CLINIVION

Your FDA audit shouldn't keep you up at night.

Nessa automates pharmaceutical data integrity so you can focus on the science.

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$2.5B+
Lost annually to data integrity failures across pharma

65%
Of FDA 483 observations cite data integrity gaps

12-18 mo
Average approval delay after a warning letter

What Nessa replaces

Spreadsheet-based audit trails → **Tamper-proof, cryptographically verified records**

Unencrypted sensitive data → **Military-grade field-level encryption**

Manual compliance checks → **Automated ALCOA+ validation in real-time**

Reactive quality reviews → **AI that catches anomalies before auditors do**

Paper signatures → **FDA-compliant electronic signatures**

Siloed access controls → **Role-based permissions across your entire team**

How it works

1 Connect
Integrates with your existing lab systems in days, not months

2 Protect
Every data point gets an immutable proof of integrity

3 Prove
One-click audit reports when the FDA walks in

Start with a $10,000 Proof of Concept

30 days, fully credited toward your annual contract. No risk. No long procurement cycle.

Watch the 2-minute product demo →

Compliance coverage

FDA 21 CFR Part 11 | ALCOA+ | GAMP 5 | ISO 27001 | GDPR | HIPAA

How Nessa compares

	Nessa	Veeva Vault	MasterControl
Annual cost	**$75K -- $250K**	$500K+	$200K+
Time to deploy	**Days**	6-12 months	3-6 months
Tamper-proof audit trails	✓	✗	✗
AI anomaly detection	✓	✗	✗
Built for biotech scale	✓	Enterprise only	Enterprise only

Who it's for

VP Regulatory Affairs
Stop worrying about 483 observations. Nessa gives you audit-ready proof at all times.

Head of Quality
Replace manual SOPs with automated compliance that scales with your pipeline.

CTO / Chief Data Officer
Modern infrastructure that passes technical due diligence from both FDA and investors.

BUILT ON TECHNOLOGY TRUSTED BY

aws Google

UNDER THE HOOD

Nessa runs on **AWS** infrastructure with **Rust** for memory-safe, high-performance processing and **PostgreSQL** for enterprise-grade data reliability. Cryptographic integrity is powered by the same **Certificate Transparency** framework that **Google** developed to secure the internet's public key infrastructure. Encryption uses **AES-256-GCM** — the same standard used by the **US Department of Defense**. Digital signatures use **ED25519**, the algorithm behind **Signal** and **SSH**. Caching and real-time operations run on **Redis**, trusted by **Twitter**, **GitHub**, and **Stripe**.

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