

Report Reviewer

Upload any CMC section or report written anywhere and get a list of what a reviewer would find missing, with the guidance that asks for it and what to add.

WRITES 3.2.S 3.2.P 3.2.A 3.2.R 2.3 OOS, validation, stability, nitrosamine and Q3D reports	PRODUCT TYPE Small molecule and biologics	GUIDANCE IT FOLLOWS ICH M4Q(R1), ICH Q1A–Q14, ICH M7, FDA guidance cited per item	TIME TO LEARN About 20 minutes with the example
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Open the tool at <https://app.cmcfy.com/app/report-reviewer.html>. This guide is also online at <https://cmcfy.com/guides/report-reviewer.html>

1. What this module does

The Report Reviewer checks documents that were not written in CMCfy: a CTD section from a CRO, a legacy stability report, a validation report or a whole Module 3. Each section is checked against what ICH M4Q and the cited guidance expect for that section, for the region and product type you choose.

Upload a whole Module 3 or QOS and it finds each section by its heading. You can also load the approved protocol to check that each requirement and acceptance criterion appears in the report.

What you get

- A list of findings on screen, each with what is missing, why (the guidance) and what to add.

2. Before you start

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

- The document as Word, PDF, scanned pages, Excel or text, or its text to paste.
- Optionally the protocol it was written against.

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/report-reviewer.html. The example (a short 3.2.P.5.4 batch analyses section) is checked automatically when the page opens.

1 Choose what you are checking

Choose the [Section or report type](#), the [Region](#) and the [Product type](#) (small molecule, large molecule, or not sure to check both).

The screenshot shows the CMCfy Report Reviewer interface. At the top, there's a navigation bar with the CMCfy logo, 'Report Reviewer', and links for 'Projects', 'All modules', 'Training', and 'Security'. On the right, it says 'Runs entirely on this device' and has a 'Training guide' link. Below the navigation bar, there's a 'PROJECTS' section with a description and two buttons: 'Choose projects folder' and 'Keep in this browser'. The main content area has three status indicators: 'Network requests since load: 0', 'Works offline', and 'Locked offline copy'. Below these, there's a list of categories: '3.2.S', '3.2.P', '3.2.A', '3.2.R', '2.3', and '00S, validation, stability, nitrosamine and Q3D reports'. The '3.2.P' category is selected. The main text area says 'Upload a report or CTD section written anywhere, in any tool. CMCfy lists what a reviewer would find missing, with the guidance that asks for it and what to add. Upload a whole Module 3 or QOS and it finds each section by its heading. Guidance: ICH M4Q(R1), ICH Q1A–Q14, ICH M7, FDA guidance cited per item'. Below this, there's a section titled '1 · CHECK A DOCUMENT FOR MISSING INFORMATION'. It contains three dropdown menus: 'Section or report type' (set to '3.2.P.5.4 Batch analyses'), 'Region' (set to 'US: FDA (NDA, ANDA, BLA, IND)'), and 'Product type' (set to 'Small molecule (chemical)'). Below these is a 'Document text' area with a text box containing sample text: '3.2.P.5.4 Batch Analyses', 'Results for three batches of CMX-101 Tablets 50 mg are provided in the table below. All results comply with the specification.', 'Batch CMX-26-0101: Assay 99.6%, total degradation products 0.42%, dissolution 94%. Batch CMX-26-0102: Assay 101.2%, total degradation products 0.38%, dissolution 96%.', and 'Protocol to compare with (optional)'.

2 Load the document

Press [Load files](#) (several files are checked together) or paste the text. Scanned pages are read by text recognition on your computer.

3 Compare with the protocol (optional)

Paste or press **Load protocol**. Each requirement and acceptance criterion in it is looked for in the document.

4 Read the findings

Press **Check document**. Each finding says what is missing, the guidance that expects it, and what to add. For the example, the short batch analyses section has batch numbers, batch size and results, but is missing the site and date of manufacture, the use of each batch and the drug substance batch used.

1 · CHECK A DOCUMENT FOR MISSING INFORMATION

Upload a report or CTD section (Word, PDF, scanned pages, Excel or text), or paste its text. CMCfy checks it against what ICH M4Q and the cited guidance expect, and lists what is missing and what to add. The text stays in this browser tab unless you run the AI review.

Section or report type 3.2.P.5.4 Batch analyses Region US: FDA (NDA, ANDA, BLA, IND)

Product type Small molecule (chemical)

Document text

3.2.P.5.4 Batch Analyses

Results for three batches of CMX-101 Tablets 50 mg are provided in the table below. All results comply with the specification.

Batch CMX-26-0101: Assay 99.6%, total degradation products 0.42%, dissolution 94%.
Batch CMX-26-0102: Assay 101.2%, total degradation products 0.38%, dissolution 96%.

Protocol to compare with (optional)

Paste the approved protocol, or load it. Each requirement and acceptance criterion is looked for in the document.

Load files **Load protocol** **Check document** **AI review**

4 items missing or not found. Each one says what to add. Words that mean the same thing but are not recognised may show as missing, so check each finding.

3.2.P.5.4 Batch analyses 4 missing

REQUIRED Site of manufacture: not found
ICH M4Q
Give the manufacturing site of each batch.

REQUIRED Date of manufacture: not found
ICH M4Q
Give the date of manufacture of each batch.

REQUIRED Use of each batch: not found
ICH M4Q
State what each batch was used for (clinical, stability, registration, validation).

RECOMMENDED Drug substance batch used: not found
ICH M4Q 3.2.P.5.4

Findings for the example batch analyses section.

5 Optional AI review against guidance

Press **AI review**. AI reads the document, the protocol and any data against the ICH, FDA or EMA requirements for the section, and lists gaps with the guideline it applies, protocol and data mismatches, and how to fix each. A box first shows the exact text that will be sent, and nothing leaves the computer until you press **Send**. Quotes and numbers the AI cites are checked against your documents. Where the text goes is set in **AI settings** in the header.

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.

Check a document for missing information

FIELD	WHAT TO ENTER
Section or report type	The CTD section or report type to check against (for example 3.2.P.5.4, a stability report, an OOS report, a nitrosamine or Q3D report).
Region	US, EU or both: decides the regional references expected.
Product type	Small molecule, large molecule (biotechnology product) or not sure: check both.
Document text	Paste the text, or Load files (Word, PDF, scanned pages, Excel or text).
Protocol to compare with (optional)	Paste it or Load protocol .

5. Checks and alerts

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

- Required content for the section or report type, by ICH M4Q and the cited ICH, FDA and EMA guidance, for the region and product type.
- Whole Module 3 or QOS documents are split by section heading and each section is checked.
- Protocol comparison: requirements, acceptance criteria, batches and time points named in the protocol but not in the report.
- The checks look for content by keywords, so wording they do not recognise can show as missing: check each finding.

6. Preview, gap review and download

The Report Reviewer does not write documents; the findings on screen are the result. Fix the document in its own editor, then check it again.

1. Press **Check document** again after each change; changing the region or product type re-runs the check.
2. The document text stays in this browser tab unless you press **AI review** and approve what is sent.

7. US and EU submissions

Choose the region the document will be filed in. US mode expects USP and FDA references and US regional content; EU mode expects Ph. Eur. and EMA references and EU regional content; both checks for both.

8. Working with other modules

- Every CMCfy module has the same check built in under **Check a document for missing information**, with a **Use this tool's draft** button that checks the module's own draft.
- Once a section is complete, add it to the eCTD folder in the QOS Composer & Dossier Assembler.

9. Common pitfalls

- Checking a whole Module 3 with the wrong section type selected: choose the Module 3 or QOS option so it splits by heading.
- Treating a keyword miss as a real gap without reading the document: if the content is there in other words, ignore the finding.
- Forgetting to set the product type for a biologic, so Q6B and Q5 items are not checked.

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. Check a thinner section

Replace the document text with "3.2.P.5.4 Batch Analyses. All batches comply." and press **Check document**.

EXPECTED RESULT

The findings list the missing batch information, starting with the results table.

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.