FDA INSPECTIONS AND ENFORCEMENT · TRAINING GUIDE

Remediation Tracker

Track every commitment made to FDA in a 483 or warning letter response to completion and effectiveness, and write the periodic update letter to FDA and the status report for management review.

WRITES	PRODUCT TYPE	GUIDANCE IT FOLLOWS	TIME TO LEARN
`FDA remediation`	FDA inspections	FDA Regulatory Procedures Manual Chapter 4 (warning letter follow-up and close-out letters); FDA notice Review of Post-Inspectional Responses (2009); 21 CFR 211.22, 211.192; 21 CFR 820 (QMSR); ICH Q10 3.2.2 (CAPA effectiveness) and 4.1 (management review); ICH Q9(R1)	About 20 minutes with the example

Open the tool at https://app.cmcfy.com/app/remediation-tracker.html. This guide is also online at https://cmcfy.com/guides/remediation-tracker.html

1. What this module does

You give the response the commitments come from, the status date, when the last update went to FDA and the interval, then one row per commitment with its owner, committed date, any revised date and whether FDA was told, status, evidence and effectiveness check.

The tool flags commitments past the date given to FDA, revised dates FDA has not been told, completed actions without evidence or an effectiveness check, actions found not effective and an update that is due. When every commitment is verified effective it says the site can ask FDA for close-out.

What you get

- Two Word or PDF files: the update letter to FDA, and the remediation status report for management review.

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2. Before you start

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

- Your 483 or warning letter response with its commitments.
- Evidence for each completed action.
- Effectiveness check results.

> **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.

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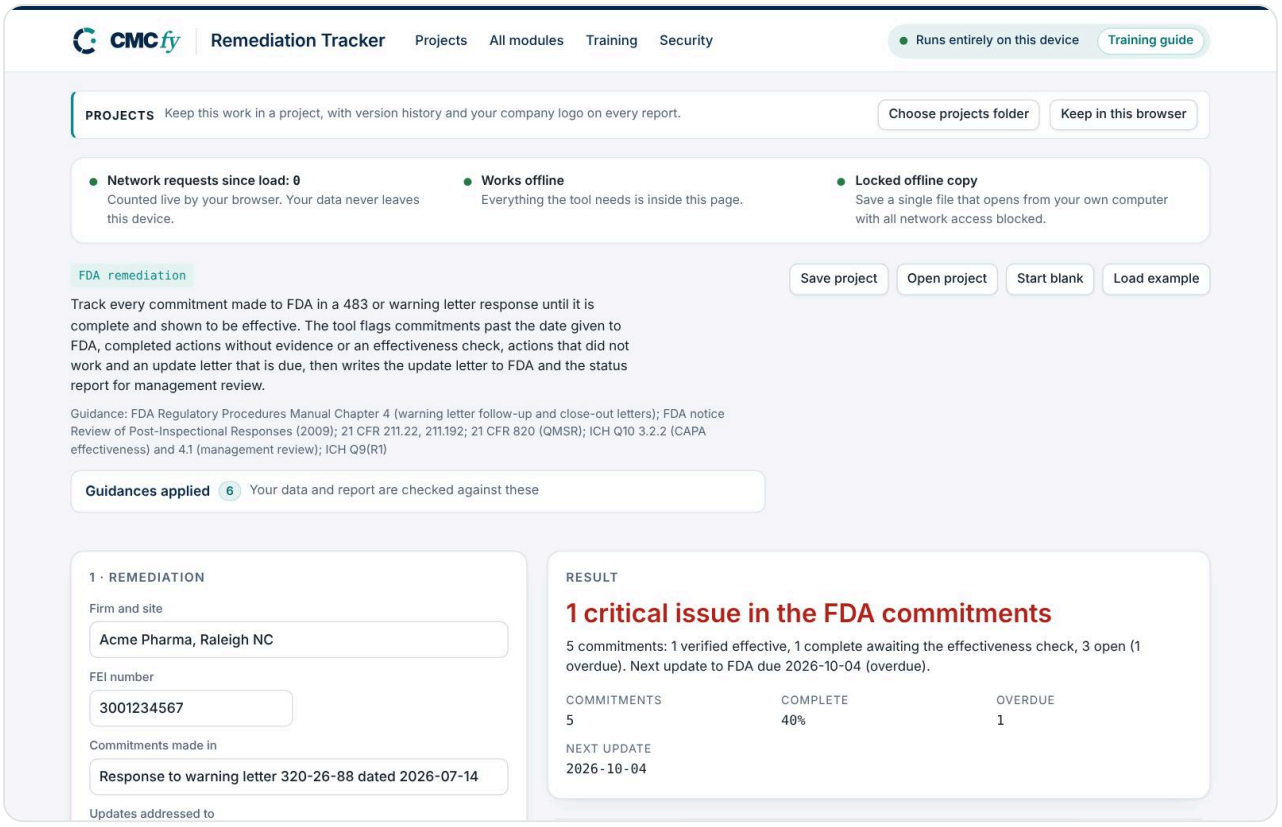
3. Step by step with the example

Open the tool at app.cmcfy.com/app/remediation-tracker.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 remediation

Give the firm, the response the commitments come from, who updates go to, the status date and the last update.



2 List the commitments

One row per commitment. Status is open, complete or verified; effectiveness is planned, effective or not effective.

3 Read the result

The headline gives the outcome, for example "60% of commitments complete · 2 open".

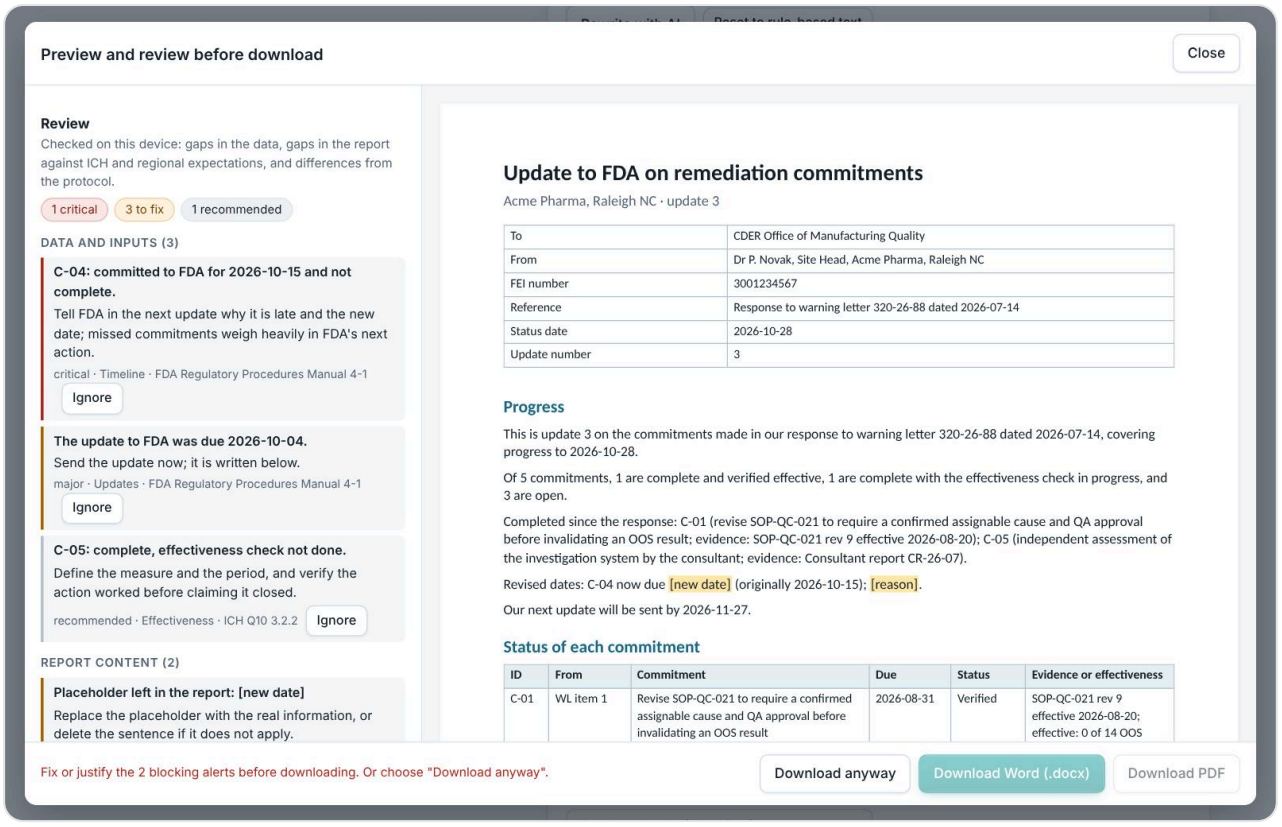
COMMITMENTS

ID	FROM	COMMITMENT	OWNER	DUE	STATUS	EFFECTIVENESS
C-01	WL item 1	Revise SOP-QC-021 to require a confirmed assignable cause and QA approval before invalidating an OOS result	QC manager	2026-08-31	verified	effective: 0 of 14 OOS invalidated without a confirmed cause in Sep–Oct
C-02	WL item 1	Retrospective review of all OOS and deviation investigations since 2024	QA manager	2026-12-31	open	planned
C-03	WL item 2	Unique logins and removal of deletion rights in the chromatography data system	IT and QC	2026-11-15 (was 2026-09-30)	open	planned
C-04	WL item 2	Assessment of all 14 computerised systems in QC and production	CSV lead	2026-10-15	overdue	planned
C-05	WL request A	Independent assessment of the investigation system by the consultant	Head of quality	2026-09-15	complete	–

Commitments with their due dates and status.

4 Resolve alerts and download

A commitment past the date FDA was given, without a revised date, and an action found not effective are critical. Then preview and download the update letter and the status report.



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 · Remediation

FIELD	WHAT TO ENTER
Firm and site	Type it in.
FEI number	Type it in.
Commitments made in	Type it in.
Updates addressed to	Type it in.
Status date	Type it in.
Last update sent to FDA	Type it in.
Update interval (days)	Type a number.

FIELD	WHAT TO ENTER
Update number	Type a number.
Signed by	Type it in.

2 · Commitments

One row per commitment. Status: open, complete or verified (effective). Effectiveness: planned, effective or not effective.

FIELD	WHAT TO ENTER
Commitments	Revised date counts only when FDA was told of it; otherwise the original date applies. A table. Columns: ID | From (obs./item) | Commitment | Owner | Committed date | Revised date | Revision told to FDA (yes/no) | Status (open/complete/verified) | Evidence | Effectiveness check. Paste rows from Excel, type comma-separated rows, or press `Load file` (Excel, CSV, Word, PDF or a scan).

5. Checks and alerts

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

- Commitments past the date given to FDA.
- Evidence and effectiveness checks.
- Update letter due and close-out readiness.

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: Update letter. 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.

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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	Update to FDA on remediation commitments
Report	Remediation status 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.

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7. US and EU submissions

US only: FDA 483 and warning letter commitments.

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8. Working with other modules

- Commitments come from the Form 483 Response or the Warning Letter Response.

9. Common pitfalls

- Missing a committed date without telling FDA.
- Closing commitments before checking they worked.

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. **Complete the system assessment**

   Mark C-04 complete with its report as evidence.

   EXPECTED RESULT

   No commitment is overdue.

2. **Find an action that did not work**

   Change the effectiveness of C-01 to "not effective".

   EXPECTED RESULT

   The failed action is critical.

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.