

FDA Inspection Readiness

Prepare a site for an FDA inspection and write the mock inspection report: every inspection system reviewed, findings written as FDA observations, repeat-observation risk, data integrity and the pre-approval objectives checked.

WRITES

FDA inspection

PRODUCT TYPE

FDA inspections

GUIDANCE IT FOLLOWS

FD&C Act 704(a) and 704(a)(4); FDA Compliance Program 7356.002 (drug manufacturing inspections) and 7346.832 (pre-approval inspections); FDA Investigations Operations Manual; FDA Data Integrity and Compliance with Drug CGMP Q&A (2018); FDA guidance on delaying, denying, limiting or refusing a drug inspection (FD&C Act 501(j)); FDA Conducting Remote Regulatory Assessments Q&A; 21 CFR 210, 211; 21 CFR 820 (QMSR); ICH Q7, Q9(R1), Q10

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You choose the programme and the inspection type, list the systems your mock investigators reviewed, write each finding the way an FDA investigator writes a Form 483 observation, and list the observations from the last FDA inspection with the status of their CAPA.

The tool works out readiness for each system (CP 7356.002 for drugs, biologics and APIs; the QMSR areas for devices), flags systems not reviewed, open critical and major findings, findings that repeat an earlier FDA observation, earlier CAPAs that are open or not verified effective, data integrity gaps and slow records production. For a pre-approval inspection it checks the three PAI objectives of CP 7346.832.

What you get

- A Word or PDF file: mock FDA inspection report with readiness by system, observations, earlier FDA observations, logistics and the conclusion.

2. Before you start

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

- The mock inspection notes for each system.
- The last Form 483 and your response.
- CAPA and effectiveness records for the earlier observations.

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/inspection-readiness.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 site and inspection

Give the site, FEI number, programme and inspection type. For a pre-approval inspection, name the application.

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.

FDA inspection [Save project](#) [Open project](#) [Start blank](#) [Load example](#)

Prepare a site for an FDA inspection and write the mock inspection report. The tool checks every inspection system was reviewed, classifies the mock findings written the way an investigator writes a Form 483 observation, flags findings that repeat an earlier FDA observation, earlier CAPAs that are open or not verified, data integrity gaps and, for a pre-approval inspection, the three PAI objectives.

Guidance: FD&C Act 704(a) and 704(a)(4); FDA Compliance Program 7356.002 (drug manufacturing inspections) and 7346.832 (pre-approval inspections); FDA Investigations Operations Manual; FDA Data Integrity and Compliance with Drug CGMP Q&A (2018); FDA guidance on delaying, denying, limiting or refusing a drug inspection (FD&C Act 501(j)); FDA Conducting Remote Regulatory Assessments Q&A; 21 CFR 210, 211; 21 CFR 820 (QMSR); ICH Q7, Q9(R1), Q10

Guidances applied 9 Your data and report are checked against these

1 - SITE AND INSPECTION

Site
Acme Pharma, Raleigh NC (oral solid dose manufacturing an

FEI number
3001234567

Programme
Human drugs: 21 CFR 211

Inspection type
Pre-approval or pre-licen

Application under review
NDA 219999, tablets 10 mg

RESULT

Not ready: 1 critical issue

6 of 6 systems reviewed; 4 mock findings (0 critical, 2 major, 2 minor), 3 open. 3 earlier FDA observations, 1 not closed and verified.

SYSTEMS READY 4 of 6	OPEN FINDINGS 3	REPEAT RISK 1
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INSPECTION
Pre-approval

2 List the systems and findings

One row per system reviewed, then one row per finding with the system, the observation, the 21 CFR section, its class and the CAPA.

3 Add the earlier FDA observations

One row per observation from the last Form 483, with whether the CAPA is closed and its effectiveness verified.

4 Read the result

The headline gives the outcome, for example "Not ready: 1 critical issue" or "Ready with 4 gaps to close".

READINESS BY SYSTEM			
SYSTEM	REVIEWED	FINDINGS (OPEN)	READINESS
Quality system	2026-10-20	1 (1)	ready
Facilities and equipment	2026-10-20	1 (0)	ready
Materials	2026-10-21	0 (0)	ready
Production	2026-10-21	1 (1)	gaps
Packaging and labeling	2026-10-22	0 (0)	ready
Laboratory control	2026-10-22	1 (1)	gaps

Readiness by system and the mock findings.

5 Resolve alerts and download

Open critical findings, findings that repeat an earlier FDA observation and unconfirmed PAI objectives are critical. Systems not reviewed, open major findings, earlier CAPAs not verified and data integrity gaps 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.

1 critical

4 to fix

DATA AND INPUTS (5)

PAI objective 3, data integrity of the application data, is not confirmed.

Confirm it before the inspection; FDA recommends withholding approval when an objective is not met.

critical · Pre-approval · CP 7346.832 Part III

Ignore

MI-01: open major finding likely to be cited on a Form 483: Audit trails of the HPLC data system are not reviewed before batch release for 4 of 6 batches sampled.

Close it, or have the CAPA with evidence of progress ready to show the investigator.

major · Findings · FDA IOM; ICH Q10 3.2.2

Ignore

MI-02: open major finding likely to be cited on a Form 483: Two batch records show granulation hold times beyond the validated 72 h without a deviation.

Close it, or have the CAPA with evidence of progress ready to show the investigator.

major · Findings · FDA IOM; ICH Q10 3.2.2

Ignore

483-2 (2024): CAPA closed but its effectiveness was

Mock FDA inspection report

Acme Pharma, Raleigh NC (oral solid dose manufacturing and QC) · MI-2026-03

Site	Acme Pharma, Raleigh NC (oral solid dose manufacturing and QC)
FEI number	3001234567
Inspection type	Pre-approval (CP 7346.832): NDA 219999, tablets 10 mg and 20 mg
Mock inspection date	2026-10-22
Last FDA inspection	March 2024, VAI: Form 483 with 3 observations

1. Readiness by system

System	Reviewed	Mock investigator	Findings (open)	Readiness
Quality system	2026-10-20	K. Osei (QA)	1 (1)	ready
Facilities and equipment	2026-10-20	External consultant	1 (0)	ready
Materials	2026-10-21	K. Osei (QA)	0 (0)	ready
Production	2026-10-21	External consultant	1 (1)	gaps
Packaging and labeling	2026-10-22	L. Brandt (QA)	0 (0)	ready
Laboratory control	2026-10-22	External consultant	1 (1)	gaps

2. Observations

Each finding is written as an FDA investigator would write a Form FDA 483 observation.

ID	Observation	21 CFR	Class	CAPA	Owner	Due	Status
MI-01	Audit trails of the HPLC data system are not reviewed before batch release for 4 of 6 batches	211.68(b); 211.194(a)	major	Audit trail review step added to SOP-QC-110 and to the release	QC manager	2026-11-15	Open

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

Download anyway

Download Word (.docx)

Download PDF

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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 - Site and inspection

FIELD	WHAT TO ENTER
Site	Type it in.
FEI number	Type it in.
Programme	Choose one: Human drugs: 21 CFR 210 and 211; APIs: ICH Q7, FD&C Act 501(a)(2)(B); Biologics: 21 CFR 600–680 and 211; Medical devices: 21 CFR 820 (QMSR).
Inspection type	Choose one: Surveillance (routine); Pre-approval or pre-licence (CP 7346.832); For-cause; Follow-up after a 483 or warning letter.
Application under review when it applies	Type it in.
Mock inspection report number	Type it in.
Mock inspection date	Type it in.
Last FDA inspection and outcome	Type it in.
Hours to produce a standard records request in the mock	Type a number.

2 - Systems reviewed

One row per system reviewed in the mock inspection. Drugs: quality system, facilities and equipment, materials, production, packaging and labeling, laboratory control.

FIELD	WHAT TO ENTER
Systems	A table. Columns: System Date reviewed Mock investigator (independent of the area) Records sampled. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Mock inspection findings

Write each finding as an FDA observation: what was seen, with the record and date. Class: critical, major or minor.

FIELD	WHAT TO ENTER
Findings	Write the observation as the investigator would: what was seen, in which record, how many of how many sampled. A table. Columns: ID System Observation 21 CFR Class (critical/major/minor) 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).

4 · Earlier FDA observations

FIELD	WHAT TO ENTER
Earlier Form 483 observations	Effectiveness verified means you have data that the CAPA worked, not only that it was done. A table. Columns: Observation Year Observation text CAPA status (open/closed) Effectiveness verified (yes/no). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

5 · Inspection logistics

FIELD	WHAT TO ENTER
Inspection management SOP current; host, scribes and runners trained	Tick the box if it applies.
Front room and back room set up, with a request log	Tick the box if it applies.

FIELD	WHAT TO ENTER
Subject matter experts named and rehearsed for each system	Tick the box if it applies.
Data integrity walk-through done (audit trails, user access, shared logins, deleted data)	Tick the box if it applies.
Storyboards ready for open deviations, OOS results, complaints and recalls	Tick the box if it applies.
Process for records requests under FD&C Act 704(a)(4) and remote regulatory assessments	Tick the box if it applies.
PAI objective 1: ready for commercial manufacturing when it applies	Tick the box if it applies.
PAI objective 2: conformance to the application (process, methods, specifications) when it applies	Tick the box if it applies.
PAI objective 3: data in the application traced to raw data when it applies	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 inspection system reviewed.
- Open findings and repeat-observation risk.
- Data integrity, records requests and the PAI objectives.

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	Mock FDA 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

US only: FDA inspections under FD&C Act 704. For EU GMP inspections, use the Self-Inspection Report report with EU GMP Chapter 9.

8. Working with other modules

- Answer a real Form 483 with the Form 483 Response, and check what FDA cites most with FDA Citation Trends.

9. Common pitfalls

- Mock findings written as opinions rather than as evidence an investigator would record.
- Earlier 483 CAPAs closed on paper but never checked for effectiveness.

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. Confirm the third PAI objective

Tick "PAI objective 3: data in the application traced to raw data".

EXPECTED RESULT

No critical issue remains; the open major gaps are listed.

2. Repeat an earlier FDA observation

Change finding MI-04 to "Cleaning validation did not include the worst-case product for granulator G-2".

EXPECTED RESULT

The repeat of 483-2 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.