

Investigation Studio (OOS, deviation, CAPA)

Run an out-of-specification, out-of-trend or deviation investigation from the first laboratory check to CAPA and closure, with the rules of the FDA OOS guidance and EU GMP built in.

WRITES

OOS / OOT
report

Deviation
report

CAPA plan

PRODUCT TYPE

Small molecule and
biologics

GUIDANCE IT FOLLOWS

21 CFR 211.192, FDA
OOS guidance
(2022), EU GMP
Chapters 1, 6 and 8,
Annex 16, ICH Q9
and Q10

TIME TO LEARN

About 20 minutes
with the example

Open the tool at <https://app.cmcfy.com/app/investigation-studio.html>. This guide is also online at <https://cmcfy.com/guides/investigation-studio.html>

1. What this module does

The tool follows the investigation as it happens: the event, the original result, the Phase I laboratory checklist and hypothesis testing, retest and resample, the Phase II manufacturing investigation, root cause, impact on other batches, the CAPA plan, and the disposition.

It decides the outcome by rule, for example that passing retests alone cannot invalidate an original OOS result, and blocks a release that the investigation does not support.

What you get

- An investigation report in Word or PDF with results chart, checklists, root cause, impact, CAPA, disposition and sign-off lines.

2. Before you start

Have these ready. You can still start with the example data and replace it piece by piece.

- Event type, investigation number, date, product, batch and stage, a description and the immediate actions.

- For OOS/OOT: test, method, limits, unit, analyst and the individual results; whether the reportable result is a mean.
- Phase I checklist outcomes and any hypothesis testing; retest plan and results; resample decision.
- Phase II review outcomes, root cause, other batches that could be affected, CAPA actions with owner, due date and effectiveness check.
- Records can be loaded from Word, PDF, Excel, CSV or a scan at each step.

Your data stays on your computer. The bar under the title counts every network request the page makes; it stays at 0 because your data never leaves your computer. [Download offline copy](#) saves a single file that opens from your own computer with all network access blocked, for air-gapped PCs.

3. Step by step with the example

Open the tool at app.cmcfy.com/app/investigation-studio.html. The example investigation (INV-2026-0187, assay of batch CMX-26-0412 at 94.0% against 95–105%) is loaded when the page opens. It contains deliberate gaps so you can see the alerts.

1 Record the event

Choose the event type (OOS, OOT or deviation) and the region, and enter the investigation details. [Load deviation or event record](#) reads the description from a file.

The screenshot displays the CMCfy Investigation Studio interface. The top navigation bar includes 'Investigation Studio', 'Projects', 'All modules', 'Training', and 'Security'. A status bar indicates 'Runs entirely on this device' and provides links for 'Training guide' and 'Protocol builder'.

The main content area is divided into two columns. The left column, titled '1 - EVENT', contains a form for recording an event. The 'Event type' is set to 'Out of specification (OOS) result'. The 'Region' is 'US: FDA (21 CFR 211.192, FDA OOS guidance)'. The 'Investigation number' is 'INV-2026-0187' and the 'Event date' is '09/28/2026'. The 'Product' is 'CMX-101 Tablets, 50 mg'. The 'Batch' is 'CMX-26-0412' and the 'Stage' is 'Release testing'. The 'Description of the event' text area contains: 'During release testing of batch CMX-26-0412, the assay result for CMX-101 Tablets was 94.0% label claim (mean of two preparations), below the specification of 95.0–105.0%'. Below the description is a button labeled 'Load deviation or event record'.

The right column, titled 'INVESTIGATION OUTCOME', displays a 'Confirmed OOS: original result stands' alert. The text states: 'The 3 retests are within the specification, but no laboratory error was confirmed. Passing retests alone cannot invalidate the original result under the FDA OOS guidance (2022). Phase II must explain the difference.' Below this is a table with the following data:

INVESTIGATION	BATCH	LIMITS	REPORTABLE
INV-2026-0187	CMX-26-0412	95–105 % label claim	94.00

Below the table, the 'TYPE' is 'OOS investigation' and the 'DISPOSITION' is 'Release'.

At the bottom right, a 'RESULTS AGAINST LIMITS' chart shows a horizontal axis with values 92.1, 95.8, 99.4, 103.0, and 106.7. A dashed red line at 95.8 is labeled 'LSL 95' and a dashed red line at 105.0 is labeled 'USL 105'. Data points are plotted as purple dots at approximately 94.0, 94.5, and 95.0, all below the LSL 95 line.

2 Enter the original result

Enter the test, method, limits and the individual results. Choose whether the reportable result is the mean or each individual result. The chart plots the results against the limits.

2 · ORIGINAL RESULT

Test
Assay (HPLC)

Method
AM-0142 v2

Lower specification limit
95.0

Upper specification limit
105.0

Unit
% label claim

Analyst
A. Patel

Reportable result
Mean of the individual results

Individual results, one per line
93.8
94.2

Load results file

Word, PDF, Excel, CSV or a scan

The original result panel.

3 Work through Phase I

Mark each laboratory check as no issue, issue found or not checked, and record any hypothesis testing. In the example no laboratory error was confirmed.

3 · PHASE I: LABORATORY INVESTIGATION

Correct method and version used No issue

Note or reference (optional)

System suitability met No issue

Note or reference (optional)

Instrument qualified and in calibration No issue

Note or reference (optional)

Reference standard: correct lot, in date, prepared correctly No issue

Note or reference (optional)

Sample preparation followed the method (weights, dilutions, extraction) No issue

Note or reference (optional)

Reagents, mobile phase and glassware correct and in date No issue

Note or reference (optional)

Chromatograms or raw data reviewed (integration, peaks, baseline) No issue

Note or reference (optional)

Calculations and transcriptions verified No issue

Note or reference (optional)

Analyst trained on the method No issue

Phase I laboratory checklist.

4 Retest, Phase II and root cause

Enter the retest plan, analyst and results, then the manufacturing review, the root cause, other batches and the CAPA plan.

5 Read the outcome

The outcome reads "Confirmed OOS: original result stands". The 3 retests are within the specification, but no laboratory error was confirmed, so passing retests alone cannot invalidate the original result.

INVESTIGATION OUTCOME

Confirmed OOS: original result stands

The 3 retests are within the specification, but no laboratory error was confirmed. Passing retests alone cannot invalidate the original result under the FDA OOS guidance (2022). Phase II must explain the difference.

INVESTIGATION	BATCH	LIMITS	REPORTABLE
INV-2026-0187	CMX-26-0412	95-105 % label claim	94.00
TYPE	DISPOSITION		
OOS investigation	Release		

6 Resolve alerts

The example has a critical alert because the batch is proposed for release while the result has not been invalidated, and major alerts for an incomplete Phase II and a CAPA plan with corrections only. Change the disposition, complete the checks and add a corrective action.

ALERTS TO RESOLVE

3 alerts to fix, justify, or proceed without before the report can be exported. It is your call: "Proceed without it" lets you continue when the information is not available.

MINOR The retest was done by the original analyst.

Retest

Where possible, use a second analyst for retesting.

Justification

Accept justification

CRITICAL The batch is proposed for release while the out-of-limit result has not been invalidated.

Disposition

Change the disposition, or confirm a laboratory cause. Passing retests alone cannot support release.

Proceed without it

MAJOR 2 of 7 manufacturing checks are not completed.

Phase II

No laboratory cause was confirmed, so the manufacturing investigation must be completed (21 CFR 211.192).

Justification

Accept justification

Proceed without it

MINOR 1 batch is still under evaluation (CMX-26-0415).

Impact

Complete the assessment before closure.

Justification

Accept justification

MAJOR The CAPA plan has corrections only; nothing addresses the root cause.

CAPA

Add a corrective or preventive action.

Justification

Accept justification

Proceed without it

MINOR The investigation has been open 31 days.

Timeline

Investigations are usually closed within 30 days; document an extension.

Justification

Accept justification

7 Preview, review and download

Press **Preview and download report**, read the review and download Word or PDF once no blocking alert remains.

Justification

Accept justification

Preview and review before download

Close

Review

Checked on this device: gaps in the data, gaps in the report against ICH and regional expectations, and differences from the protocol.

1 critical 2 to fix 3 recommended

MISSING INFORMATION (1)

2 of 7 manufacturing checks are not completed.
No laboratory cause was confirmed, so the manufacturing investigation must be completed (21 CFR 211.192).
major · Phase II

DATA AND INPUTS (5)

The batch is proposed for release while the out-of-limit result has not been invalidated.
Change the disposition, or confirm a laboratory cause. Passing retests alone cannot support release.
critical · Disposition

The CAPA plan has corrections only; nothing addresses the root cause.
Add a corrective or preventive action.
major · CAPA

The retest was done by the original analyst.
Where possible, use a second analyst for retesting.
recommended · Retest

1 batch is still under evaluation (CMX-26-0415).

Out-of-Specification Investigation Report

CMX-101 Tablets, 50 mg · Batch CMX-26-0412

Investigation number	INV-2026-0187
Product	CMX-101 Tablets, 50 mg
Batch	CMX-26-0412
Stage	Release testing
Test and method	Assay (HPLC) (AM-0142 v2)
Specification	95–105 % label claim
Event date	2026-09-28
Outcome	Confirmed OOS: original result stands
Proposed disposition	Release
Region	US (FDA)
References	21 CFR 211.192; FDA Guidance, Investigating OOS Test Results (Rev. 1, 2022); ICH Q9(R1), Q10
Date drafted	2026-10-29

1. Description of the event

During release testing of batch CMX-26-0412, the assay result for CMX-101 Tablets was 94.0% label claim (mean of two preparations), below the specification of 95.0–105.0%.

2. Immediate actions and containment

Batch placed on QA hold on 2026-09-28. Sample solutions, standards and chromatographic data retained. Remaining retained samples quarantined.

3. Original result

Fix or justify the 3 blocking alerts before downloading. Or choose "Download anyway".

Original sample solutions were re-injected

4. Field reference

Every input in the tool, panel by panel. Tables accept rows pasted straight from Excel, comma-separated text, or a loaded file; check the columns after loading a file. Fields marked “when it applies” appear only for the choices that need them.

1 · Event

FIELD	WHAT TO ENTER
Event type	OOS, OOT or deviation. OOS and OOT open the result, Phase I and retest panels; a deviation opens classification.
Region	US (21 CFR 211.192, FDA OOS guidance), EU (EU GMP Chapters 1, 6 and 8, Annex 16) or both.
Investigation number, date, product, batch, stage	Type them in.
Description of the event, Immediate actions and containment	Text, or Load deviation or event record .

2 · Original result

FIELD	WHAT TO ENTER
Test, method, limits, unit, analyst	Type them in; leave a limit empty for a one-sided specification.
Reportable result	Mean of the individual results, or each individual result is reportable. Averaging cannot hide an individual result outside the limits.
Individual results	One per line, or Load results file .

3–5 · Phase I, retest and Phase II

FIELD	WHAT TO ENTER
Checklists	Each item: not checked, no issue, or issue found.
Hypothesis testing	Not performed; laboratory error confirmed; or not confirmed, with what was tested.
Retests	Number predefined in the SOP, retest analyst, results one per line, and whether a resample was taken.

6–9 · Root cause, impact, CAPA and closure

FIELD	WHAT TO ENTER
Root cause category and statement	Choose the category and describe the cause; optional five whys or fishbone notes.
Impact on other batches	Rows of batch, link to this event, assessment (not affected, affected, under evaluation), or tick that no other batch could be affected.
CAPA	Rows of action, type (correction, corrective, preventive), owner, due date, effectiveness check.
Disposition and closure	Pending, reject, release or rework; closure date; prepared by; optional conclusion (written for you if empty).

5. Checks and alerts

Calculations and pass/fail outcomes always come from fixed rules, never from AI. The tool checks:

- Description and containment recorded; Phase I checklist completed; hypothesis testing consistent with the checklist.
- Averaging does not hide an individual out-of-limit result; retests follow the predefined plan and do not exceed it; ideally a second analyst; a resample is justified.
- Release is critical when the original result has not been invalidated; a deviation released without classification is flagged.
- Phase II completed when no laboratory cause is confirmed; root cause identified and aligned with Phase I; CAPA addresses the root cause, not only corrections.
- Impact on other batches assessed and closed; affected batches handled.
- Notification (FDA Field Alert for distributed batches in the US; QP and competent authority in the EU) and investigation timelines.

How to resolve alerts

- **Critical** alerts must be fixed in the data; they cannot be justified.
- **Major** and **minor** alerts can be fixed, or justified: type the reason and press **Accept justification**. The report lists every justification.
- The report download is blocked while a critical or unjustified major alert is open. The preview still opens, so you can see the draft.

6. Preview, gap review and download

1. Press **Preview** next to a section, or **Preview and download all**. The document opens in a preview window, exactly as the Word file will read.
2. The left side lists the review, run on your device: **gaps in the data** (missing values, open alerts), **gaps in the report** (missing content the guidance expects, placeholders such as [site] or TBD left in the text) and, if you load the approved protocol under **Compare with the protocol**, **differences from the protocol** (requirements, criteria, batches or time points it plans that the report does not show).
3. Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
4. Optional **AI review**: a second read for contradictions, claims without data and vague wording. The report text is sent to Claude only when you press it, and only where your plan includes AI. Check every AI finding; AI can be wrong.
5. Press **Download Word (.docx)** or **Download PDF**. With several documents open, **All as Word (.zip)** and **All as PDF (.zip)** download the set. The download buttons stay disabled while a blocking alert is open; the preview still works.

Documents this module produces

SECTION	DOCUMENT
Report	Investigation report (OOS, OOT or deviation) with CAPA plan

7. US and EU submissions

US mode applies 21 CFR 211.192 and the FDA OOS guidance (2022), including the Field Alert Report for distributed batches. EU mode applies EU GMP Chapter 1 (CAPA), Chapter 6 (OOS) and Chapter 8 and Annex 16 (QP certification and notification of quality defects).

8. Working with other modules

- Failing results in the Batch Analysis & CoA are linked to the investigation by its reference.
- Out-of-limit stability results from the Stability Studio or Biologics Stability Studio should be investigated here.

9. Common pitfalls

- Releasing on passing retests without a confirmed laboratory error.
- Averaging an out-of-limit individual result with passing ones.
- Retesting more times than the SOP predefines ("testing into compliance").
- A CAPA plan that only corrects the batch and does nothing about the cause.

10. Practice exercises

Each exercise starts from the example (press **Load example** to reset). We run these on every update of this guide, so the result you see should match.

1. Hold the batch instead of releasing it

Set **Proposed batch disposition** to "Pending (hold)".

EXPECTED RESULT

The critical alert about release while the result has not been invalidated is gone.

2. **Use a second analyst for the retest**

Set `Retest analyst` to "Different analyst".

EXPECTED RESULT

The minor alert about the original analyst doing the retest is gone.

Guide updated 28 October 2026 for the current version of the tool. CMCfy drafts are for review by a qualified person before use in a submission.