

Self-Inspection Report

Write the annual self-inspection report: coverage of every GMP area within the cycle, findings by class with their CAPA, overdue actions and repeat findings.

WRITES

GMP

PRODUCT TYPE

Small molecule and biologics

**GUIDANCE IT
FOLLOWS**

EU GMP Chapter 9
Self inspection; ICH
Q10 2.5 and 3.2.4;
ICH Q7 2.4 (internal
audits); 21 CFR
211.180(e) and
211.22; PIC/S PE
009 Chapter 9;
WHO TRS 961
Annex 3 section 8

TIME TO LEARNAbout 20 minutes
with the example

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

1. What this module does

You enter the audits performed and the findings with their CAPA, owner, due date and status. The tool maps each audit to a GMP area and checks every area was audited within the cycle.

It flags critical findings, overdue CAPAs, findings without owners and findings that repeat earlier ones.

What you get

- A Word or PDF report: Self-inspection report.

2. Before you start

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

- The audits performed in the cycle.
- Findings with CAPA, owner and due date.
- Findings from earlier self-inspections.

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/self-inspection.html. The example is loaded when the page opens, so every panel already has realistic data. Follow the steps to see how it works, then replace the example with your own data.

1 Describe the programme

Enter the site, the cycle length and the report date.

The screenshot shows the CMCfy Self-Inspection Report tool interface. At the top, there's a navigation bar with the CMCfy logo and links for 'Self-Inspection Report', 'Projects', 'All modules', 'Training', and 'Security'. A status bar indicates 'Runs entirely on this device' and provides a 'Training guide' link.

The main content area is divided into several sections:

- PROJECTS:** A section with a description and two buttons: 'Choose projects folder' and 'Keep in this browser'.
- Network requests since load: 0:** A status indicator showing 'Counted live by your browser. Your data never leaves this device.'
- Works offline:** A status indicator showing 'Everything the tool needs is inside this page.'
- Locked offline copy:** A status indicator showing 'Save a single file that opens from your own computer with all network access blocked.'
- GMP:** A section with a description of the GMP (Good Manufacturing Practice) audit process and a list of guidance documents: 'EU GMP Chapter 9 Self inspection; ICH Q10 2.5 and 3.2.4; ICH Q7 2.4 (internal audits); 21 CFR 211.180(e) and 211.22; PIC/S PE 009 Chapter 9; WHO TRS 961 Annex 3 section 8'.
- 1 · PROGRAMME:** A form for entering audit details. It includes fields for 'Site' (Acme Pharma, Raleigh NC (oral solid dose manufacturing an...)), 'Regulations' (Both US and EU), 'Report number' (SI-2026-ANNUAL), 'Programme cycle (months)' (12), and 'Report date' (10/20/2026).
- RESULT:** A summary section showing 'All 10 areas audited · 6 findings'. It also provides a breakdown: '10 audits; findings: 0 critical, 2 major, 4 minor; 2 open.' and a table with columns 'AUDITS', 'FINDINGS', and 'OPEN'.
- 2 · AUDITS PERFORMED:** A section for listing audits performed, with a table header 'Audits' and a note 'Columns: Audit, Area, Date, Lead auditor (independent of the area)'.
- COVERAGE:** A table showing the coverage of the audit. It has columns 'GMP AREA', 'AUDITS IN THE CYCLE', and 'OUTCOME'. The first row shows 'Personnel and training' with 'SI-26-01 (2026-01-20)' audits and a 'covered' outcome.

2 Enter audits and findings

One row per audit and per finding. Paste earlier findings one per line to check for repeats.

3 Read the result

The headline gives the outcome: "All 10 areas audited · 6 findings".

COVERAGE		
GMP AREA	AUDITS IN THE CYCLE	OUTCOME
Personnel and training	SI-26-01 (2026-01-20)	covered
Premises and equipment	SI-26-02 (2026-02-17)	covered
Documentation and data integrity	SI-26-03 (2026-03-24)	covered
Production	SI-26-04 (2026-04-21)	covered
Quality control	SI-26-05 (2026-05-19)	covered
Outsourced activities and suppliers	SI-26-06 (2026-06-16)	covered
Complaints, quality defects and recalls	SI-26-07 (2026-07-14)	covered
Pharmaceutical quality system (deviations, CAPA, change control, management review)	SI-26-08 (2026-08-18)	covered
Storage and distribution	SI-26-09 (2026-09-15)	covered
Self-inspection programme	SI-26-10 (2026-10-06)	covered

Coverage of GMP areas.

4 Resolve alerts and download

Critical findings, areas not audited, overdue CAPAs and repeat findings are flagged. Then preview and download.

Preview and review before download

Review

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

No open gaps

No open gaps: the data, the report and the protocol (if given) match every rule checked, or you accepted the rest. Read the review before you sign.

Compare with the protocol

Load or paste the approved protocol. Every requirement and acceptance criterion in it is looked for in the report.

Paste the protocol text here, or load the file.

Load protocol fileCompare

AI review against guidance

AI reads the report, the protocol and the data against the ICH, FDA or EMA requirements for these sections, and lists gaps with the guideline it applies, protocol and data mismatches, and how to fix them. You see exactly what is sent before anything leaves this device. Results and pass/fail are not changed.

Run AI review

Self-inspection report

SI-2026-ANNUAL - US (FDA) and EU (EMA)

Site	Acme Pharma, Raleigh NC (oral solid dose manufacturing and QC)
Report number	SI-2026-ANNUAL
Cycle	12 months to 2026-10-20
Regulations	US (FDA) and EU (EMA)

1. Audits performed

Audit	Area	Date	Lead auditor
SI-26-01	Personnel and training	2026-01-20	K. Osei (QA)
SI-26-02	Premises and equipment	2026-02-17	K. Osei (QA)
SI-26-03	Documentation and data integrity	2026-03-24	R. Mehta (QA)
SI-26-04	Production	2026-04-21	R. Mehta (QA)
SI-26-05	Quality control	2026-05-19	L. Brandt (QA)
SI-26-06	Outsourced activities and suppliers	2026-06-16	K. Osei (QA)
SI-26-07	Complaints and recalls	2026-07-14	L. Brandt (QA)
SI-26-08	Deviations CAPA and change control	2026-08-18	R. Mehta (QA)
SI-26-09	Storage and distribution	2026-09-15	L. Brandt (QA)
SI-26-10	Self-inspection programme	2026-10-06	External auditor

2. Coverage of GMP areas

GMP area	Audits
Personnel and training	SI-26-01

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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 • Programme

FIELD	WHAT TO ENTER
Site	Type it in.
Regulations	Choose one: US: 21 CFR 211, ICH Q10; EU: EU GMP Chapter 9; Both US and EU.
Report number	Type it in.
Programme cycle (months)	Type a number.
Report date	Type it in.

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2 · Audits performed

FIELD	WHAT TO ENTER
Audits	Name the area in words the tool recognises, such as "Quality control" or "Storage and distribution". A table. Columns: Audit Area Date Lead auditor (independent of the area). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Findings

FIELD	WHAT TO ENTER
Findings	A table. Columns: Finding Audit Class (critical/major/minor) Description CAPA Owner Due Status (open/closed). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Findings from earlier self-inspections (one per line)	Type or paste text.
Reported to management review	Tick the box if it applies.

5. Checks and alerts

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

- Every GMP area within the cycle.
- Findings by class with CAPA, owner and due date.
- Overdue and repeat findings; management review.

How to resolve alerts

- **Critical** alerts block the download and must be fixed in the data. A failing result can instead be linked to an investigation: type the investigation reference and outcome and press [Record](#).
- **Major** alerts block the download until you fix them or type a justification and press [Accept justification](#).
- **Minor** alerts do not block anything. They are listed in the documents so the reviewer sees them.
- Some alerts have an [Apply fix](#) button that makes the change for you. [Reopen](#) undoes a justification.

Narratives

This module writes: Summary and conclusion. Each narrative is written by fixed rules from your data. You can edit it in the box. [Rewrite with AI](#) (where your plan includes AI) rewrites it in regulatory style; every number in the text is checked against your data, and a number that does not match is flagged under the box and blocks the download until you correct it. [Reset to rule-based text](#) brings back the original.

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	Self-inspection report

Use [Save project](#) to keep your work as a file on your computer, and [Open project](#) to continue later. [Start blank](#) clears every field; [Load example](#) brings the example back. Nothing is stored on CMCfy servers.

7. US and EU submissions

EU follows EU GMP Chapter 9. US expectations follow ICH Q10 and the quality unit responsibilities in 21 CFR 211.22.

8. Working with other modules

- Supplier audits are reported in Supplier Qualification Report.

9. Common pitfalls

- Areas skipped year after year.
- Auditors auditing their own area.

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. Miss an area

Move the storage and distribution audit to June 2025, outside the cycle.

EXPECTED RESULT

The headline shows one GMP area not audited in the cycle.

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.