

Complaint Trending & Recall Report

Write the periodic complaint report and the recall decision: complaints by category and batch, closure times, root causes, repeat complaints, and for critical defects the health hazard evaluation, recall class and notifications.

WRITES

GMP

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

21 CFR 211.198 (complaint files), 211.204, 314.81(b)(1) (field alert reports); 21 CFR Part 7 (recalls); FDA Guidance for Industry: Product Recalls (2020); EU GMP Chapter 8 (2015) Complaints, quality defects and product recalls; EMA Compilation of procedures: rapid alert system; ICH Q9(R1), Q10

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You enter each complaint with its batch, description, category, severity, root cause, CAPA and closure date. The tool trends them by category and batch and calculates the rate per million units.

It flags critical defects without a recall decision, repeat complaints, late closures, missing root causes and adverse events not referred to pharmacovigilance.

What you get

- A Word or PDF report: Complaint trending and recall report.

2. Before you start

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

- The complaints received in the period.
- Units distributed.
- The health hazard evaluation for any critical defect.

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/complaints-recalls.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 period

Enter the product, the period, the units distributed and the closure target.

Complaint Trending & Recall Report
Projects
All modules
Training
Security
Runs entirely on this device
Training guide

PROJECTS Keep this work in a project, with version history and your company logo on every report.
Choose projects folder
Keep in this browser

- Network requests since load: 0**
Counted live by your browser. Your data never leaves this device.
- Works offline**
Everything the tool needs is inside this page.
- Locked offline copy**
Save a single file that opens from your own computer with all network access blocked.

GMP
Save project
Open project
Start blank
Load example

Write the periodic complaint trending report and, when needed, the recall decision. The tool counts complaints by category and batch, checks closure times and investigations, flags repeat complaints and critical defects, and checks the health hazard evaluation, recall class, notifications and effectiveness checks.

Guidance: 21 CFR 211.198 (complaint files), 211.204, 314.81(b)(1) (field alert reports); 21 CFR Part 7 (recalls); FDA Guidance for Industry: Product Recalls (2020); EU GMP Chapter 8 (2015) Complaints, quality defects and product recalls; EMA Compilation of procedures: rapid alert system; ICH Q9(R1), Q10

1 · REPORT

Product
CMX-101 tablets 50 mg

Regulations
Both US and EU

Report number
CT-R-2026-Q3

Period
2026-07-01 to 2026-09-30

Units distributed in the period
4200000

Closure target (days)
30

Report date
10/15/2026

RESULT

6 complaints · no adverse trend

6 complaints in 2026-07-01 to 2026-09-30 (1 open); 1.19 product complaints per million units. By category: quality defect 3, packaging or labelling 2, adverse event 1.

COMPLAINTS	OPEN	PER MILLION UNITS
6	1	1.19

CRITICAL
0

COMPLAINTS

COMPLAINT	RECEIVED	BATCH	DESCRIPTION	CATEGORY	SEVERITY	DAYS TO CLOSE
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2 Enter the complaints

One row per complaint. Leave the closed date empty while it is open.

3 Read the result

The headline gives the trend: "6 complaints · no adverse trend".

COMPLAINTS

COMPLAINT	RECEIVED	BATCH	DESCRIPTION	CATEGORY	SEVERITY	DAYS TO CLOSE
CP-2611	2026-07-08	B2604	Broken tablets in bottle	Quality defect	minor	21
CP-2614	2026-07-19	B2606	Missing leaflet	Packaging or labelling	major	26
CP-2619	2026-08-02	B2606	Black speck on tablet	Quality defect	minor	28
CP-2622	2026-08-21	B2609	Bottle cap hard to open	Packaging or labelling	minor	12
CP-2627	2026-09-12	B2610	Headache after taking	Adverse event	minor	6
CP-2630	2026-09-25	B2611	Crushed tablet in blister	Quality defect	minor	open 20

Complaints and closure.

4

Resolve alerts and download

A critical defect without a recall decision is critical. Repeat complaints and missing root causes are major. Then preview and download.

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.

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 file

Compare

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

Complaint trending and recall report
 CMX-101 tablets 50 mg · CT-R-2026-Q3 · US (FDA) and EU (EMA)

Product	CMX-101 tablets 50 mg
Report number	CT-R-2026-Q3
Period	2026-07-01 to 2026-09-30
Units distributed	4200000
Regulations	US (FDA) and EU (EMA)

1. Complaints received

Complaint	Batch	Description	Category	Severity	Root cause	Closed
CP-2611	B2604	Broken tablets in bottle	Quality defect	minor	Transport damage (no manufacturing cause)	21 days
CP-2614	B2606	Missing leaflet	Packaging or labelling	major	Leaflet feeder sensor failure	26 days
CP-2619	B2606	Black speck on tablet	Quality defect	minor	Degraded lubricant from tablet press (cosmetic)	28 days
CP-2622	B2609	Bottle cap hard to open	Packaging or labelling	minor	Within specification for removal torque	12 days
CP-2627	B2610	Headache after taking	Adverse event	minor	Referred to pharmacovigilance; batch review no defect	6 days
CP-2630	B2611	Crushed tablet in blister	Quality defect	minor	Under investigation	Open

2. Trend by category

Category	Complaints
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Download Word (.docx)

Download PDF

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 • Report

FIELD	WHAT TO ENTER
Product	Type it in.
Regulations	Choose one: US: 21 CFR 211.198, Part 7; EU: EU GMP Chapter 8; Both US and EU.
Report number	Type it in.
Period	Type it in.
Units distributed in the period	Type a number.
Closure target (days)	Type a number.

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FIELD	WHAT TO ENTER
Report date	Type it in.

2 · Complaints

One row per complaint. Severity: critical, major or minor.

FIELD	WHAT TO ENTER
Complaints	A table. Columns: Complaint Received Batch Description Category Severity Root cause CAPA Closed. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Recall decision

FIELD	WHAT TO ENTER
Recall	Choose one: No recall needed; Recall initiated.
Health hazard evaluation	Name each critical complaint (for example CP-2611) in the health hazard evaluation. Type or paste text.
Recall class when it applies	Choose one: Class I / 1; Class II / 2; Class III / 3.
Recall depth when it applies	Choose one: Wholesale; Retail (pharmacy); Patient level.
Authorities notified (FDA field alert / district; EU rapid alert / competent authority) when it applies	Tick the box if it applies.
Effectiveness checks (level and result) when it applies	Type or paste text.

5. Checks and alerts

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

- Trend by category and batch.
- Closure time and root cause.
- Recall decision, class, notifications and effectiveness checks.

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: Trend evaluation 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	Complaint trending and recall 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

US follows 21 CFR 211.198, field alert reports (314.81) and Part 7 recalls. EU follows EU GMP Chapter 8 and the rapid alert system.

8. Working with other modules

- Complaints are investigated in the Investigation Studio (OOS, deviation, CAPA) and summarised in the Annual Product Review.
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9. Common pitfalls

- Closing complaints without a root cause.
 - Missing a repeat complaint on the same batch.
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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. Escalate a complaint

Change complaint CP-2611 from minor to critical.

EXPECTED RESULT

The headline shows one critical defect needing a recall decision.

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.