

OOS / OOT Investigation

Pharma, Chemicals & Life Sciences

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This guide explains what the tool produces, how to use the output, and what to watch for. The actual output (draft/report) is generated on the tool page.

Background

Builds an OOS/OOT investigation framework — Phase 1 lab investigation, Phase 2 full investigation, root cause, retest and resample rules, and impact and disposition — with an investigation report. Use this to investigate out-of-specification results properly. Follow your OOS SOP and GMP guidance with QA approval.

Purpose of this tool & output

Investigate out-of-spec results properly

How the output is used

Use it to run a proper phase-1 and phase-2 out-of-specification investigation, assign a root cause and decide on the result before you release or reject the batch.

Who should vet it

The QC and QA heads must review and approve the investigation and the release/reject decision — this is a regulated, safety-critical call.

Important cautions

AI-generated framework; follow your OOS SOP and GMP guidance and QA approval.

Companion documents

- QC Laboratory SOP
- Stability Study Protocol
- Analytical Method & Validation
- Certificate of Analysis (COA)
- Quality Manual Builder
- Document Control & Data Integrity

This is AI-assisted guidance. Verify with a qualified professional before any binding decision. Fees, authorities and processes vary by state and change over time — confirm with your state authority.