

AI-CSV Readiness Assessment

Three weeks. One answer.

FDA's 2026 computer-system findings cluster into six recurring themes under 21 CFR 211.68 — shared logins, missing audit trails, unvalidated systems, backdated records, deletable data, and AI used without controls. This assessment tells you exactly where your systems sit against all six, what to fix first, and what it will take — before an inspector tells you instead.

WHAT GETS ASSESSED

	THEME	THE QUESTION ANSWERED
01	Access & attribution	Can every GxP action be traced to a unique person — or do shared logins exist?
02	Audit trails	Are they on, complete, reviewed, and reconstructable?
03	Validation state	Which systems are making GxP decisions without defensible validation?
04	Record integrity	Can records be altered or backdated without a trace?
05	Backup & retention	Can data be deleted or overwritten without detection?
06	AI governance	Where is AI influencing GxP decisions — and is it controlled?

WHAT YOU RECEIVE

- **Readiness scorecard** — every system scored against the six themes, red / amber / green, with the evidence behind each score.
- **Gap register** — each gap rated by inspection risk and effort to close, so the sequence is obvious.
- **90-day remediation plan** — what to fix first, who owns it, and what "done" looks like.
- **Executive readout** — a deck your leadership can act on, written so you don't have to translate it.

DURATION

3 weeks

Kickoff, evidence review and interviews, readout. Roughly 4-6 hours of your team's time in total.

INVESTMENT

\$18,500

Fixed fee. No hourly billing, no scope creep, no \$400/hr surprise.

WHO THIS IS FOR

- QA Directors, CSV Leads, and IT Compliance Heads at **startup and mid-size pharma and biotech**.
- Teams deploying an **AI-enabled system** and unsure what "validating AI" actually requires.
- Anyone who would struggle to answer **"show me your audit trail review evidence"** in the next 30 days.

The assessment is the starting point, not the pitch.

You get the scorecard and the plan whether or not you ever use our platform. If the remediation is bigger than your team's capacity, we can run it with you — that's a separate conversation, held after you have the findings.

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