



Every audit-trail entry checked, not a sample

We check every change in your lab and manufacturing systems against your SOPs and approved records. Rules catch the known patterns; an AI model spots unusual behaviour no rule covers. Your QA team decides; your eQMS keeps the record.

Every entry checked, by rules and AI

→ ARITHMIA ASSURE

- ✓ Installed in your own Azure; reads CDS, LIMS, MES and batch records, read-only
- ✓ Approved changes, deviations, training and rosters clear what is explained
- ✓ The AI model is fixed and validated: it flags, your QA team decides

What it saves

→ AT ONE SITE

- ✓ **£35,000 a year** of QA time at 1,000 batches, review cut from 45 to 10 minutes each (illustrative)
- ✓ Problems found within days, not at the next inspection
- ✓ One evidence pack a month, for inspectors and client auditors

Arithmia

Assure · AI audit-trail review and cloud compliance evidence

MOCK-UP · SYNTHETIC DATA

Site Demo · AWS eu-west-2 (London)

Connected systems

Rule sources 1

Audit-trail review 7

Cloud controls 1

Evidence pack

What it saves

Audit-trail review

Rules catch known data-integrity patterns; a machine-learning model flags unusual behaviour no rule covers. Each event is checked against approved changes, deviations, training and rosters first, so only unexplained events are flagged. A reviewer decides; a confirmed issue is raised as a deviation in the eQMS.

Flags

7 open of 7

F-102 Reprocessed until the result passed

Rule DI-07

A sample reprocessed until it passed, flagged with its reason and SOP step. Shown with sample data.

	MANUAL REVIEW	WITH ARITHMIA ASSURE
What gets checked	A sample of entries	Every entry
Reviewer time	Hours per batch	Minutes per batch
Spotting the unusual	A reviewer's experience	An AI model trained on your patterns
Evidence	Spreadsheets and folders	One pack a month, in your eQMS

GxP cloud checked daily

→ ARITHMIA CHECK

Encryption, access, logging and backups checked against Annex 11 and Part 11, with a GAMP 5 validation pack.

Learn across sites, share no data

→ FEDERATED AI · IN DEVELOPMENT

Models train inside each member's site; only encrypted updates leave. Founding members welcome.