

LIFE SCIENCES

The evidence delay inside a quality investigation

Fragmented records can consume investigation time before a qualified team reaches the actual scientific question.

THE EXECUTIVE FINDING

Improve the availability and traceability of quality evidence before asking AI to explain a deviation. A fluent explanation is not a validated conclusion.

THREE DECISIONS FOR LEADERSHIP

- 01 Select a narrowly defined evidence-preparation task within the quality system.
- 02 Document which outputs are factual extraction and which require scientific interpretation.
- 03 Test failure cases and record the acceptance criteria before selecting a model.

THE TRADE-OFF TO EXAMINE

Centralising records can improve access but amplify a faulty batch mapping or permission rule. Test lineage and access boundaries before scaling. A failure to retrieve a document should remain distinguishable from evidence that the document does not exist.

HOW GENELLIPSE CAN HELP

Genellipse can connect approved quality and operational records with GeneData, structure evidence preparation through Cortex AI and support access and audit evidence with GeneSecure and GeneComply. The engagement would include intended-use boundaries and validation support; qualified customer teams retain scientific and release authority.

THE ANALYSIS IN ONE VIEW

Illustrative investigation effort

hours per investigation | Synthetic example

Locate records		10
Verify applicability		8
Scientific investigation		14
Review and approval		8

10 + 8 + 14 + 8 = 40 hours; information preparation is 18 hours.

Synthetic labour model, not cycle time or a pharmaceutical benchmark. Faster preparation does not remove scientific review.

INTERPRETATION

If evidence location falls from ten to five hours, an illustrative 40-hour investigation becomes 35 hours only if no additional verification is required. The useful outcome is a complete evidence pack accepted by the investigator. Any time released should be evaluated against validation, review, monitoring and maintenance costs.

SOURCES AND METHOD

Original Genellipse analysis informed by the primary sources below. Examples are synthetic, not customer results, forecasts or industry benchmarks. Sources reviewed 14 October 2026.

- FDA - Q10 Pharmaceutical Quality System
- FDA - AI supporting drug and biological regulatory decisions

Read the complete report and its assumptions at genellipse.com/insights

Discuss your priorities: info@genellipse.com