog).

22 **DIA exhibitor company list (PDF)** — Generis listing — London address (directory).

23 **PRLog / Mammoth Times (Apr 2, 2025)** — Generis and Regenold announce partnership for medical-device regulatory and quality management (company press release).

24 **Generis — CARA sovereign cloud hosting announcement** — CARA to be available on sovereign cloud infrastructure from early 2027 (company-stated).

25 **LORENZ Life Sciences Group — website** — docuBridge, eValidator, Automator; Frankfurt am Main, Germany (company site).

26 **PitchBook — LORENZ profile** — Private company profile; no funding or investors on record (directory).

27 **Halloran CG (May 7, 2024)** — Egnyte and LORENZ Life Sciences announce integration for regulatory document management (company announcement).

28 **GovDash — federal solicitation** — NIAID: training and migration of data into existing LORENZ docuBridge license (public procurement notice; undated in our review).

29 **Celegence — CAPTIS** — MDR/IVDR compliance tool CAPTIS (company site).

30 **Manufacturing Chemist** — Celegence pioneers industry-first automation of CMC Module 3 — 80–95% alignment, 60% faster drafts in a pilot; customer not named (company-stated).

31 **Mergr** — Celegence acquires Qdossier (Netherlands), Jul 18, 2022 (deal database).

32 **Celegence — AI in regulatory writing: key lessons from RAPS 2026** — Human review and traceability; repeats the 75–80% effort-reduction claim (company-stated).

Disclosure: Companies featured in this issue may include current or prospective advisory relationships of Avery & Riley. Lifecycle-footprint and source-class reads use Avery & Riley's vendor framework compiled from public materials and directory review; they are a snapshot of the latest publicly known data and may change as vendors ship or reposition capabilities. This is not a ranking and not a buying recommendation.