FDA INSPECTIONS AND ENFORCEMENT · TRAINING GUIDE

FDA Citation Trends

See what FDA cites most in its public inspection and warning letter data, by 21 CFR section, inspection system and fiscal year, and check your own open findings against the most cited areas.

WRITES	PRODUCT TYPE	GUIDANCE IT FOLLOWS	TIME TO LEARN
`FDA citation trends`	FDA inspections	FDA Data Dashboard (inspections, citations and compliance actions); FDA warning letters posted under the Freedom of Information Act; FDA Compliance Program 7356.002 (six-system inspection model); FDA Report on the State of Pharmaceutical Quality; 21 CFR 210, 211; 21 CFR 820 (QMSR); ICH Q9(R1), Q10	About 20 minutes with the example

Open the tool at https://app.cmcfy.com/app/fda-citation-trends.html. This guide is also online at https://cmcfy.com/guides/fda-citation-trends.html

1. What this module does

You load the citations exported from the FDA Data Dashboard (or the violations from posted warning letters), set the period, programme and country, and list your own open findings with their 21 CFR section.

The tool groups the citations by section, places each in its inspection system, counts them by FDA fiscal year, shows which sections are rising, and flags your open findings that sit in FDA's most cited areas. Nothing is fetched; the export you load stays on your computer.

What you get

- A Word or PDF file: FDA citation trend report with the most cited sections, systems, fiscal years and the comparison with your site.

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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.

- The citations export from the FDA Data Dashboard (inspections, citations).
- Your open self-inspection, mock inspection or audit findings.

> **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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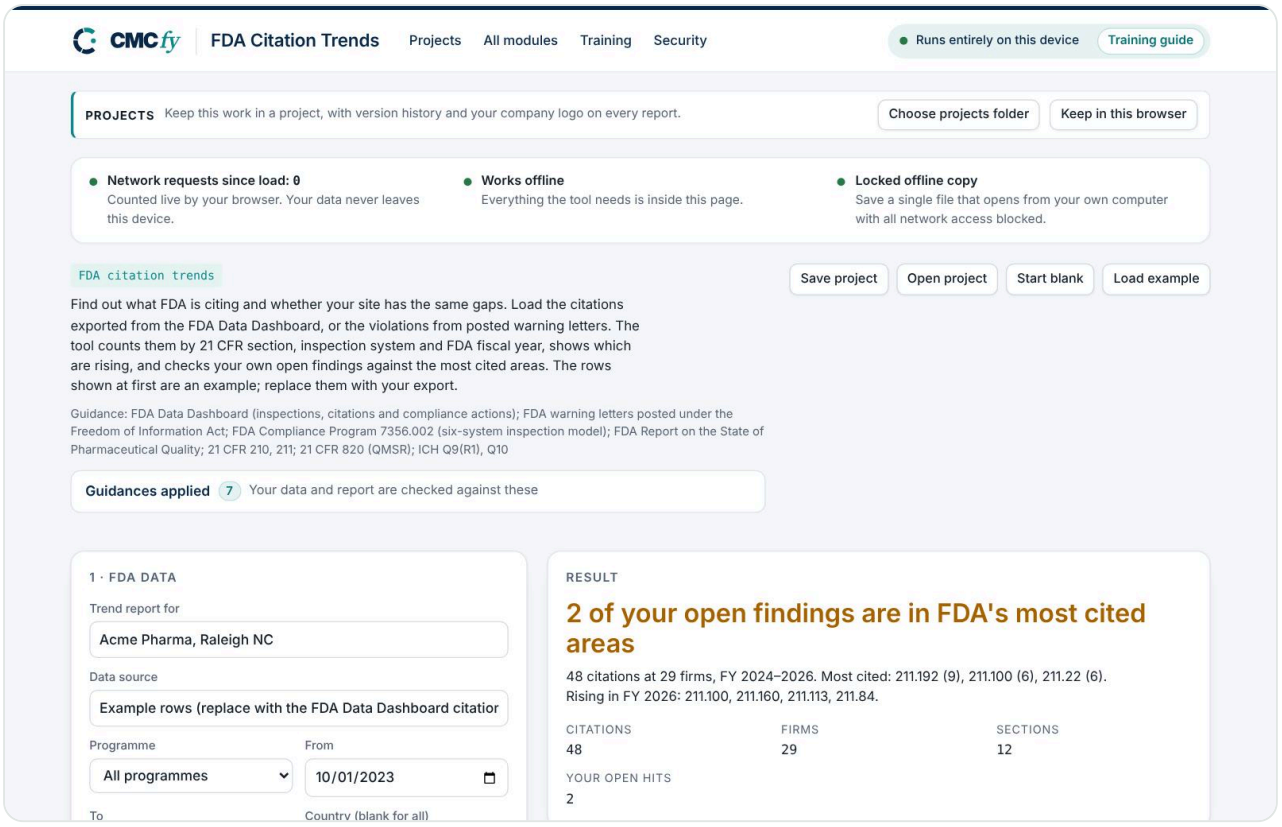
3. Step by step with the example

Open the tool at app.cmcfy.com/app/fda-citation-trends.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 Load the FDA data

Load the export with "Load file" on the citations table. Columns are matched by name: inspection end date, firm, country, programme, CFR number and short description. The rows shown at first are an example.



2 Set the filters

Choose the period, programme and country, and how many sections to show.

3 Add your findings

One row per finding with its 21 CFR section and status.

4 Read the result

The headline gives the outcome, for example "2 of your open findings are in FDA's most cited areas".

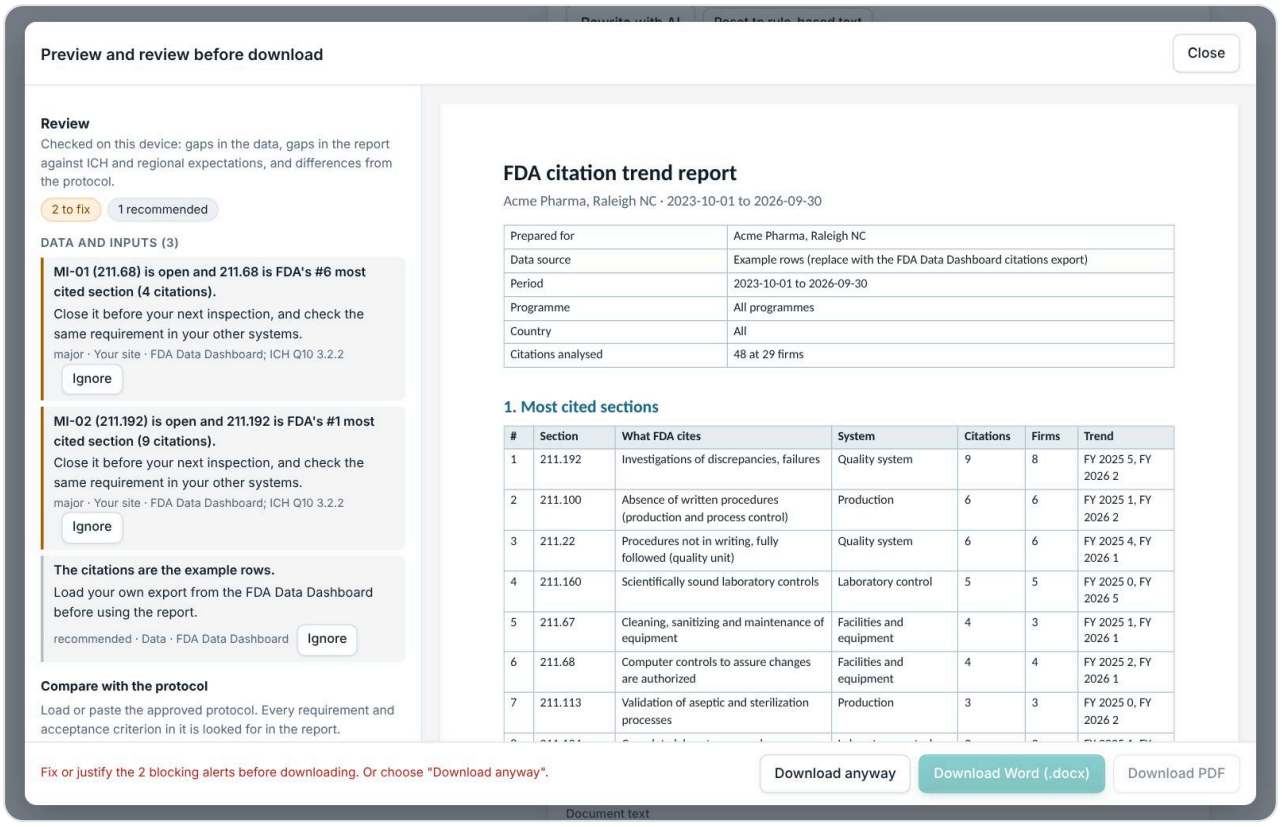
MOST CITED SECTIONS (TOP 10)

#	SECTION	WHAT FDA CITES	SYSTEM	CITATIONS	FIRMS	FY 25→26
1	211.192	Investigations of discrepancies, failures	Quality system	9	8	5 → 2
2	211.100	Absence of written procedures (production and process control)	Production	6	6	1 → 2
3	211.22	Procedures not in writing, fully followed (quality unit)	Quality system	6	6	4 → 1
4	211.160	Scientifically sound laboratory controls	Laboratory control	5	5	0 → 5
5	211.67	Cleaning, sanitizing and maintenance of equipment	Facilities and equipment	4	3	1 → 1
6	211.68	Computer controls to assure changes are authorized	Facilities and equipment	4	4	2 → 1
7	211.113	Validation of aseptic and sterilization processes	Production	3	3	0 → 2
8	211.194	Complete laboratory records	Laboratory control	3	3	1 → 0
9	211.84	Testing of components for identity	Materials	3	3	1 → 2
10	211.110	Control procedures to monitor and validate performance	Production	2	2	1 → 1

Most cited sections and the trend by fiscal year.

5 Download

Open findings in the most cited areas are flagged. Then preview and download.



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 · FDA data

FIELD	WHAT TO ENTER
Trend report for	Type it in.
Data source	Type it in.
Programme	Choose one: All programmes; Drugs (21 CFR 210, 211); Biologics; Devices (21 CFR 820).
From	Type it in.
To	Type it in.
Country (blank for all)	Type it in.
Most cited sections to show	Type a number.

FIELD	WHAT TO ENTER
Citations	Paste or load the FDA Data Dashboard citations export; one row per citation. A table. Columns: Inspection End Date | Legal Name | Country/Area | Program Area | CFR/Act Number | Short Description. Paste rows from Excel, type comma-separated rows, or press `Load file` (Excel, CSV, Word, PDF or a scan).

2 · Your site

Open findings from your self-inspections, mock inspections or audits, to check against what FDA cites most.

FIELD	WHAT TO ENTER
Your findings	Use the section as cited, for example 211.192 or 211.68(b). A table. Columns: Finding | 21 CFR | Description | Status (open/closed). 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:

- Most cited sections and the firms cited.
- Rising sections by FDA fiscal year.
- Your open findings in FDA's top areas.

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: What this means for our site. 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	FDA citation trend 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 only: FDA public data. Counts depend on the export you load; they are not an FDA statistic.

8. Working with other modules

- Feed the most cited areas into your FDA Inspection Readiness mock inspection and Self-Inspection Report programme.

9. Common pitfalls

- Drawing trends from a few dozen citations.
- Comparing different programmes (drugs and devices) in one count.

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. **Close a finding**

   Mark MI-02 as closed.

   EXPECTED RESULT

   One open finding remains in the top areas.

2. **Filter to devices**

   Choose Devices as the programme.

   EXPECTED RESULT

   The example has no device citations.

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.