

# Annual Product Review

Write the US annual product review (21 CFR 211.180(e)) or the EU product quality review (EU GMP 1.10), or both in one report: batches and yields, capability and trend rules for each critical attribute, quality events by type, and every review item the regulations name.

**WRITES**

Report

**PRODUCT TYPE**

Small molecule and biologics

**GUIDANCE IT  
FOLLOWS**

21 CFR 211.180(e);  
EU GMP Part I  
Chapter 1 (1.10–1.11);  
ICH Q10 (3.2.4 and 4.1); ICH Q7 2.5  
(product quality review for APIs);  
FDA Process  
Validation guidance  
(2011) stage 3

**TIME TO LEARN**About 20 minutes  
with the example

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

## 1. What this module does

You enter the batches of the period, the critical attribute results in batch order, the quality events (OOS, deviations, CAPAs, complaints, returns, recalls, changes and variations) and the review items. The tool calculates Ppk per attribute and applies trend rules: 7 or more results on one side of the mean, or 6 rising or falling in a row.

It checks that rejected batches and OOS results have investigations, that every required review item is covered for the region, and writes the review with the summary, tables, conclusion and actions.

### What you get

- A Word or PDF report: Annual product review, Product quality review, or both combined.
- A summary file with the period, batch counts and trends.

## 2. Before you start

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

- The review period (no more than about 12 months) and the marketing authorisations.
- Every batch made in the period with its status and yield, including rejected and pending ones.
- Critical in-process and release results in batch order.
- The quality events with their references, status and outcome, and text for each review item: materials, stability, qualification status, technical agreements, previous actions and post-marketing commitments.

**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/annual-product-review.html](https://app.cmcfy.com/app/annual-product-review.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 Set the scope

Enter the product, choose US APR, EU PQR or combined, and give the report number, period and marketing authorisations.



Annual Product Review
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.

Report

Save project
Open project
Start blank
Load example

Write the annual product review (US APR) or product quality review (EU PQR). Batches and yields are summarised, each critical attribute is trended with capability (Ppk) and trend rules, quality events are counted by type, and every review item the regulations name is checked. The report ends with the conclusion and the actions for next year.

Guidance: 21 CFR 211.180(e); EU GMP Part I Chapter 1 (1.10–1.11); ICH Q10 (3.2.4 and 4.1); ICH Q7 2.5 (product quality review for APIs); FDA Process Validation guidance (2011) / EMA process validation guideline (EMA/CHMP/CVMP/QWP/BWP/70278/2012 Rev1) stage 3

1 · REVIEW SCOPE

Product

CMX-101 Tablets, 50 mg

Review type

Report number

Combined APR / PQR

APR-101-2026

Period from

Period to

10/01/2025

09/30/2026

Marketing authorisations

NDA 212345; EU MA via DCP (DE/H/1234/001)

RESULT

12 batches · 1 rejected · 1 adverse trend

The review found points that need action; each is listed below and in the report.

PERIOD

MEAN YIELD

OOS / DEVIATIONS

2025-10-01 to 2026-09-30

97.7%

1 / 1

COMPLAINTS / RECALLS

1 / 0

ATTRIBUTE TRENDS AND CAPABILITY

| ATTRIBUTE | N  | MEAN  | RANGE  | LIMITS    | PPK  | TREND |
|-----------|----|-------|--------|-----------|------|-------|
| Assay     | 10 | 99.98 | 99.50– | 95 to 105 | 4.71 | none  |

## 2 Enter batches, results and events

One row per batch; one row per attribute and batch for results; one row per quality event.  
Tables can be loaded from Excel, CSV, Word, PDF or scans.

### 3 Read the trends

The headline gives batches, rejections and adverse trends: "12 batches · 1 rejected · 1 adverse trend". The table shows Ppk and any trend for each attribute; in the example, dissolution is falling batch after batch while still within specification.

| ATTRIBUTE TRENDS AND CAPABILITY |    |       |              |             |       |                             |
|---------------------------------|----|-------|--------------|-------------|-------|-----------------------------|
| ATTRIBUTE                       | N  | MEAN  | RANGE        | LIMITS      | PPK   | TREND                       |
| Assay                           | 10 | 99.98 | 99.50–100.60 | 95 to 105 % | 4.71  | none                        |
| Dissolution (30 min mean)       | 10 | 89.50 | 85.00–94.00  | 80 to – %   | 1.05  | 10 results falling in a row |
| Total impurities                | 10 | 0.30  | 0.28–0.33    | – to 1 %    | 15.55 | none                        |

Attribute trends and quality events.

## 4

## Resolve alerts and download

Rejected batches without investigations, OOS results without records, adverse trends, low Ppk, open CAPAs and missing review items are flagged. Then preview and download.

2026-044.

(DE/H/1234/001).

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 to fix

2 recommended

DATA AND INPUTS (3)

Dissolution (30 min mean): 10 results falling in a row.

Investigate the trend before it leads to failures; record the actions.

major · Trends · EU GMP 1.10 (ii); FDA PV guidance (2011) stage 3

Ignore

B26005: yield 91.2% is below 95%.

Discuss the low yield.

recommended · Batches · 21 CFR 211.103

Ignore

Dissolution (30 min mean): Ppk 1.05 is below 1.33.

Monitor closely and consider improvement.

recommended · Capability · ICH Q10 3.2.1

Ignore

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.

Annual product review / product quality review

CMX-101 Tablets, 50 mg · APR-101-2026 · US (FDA) and EU (EMA)

|                          |                                           |
|--------------------------|-------------------------------------------|
| Product                  | CMX-101 Tablets, 50 mg                    |
| Report number            | APR-101-2026                              |
| Period                   | 2025-10-01 to 2026-09-30                  |
| Marketing authorisations | NDA 212345; EU MA via DCP (DE/H/1234/001) |

1. Summary

This annual product review and product quality review covers CMX-101 Tablets, 50 mg manufactured from 2025-10-01 to 2026-09-30 (NDA 212345; EU MA via DCP (DE/H/1234/001)).

12 batches were made: 10 released, 1 rejected (B26005), 1 pending. Mean yield 97.7% (SD 2.08).

Assay: 10 results, mean 99.98 %, range 99.50–100.60, Ppk 4.71. All results within specification. No adverse trend.

Dissolution (30 min mean): 10 results, mean 89.50 %, range 85.00–94.00, Ppk 1.05. All results within specification. Adverse trend: 10 results falling in a row.

Total impurities: 10 results, mean 0.30 %, range 0.28–0.33, Ppk 15.55. All results within specification. No adverse trend.

Quality events: 1 OOS result, 1 deviation, 1 CAPA, 1 complaint, 1 return, 1 change, 1 variation or supplement.

2. Batches

| Batch  | Date       | Status   | Yield (%) |
|--------|------------|----------|-----------|
| B26001 | 2025-10-14 | released | 98.4      |
| B26002 | 2025-11-03 | released | 97.9      |
| B26003 | 2025-12-01 | released | 98.8      |
| B26004 | 2026-01-12 | released | 98.1      |
| B26005 | 2026-02-09 | rejected | 91.2      |

Fix or justify the 1 blocking alert before downloading. Or choose "Download anyway".

Download anyway

Download Word (.docx)

Download PDF

## 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 · Review scope

| FIELD         | WHAT TO ENTER                                                                                                          |
|---------------|------------------------------------------------------------------------------------------------------------------------|
| Product       | Type it in.                                                                                                            |
| Review type   | Choose one: US annual product review (21 CFR 211.180(e)); EU product quality review (EU GMP 1.10); Combined APR / PQR. |
| Report number | Type it in.                                                                                                            |
| Period from   | Type it in.                                                                                                            |

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| FIELD                    | WHAT TO ENTER |
|--------------------------|---------------|
| Period to                | Type it in.   |
| Marketing authorisations | Type it in.   |

## 2 · Batches

| FIELD                      | WHAT TO ENTER                                                                                                                                                                                                              |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Batches made in the period | A table. Columns: Batch   Date   Status (released / rejected / pending / reprocessed)   Yield (%). Paste rows from Excel, type comma-separated rows, or press <a href="#">Load file</a> (Excel, CSV, Word, PDF or a scan). |
| Yield alert limit (%)      | Type a number.                                                                                                                                                                                                             |

## 3 · Critical attribute results

One row per batch and attribute, in batch order.

| FIELD   | WHAT TO ENTER                                                                                                                                                                                                                                                               |
|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Results | Enter results in batch order; the trend rules depend on the order. A table. Columns: Attribute   Batch   Result   Lower limit   Upper limit   Unit. Paste rows from Excel, type comma-separated rows, or press <a href="#">Load file</a> (Excel, CSV, Word, PDF or a scan). |

## 4 · Quality events

Type: OOS, OOT, deviation, CAPA, complaint, return, recall, change, variation, reprocessing.

| FIELD  | WHAT TO ENTER                                                                                                                                                                                                                                                                                                                              |
|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Events | Type is one of OOS, OOT, deviation, CAPA, complaint, return, recall, change, variation or reprocessing. A table. Columns: Type   Reference   Description   Batch   Status (open / closed)   Root cause or outcome. Paste rows from Excel, type comma-separated rows, or press <a href="#">Load file</a> (Excel, CSV, Word, PDF or a scan). |

## 5 · Review items

| FIELD                                            | WHAT TO ENTER       |
|--------------------------------------------------|---------------------|
| Starting and packaging materials                 | Type or paste text. |
| Stability programme                              | Type or paste text. |
| Equipment and utilities qualification status     | Type or paste text. |
| Technical agreements                             | Type it in.         |
| Actions from the previous review                 | Type or paste text. |
| Post-marketing commitments                       | Type it in.         |
| Actions for the next period (owner and due date) | Type or paste text. |

## 5. Checks and alerts

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

- Period set and not longer than about 12 months.
- Rejected batches linked to an investigation; yields below the alert limit; reprocessed batches.
- Results outside specification without an OOS record; Ppk below 1.0 (major) or 1.33 (minor); trend rules (7 on one side of the mean, 6 rising or falling).
- Events without root cause or outcome; open CAPAs and investigations; recalls; complaints and returns stated (US).
- EU PQR items: starting and packaging materials, qualification status, technical agreements and post-marketing commitments; both: stability, variations and previous actions.

### 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 of the review; Conclusion and actions. 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

- 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.
- 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).
- Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
- 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.
- 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  | Annual product review / product quality review with summary, tables, conclusion and actions |

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 mode follows 21 CFR 211.180(e): a review of a representative number of batches, complaints, recalls, returned or salvaged products and investigations. EU mode follows EU GMP Part I 1.10 and its twelve review items, including starting materials from new sources, qualification status of equipment and utilities, and technical agreements. Combined mode covers both.

## 8. Working with other modules

- Trends that need action are investigated in the Investigation Studio (OOS, deviation, CAPA) and changes go through Change Control.
- The PPQ data from the Process Validation Report are the baseline for the first review.
- Stability results come from the Stability Studio or Biologics Stability Studio module.

## 9. Common pitfalls

- Leaving rejected batches out of the batch list.
- Entering results out of batch order, which hides trends.
- Writing "no trends" without looking at results that are in specification but drifting.

## 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. Release the rejected batch

In the batches table, change B26005 from rejected to released.

#### EXPECTED RESULT

The headline shows 0 rejected.

## 2. **Leave out the previous actions**

Clear **Actions from the previous review**.

### **EXPECTED RESULT**

An alert says the previous review actions were not reviewed.

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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.