

Form 483 Response

Write the response to a Form FDA 483 inside the 15 business days FDA allows: root cause, correction, corrective and preventive action, scope beyond the cited example, evidence and a date for every observation.

<div>WRITES</div> <div>FDA 483 response</div>	<div>PRODUCT TYPE</div> <div>FDA inspections</div>	<div>GUIDANCE IT FOLLOWS</div> <div>Form FDA 483; FDA notice Review of Post-Inspectional Responses (Federal Register, August 2009): 15 business days; FDA Investigations Operations Manual Chapter 5 (FDA 483 and annotation); FDA Regulatory Procedures Manual Chapter 4 (advisory actions); 21 CFR 211.22, 211.192; 21 CFR 820 (QMSR); FDA Data Integrity and Compliance with Drug CGMP Q&A (2018); ICH Q9(R1), Q10 3.2.2</div>	<div>TIME TO LEARN</div> <div>About 20 minutes with the example</div>
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Open the tool at <https://app.cmcfy.com/app/form-483-response.html>. This guide is also online at <https://cmcfy.com/guides/form-483-response.html>

1. What this module does

You give the inspection dates, the date the 483 was issued and the date you will send the response, then one row per observation with the root cause, correction, CAPA, scope, evidence, due date and status.

The tool counts the 15 business days the way FDA does (weekends and US federal holidays excluded), and flags missing root causes and CAPAs, human error given as the root cause, retraining as the only action, observations with no scope beyond the example, data integrity observations without a system-wide assessment, open actions without dates, and no commitment to send updates.

What you get

- A Word or PDF file: the response letter, observation by observation, with the summary of commitments.

2. Before you start

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

- The Form 483 as issued.
- Your investigation reports and CAPA records.
- The documents you will attach as evidence.

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/form-483-response.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

Enter the inspection

Give the firm, FEI number, inspection dates, the 483 date, who it goes to and who signs. The due date is worked out for you.

CMCfy

Form 483 Response

ProjectsAll modulesTrainingSecurity

Runs entirely on this deviceTraining guide

PROJECTS

Keep this work in a project, with version history and your company logo on every report.

Choose projects folderKeep 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.

FDA 483 response

Save projectOpen projectStart blankLoad example

Write the response to a Form FDA 483. For every observation the tool asks for the root cause, the correction, the corrective and preventive actions, how far the problem reaches beyond the example FDA cited, the evidence and the completion date. It checks the 15 business day deadline and flags the weak answers investigators and compliance officers reject.

Guidance: Form FDA 483; FDA notice Review of Post-Inspectional Responses (Federal Register, August 2009); 15 business days; FDA Investigations Operations Manual Chapter 5 (FDA 483 and annotation); FDA Regulatory Procedures Manual Chapter 4 (advisory actions); 21 CFR 211.22, 211.192; 21 CFR 820 (QMSR); FDA Data Integrity and Compliance with Drug CGMP Q&A (2018); ICH Q9(R1), Q10 3.2.2

Guidances applied

8

Your data and report are checked against these

1 - INSPECTION

Firm and site

Acme Pharma, Raleigh NC

FEI number

3001234567

Inspection dates

2026-09-28 to 2026-10-09

Date the Form 483 was issued

10/09/2026

Date the response will be sent

10/27/2026

RESULT

1 critical issue in the 483 response

3 observations; 1 complete, 2 in progress. Due 2026-11-02 (15 business days after 2026-10-09); sent after 11 business days.

OBSERVATIONS

3

RESPONSE DUE

2026-11-02

BUSINESS DAYS USED

11

OPEN ACTIONS

2

2 Answer each observation

One row per observation. Copy the observation as written; give the root cause, what you corrected, the CAPA, what else you checked, the evidence and the date.

3 Read the result

The headline gives the outcome, for example "1 critical issue in the 483 response".

RESPONSE CHECK BY OBSERVATION							
OBS.	21 CFR	ROOT CAUSE	CAPA	SCOPE	EVIDENCE	DUE	STATUS
1	211.192	given	given	assessed	attached	2026-12-15	in progress
2	211.67(b)	human error	training only	missing	attached	2026-10-20	complete
3	211.68(b); 211.194(a)	given	given	missing	attached	2027-01-31	in progress

Response check for each observation.

4

Resolve alerts and download

A late response, a missing root cause or CAPA and a data integrity observation with no system-wide assessment are critical. Human error, retraining only, no scope and missing dates are flagged. Then preview and download.

investigator; A. Lee, Chemist. We take the observations seriously and thank the investigators

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 5 to fix

DATA AND INPUTS (5)

Observation 3 concerns data integrity and has no system-wide assessment.
Assess every computerised system and the data in released batches and applications, and say what you found.
critical · Data integrity · FDA Data Integrity Q&A (2018)
Ignore

Observation 2: the root cause is given as human error.
Explain why the procedure, design or supervision let the error happen; FDA rarely accepts human error alone.
major · Root cause · FDA warning letters; ICH Q9(R1)
Ignore

Observation 2: retraining is the only action.
Add a change to the procedure, system or check, or show why training alone addresses the root cause.
major · CAPA · ICH Q10 3.2.2 Ignore

Observation 2: nothing says how far the problem reaches beyond the example FDA cited.
Review whether the evidence is sufficient to reach a conclusion.
major · CAPA · ICH Q10 3.2.2 Ignore

Response to Form FDA 483

Acme Pharma, Raleigh NC · inspection 2026-09-28 to 2026-10-09

To	Program Division Director, FDA Office of Inspections and Investigations (as named on the Form 483)
From	Dr P. Novak, Site Head, Acme Pharma, Raleigh NC
FEI number	3001234567
Inspection	2026-09-28 to 2026-10-09
Form 483 issued	2026-10-09
Date	2026-10-27

Introduction

Acme Pharma, Raleigh NC (FEI 3001234567) acknowledges the Form FDA 483 issued on 2026-10-09 at the close of the inspection of 2026-09-28 to 2026-10-09 by J. Smith, Investigator; A. Lee, Chemist. We take the observations seriously and thank the investigators for their time. This letter gives, for each observation, our investigation and root cause, the correction, the corrective and preventive actions, the scope of our review beyond the examples cited, the evidence attached and the completion dates. 2 actions are in progress; we will send written updates every 30 days until they are complete.

Responses to the observations

Observation 1

Investigations of unexplained discrepancies were not thorough: OOS assay result for lot 24-118 was invalidated without an assignable cause (21 CFR 211.192).

Root cause	The OOS procedure allowed a result to be invalidated on a suspected cause without confirming it; QC supervisors were not required to document hypothesis testing
Correction	Lot 24-118 placed on hold and the investigation reopened
Corrective and preventive action	SOP QC 001 revised to require confirmed assignable cause and QA approval before...

Fix or justify the 5 blocking alerts before downloading. Or choose "Download anyway".

Download anyway Download Word (.docx) Download PDF

Document text

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 · Inspection

FIELD	WHAT TO ENTER
Firm and site	Type it in.
FEI number	Type it in.
Inspection dates	Type it in.
Date the Form 483 was issued	Type it in.

FIELD	WHAT TO ENTER
Date the response will be sent	FDA considers a response received within 15 business days before deciding on a warning letter. Type it in.
Addressed to	Type it in.
Investigators	Type it in.
Signed by (senior management)	Type it in.
We commit to written updates every 30 days until all actions are complete	Tick the box if it applies.

2 · Observations and responses

One row per observation. Scope: what else you checked (other batches, products, lines, systems, sites) and what you found.

FIELD	WHAT TO ENTER
Observations	Scope beyond the example: the other batches, products, equipment, systems or sites you checked, and what you found. A table. Columns: Obs. Observation (as written on the 483) 21 CFR Root cause Correction Corrective and preventive action Scope beyond the example Evidence attached Due Status (complete/in progress). 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:

- 15 business day deadline.
- Root cause, CAPA and scope for every observation.
- Data integrity scope, evidence, dates and updates.

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: Opening; Closing. 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	Response to Form FDA 483

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: Form FDA 483. Due dates exclude US federal holidays.

8. Working with other modules

- Track the commitments in the Remediation Tracker. If FDA issues a warning letter, use the Warning Letter Response.
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9. Common pitfalls

- Blaming one operator and retraining them.
 - Fixing the cited batch without checking the others.
 - Missing the 15 business days because every action was to be finished first.
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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. Send the response late

Change the send date to 2026-11-05.

EXPECTED RESULT

Late response is critical.

2. Assess the data integrity scope

For observation 3, enter "All 14 computerised systems assessed; no other gaps" as the scope.

EXPECTED RESULT

No critical issue remains.

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.