

Batch Record Review & Release

Document the batch record review and the release decision: every result against the specification, the review checklist, deviations, and US quality unit release or EU QP certification.

WRITES

GMP

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

21 CFR 211.22, 211.188, 211.192; FDA Investigating OOS Test Results (2022); EU GMP Annex 16 Certification by a Qualified Person and Batch Release (2016); Directive 2001/83/EC Article 51; EU GMP Chapter 1 and Chapter 6; ICH Q7 6.7 and 2.22; ICH Q10

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You enter the results with their specifications, the review checklist and the deviations. The tool checks each result and each checklist item and decides whether the batch is ready for release.

For the EU it adds the QP checks: compliance with the marketing authorisation, import testing for batches made outside the EU and deviations assessed under Annex 16 section 3.

What you get

- A Word or PDF report: Batch record review and release (or QP certification).

2. Before you start

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

- The certificate of analysis results and specifications.
- The completed batch record review checklist.
- Deviations, OOS results and changes affecting the batch.

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/batch-release.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 batch

Enter the product, batch, manufacturing and expiry dates, and the market.

CMCfy Batch Record Review & Release 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

Prepare the batch record review and the release decision. The tool checks every certificate of analysis result against its specification, the review checklist, deviations and their status, and the release conditions that apply in the US (quality unit release) and the EU (QP certification under Annex 16, including import testing for batches made outside the EU).

Guidance: 21 CFR 211.22, 211.188, 211.192; FDA Investigating OOS Test Results (2022); EU GMP Annex 16 Certification by a Qualified Person and Batch Release (2016); Directive 2001/83/EC Article 51; EU GMP Chapter 1 and Chapter 6; ICH Q7 6.7 and 2.22; ICH Q10

1 - BATCH

Product
CMX-101 tablets 50 mg, bottles of 30

Market Batch number
Both US and EU B2611

Manufacturing and packaging sites
Drug product: Acme Pharma, Raleigh NC; packaging: Acme

Manufacturing date Expiry date
10/02/2026 09/30/2028

Marketing authorisation or

RESULT

Batch B2611: ready for release (US) and QP certification (EU)

9 results, 0 out of specification; checklist 10/10; 1 deviation (0 open). Shelf life 24 months.

BATCH	RESULTS	CHECKLIST
B2611	9/9 pass	10/10

DEVIATIONS
1 (0 open)

CERTIFICATE OF ANALYSIS

TEST	SPECIFICATION	RESULT	OUTCOME
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2 Enter results, checklist and deviations

One row per test, per checklist item (OK, NOK or NA) and per deviation.

3 Read the result

The headline gives the decision: "Batch B2611: ready for release (US) and QP certification (EU)".

CERTIFICATE OF ANALYSIS

TEST	SPECIFICATION	RESULT	OUTCOME
Appearance	White round film-coated tablet	Conforms	pass
Identity (HPLC and UV)	Conforms	Conforms	pass
Assay (%)	95.0-105.0	99.7	pass
Uniformity of dosage units (AV)	≤ 15.0	3.6	pass
Dissolution (% at 30 min; min of 6)	≥ 85	91	pass
Impurity B (%)	≤ 0.20	0.07	pass
Total impurities (%)	≤ 1.0	0.21	pass
Water (%)	≤ 3.5	2.3	pass
Microbial enumeration TAMC (cfu/g)	≤ 1000	<10	pass

Results and checklist.

4

Resolve alerts and download

A result out of specification, a NOK item or an open critical or major deviation is critical. Then preview and download the release record for signature.

QA batch record reviewer

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.

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 preview 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

Release Batch record review and release

CMX-101 tablets 50 mg, bottles of 30 - B2611 - US (FDA) and EU (EMA)

Product	CMX-101 tablets 50 mg, bottles of 30
Batch	B2611
Sites	Drug product: Acme Pharma, Raleigh NC; packaging: Acme Pharma, Raleigh NC
Manufactured	2026-10-02
Expiry	2028-09-30
Marketing authorisation	NDA 212345; EU MA DE/H/1234/001/DC
Market	US (FDA) and EU (EMA)

1. Certificate of analysis

Test	Specification	Result	Outcome
Appearance	White round film-coated tablet	Conforms	Complies
Identity (HPLC and UV)	Conforms	Conforms	Complies
Assay (%)	95.0-105.0	99.7	Complies
Uniformity of dosage units (AV)	≤ 15.0	3.6	Complies
Dissolution (% at 30 min; min of 6)	≥ 85	91	Complies
Impurity B (%)	≤ 0.20	0.07	Complies
Total impurities (%)	≤ 1.0	0.21	Complies
Water (%)	≤ 3.5	2.3	Complies
Microbial enumeration TAMC (cfu/g)	≤ 1000	<10	Complies

2. Batch record review

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Page 4 of 8

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 • Batch

FIELD	WHAT TO ENTER
Product	Type it in.
Market	Choose one: US: quality unit release; EU: QP certification; Both US and EU.
Batch number	Type it in.
Manufacturing and packaging sites	Type it in.
Manufacturing date	Type it in.
Expiry date	Type it in.
Marketing authorisation or application	Type it in.
Batch made outside the EU/EEA (import testing needed) when it applies	Tick the box if it applies.
EU import testing (site, report) when it applies	Type it in.

2 • Certificate of analysis

FIELD	WHAT TO ENTER
Results	A table. Columns: Test Specification Result. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Review

FIELD	WHAT TO ENTER
Batch record review checklist	Write a comment for every NOK or NA item. A table. Columns: Item Status (OK/NOK/NA) Comment. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Deviations	A table. Columns: Deviation Classification (minor/major/critical) Status (open/closed) Impact on the batch. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
OOS or OOT results on the batch	Type or paste text.
Reviewed by	Type it in.

5. Checks and alerts

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

- Each result against the specification.
- Review checklist complete.
- Deviations closed or assessed; EU import testing and MA compliance.

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: Release statement. 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
Release	Batch record review and release

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: the quality unit releases under 21 CFR 211.22 and 211.192. EU: a QP certifies under Directive 2001/83/EC Article 51 and EU GMP Annex 16.

8. Working with other modules

- Out-of-specification results are investigated in Investigation Studio (OOS, deviation, CAPA); release data feed the Annual Product Review.

9. Common pitfalls

- Releasing with a deviation still open and not assessed.
- Forgetting EU import testing for a batch made outside the EU.

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. Put a result out of specification

Change the assay result from 99.7 to 94.6.

EXPECTED RESULT

The headline shows the batch is not ready for release.

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.