EduCraft | QA/QC Field Guide

OOS / OOT INVESTIGATION REVIEW CHECKLIST

A practical prompt sheet for your next review meeting.

Use with your approved procedures. Record decisions in your controlled quality system. This is an educational aid, not a release decision or an approved SOP.

Review reference: _____ Date: _____

CLASSIFY THE SIGNAL

- ☐ Which approved specification or trend rule triggered this review?
- ☐ Are the units, method version, sample identity and result transcription correct?
- ☐ Is the result OOS, an OOT signal, or another unexpected observation?

LOCATE THE EVIDENCE

- ☐ Where are the original outputs, calculations and relevant electronic records?
- ☐ What observations are documented, and what is still only a hypothesis?
- ☐ Who reviewed the record, and which evidence references support the review?

Explore the 9-hour on-demand OOS/OOT masterclass

From evidence to an accountable next step

FRAME THE INVESTIGATION

- [ ] What question remains unanswered after the initial laboratory assessment?
- [ ] What supports any proposed laboratory cause, rather than just a passing repeat?
- [ ] Which related lots, products, methods or sites may need consideration?

AGREE THE NEXT DECISION

- [ ] What is the scientific purpose and approved plan for any additional testing?
- [ ] Who owns each follow-up, by when, and where will the decision be recorded?
- [ ] What remains open for quality-unit review before closure or disposition?

Scope and references

FDA OOS guidance, May 2022: chemistry-based testing of CDER-regulated drugs. OOT triggers depend on the approved procedure and context.

FDA OOS guidance

21 CFR 211.192 - investigation and follow-up

21 CFR 211.194 - laboratory records