

Post-approval Filings

Write the CMC section of the US annual report and the supplement summaries, and the EU variation present/proposed tables, from one list of implemented and planned changes.

WRITES

Report

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

21 CFR 314.70 and 314.81(b)(2); 21 CFR 601.12; FDA Changes to an Approved NDA or ANDA (2004); FDA CMC Postapproval Manufacturing Changes to Be Documented in Annual Reports (2014); Commission Regulation (EC) No 1234/2008; Variations Classification Guideline (2013/C 223/01); CMDh and EMA procedural guidance on variations

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You list each change with its US category (annual report, CBE-0, CBE-30, prior approval supplement) or EU type (IA, IA_IN, IB, II), the EU classification code, the implementation date, the present and proposed text, the conditions met and the documentation.

The tool works out the annual report due date from the approval anniversary, checks EU Type IA timing (within 12 months; IA_IN within 14 days), flags any IB or II change already implemented, and writes the US and EU documents.

What you get

- US: annual report CMC section (21 CFR 314.81(b)(2)) with the stability update, and supplement summaries.
- EU: variation application present/proposed table with conditions and documentation.

2. Before you start

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

- Approval date and reporting period.
- Each change with category, EU code, date, present and proposed text, conditions and documentation.
- Stability batches and time points reached in the period.

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/post-approval-filings.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 product and period

Choose the regions, enter the application number, approval date, reporting period and planned submission date.

CMCfy | Post-approval Filings | 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 filing documents for CMC changes after approval: the chemistry, manufacturing and controls section of the US annual report, the summary for each US supplement, and the EU present/proposed table for each variation with its conditions and documentation. Timing rules are checked for each change.

Guidance: 21 CFR 314.70 and 314.81(b)(2); 21 CFR 601.12 / Commission Regulation (EC) No 1234/2008 (variations); FDA Changes to an Approved NDA or ANDA (2004); FDA CMC Postapproval Manufacturing Changes to Be Documented in Annual Reports (2014); Commission Regulation (EC) No 1234/2008; Variations Classification Guideline (2013/C 223/01); CMDh and EMA procedural guidance on variations

1 - PRODUCT AND PERIOD

Product
CMX-101 Tablets, 50 mg

Submission region
Both US and EU

Application or MA number
NDA 212345; EU DE/H/1234/001/DC

US approval date
03/15/2024

Reporting period from
03/15/2025

Reporting period to
Planned submission date

RESULT

2 annual report changes · 3 EU variations

US annual report due by 2026-05-14 (60 days after the 2026-03-15 anniversary).

ANNUAL REPORT DUE	STABILITY UPDATES	EU TYPES
2026-05-14	3	Type IA, Type IA_IN
SUBMISSION		
2026-04-30		

US FILINGS

CHANGE	CATEGORY	IMPLEMENTED
Tightened dissolution criterion	Annual report	2025-06-02
Batch size increase 150 000 to 600 000 tablets	Annual report	2025-09-15

2 List the changes

One row per change and region: a change filed in both regions takes two rows, one with the US category and one with the EU type.

3 Read the result

The headline counts the changes per filing: "2 annual report changes · 3 EU variations". The note gives the annual report due date.

US FILINGS		
CHANGE	CATEGORY	IMPLEMENTED
Tightened dissolution criterion	Annual report	2025-06-02
Batch size increase 150 000 to 600 000 tablets	Annual report	2025-09-15

Changes and filings.

4 Resolve alerts and download

Late Type IA notifications, IB or II changes with an implementation date and a missing stability update are flagged. Then preview and download.

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 recommended

DATA AND INPUTS (1)

Several Type IA changes.

They can be grouped in one annual update or one submission.

recommended · EU variations · Regulation (EC) No 1234/2008 Art. 7, 8(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.

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.

Annual report: chemistry, manufacturing and controls

CMX-101 Tablets, 50 mg · NDA 212345; EU DE/H/1234/001/DC · 2025-03-15 to 2026-03-14 · US (FDA) and EU (EMA)

This annual report for CMX-101 Tablets, 50 mg (NDA 212345; EU DE/H/1234/001/DC) covers 2025-03-15 to 2026-03-14. 2 chemistry, manufacturing and controls changes were implemented and are reported under 21 CFR 314.70(d): tightened dissolution criterion (implemented 2025-06-02); batch size increase 150 000 to 600 000 tablets (implemented 2025-09-15).

EU variations: Tightened dissolution criterion (Type IA, B.II.d.1.a); Batch size increase 150 000 to 600 000 tablets (Type IA, B.II.b.4.a); New secondary packaging site (Type IA_IN, B.II.b.1.a).

Changes reported in this annual report (21 CFR 314.70(d))

Change	Present	Proposed	Implemented	Supporting data
Tightened dissolution criterion	Q = 75% at 30 min	Q = 80% at 30 min	2025-06-02	Updated 3.2.P.5.1 and 3.2.P.5.6; batch data for 12 batches
Batch size increase 150 000 to 600 000 tablets	150 000 tablets	600 000 tablets	2025-09-15	3.2.P.3.2; 3.2.P.3.5; batch analysis of 3 batches

Stability data update

Batch	Study	Time point	Outcome
B25003	Annual commitment batch 25 °C/60% RH	12 months	All results within specification
B24011	Annual commitment batch 25 °C/60% RH	24 months	All results within specification
LOT-2401	Registration batch 25 °C/60% RH	36 months	All results within specification; supports 36-month shelf life

Other CMC information

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 · Product and period

FIELD	WHAT TO ENTER
Product	Type it in.
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Application or MA number	Type it in.
US approval date	Type it in.
when it applies	
Reporting period from	Type it in.
Reporting period to	Type it in.

FIELD	WHAT TO ENTER
Planned submission date	Type it in.

2 · Changes

Category: AR, CBE-O, CBE-30, PAS (US) or IA, IA_IN, IB, II (EU). EU code from the Variations Guideline, for example B.II.b.4.a. Conditions met: the condition numbers, or "all".

FIELD	WHAT TO ENTER
Changes	Category: AR, CBE-O, CBE-30, PAS, IA, IA_IN, IB or II. A table. Columns: Change Category EU code Date implemented Present Proposed Conditions met (EU IA/IB) Documentation provided. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Stability data update (US annual report)	One row per batch and study. A table. Columns: Batch Study Time point reached Outcome. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Other annual report CMC items (outstanding commitments, distribution data reference)	Type or paste text.

5. Checks and alerts

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

- US annual report due within 60 days of the approval anniversary.
- EU Type IA within 12 months of implementation; IA_IN immediately (within 14 days).
- A Type IB or II change, or a US prior approval supplement, must not be implemented before approval: critical.
- Present and proposed text and documentation for each EU variation.

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 CMC changes. 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
US annual report	CMC changes and stability update
US supplements	Summary of each CBE or PAS
EU variation	Present/proposed table with conditions and documentation

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 follows 21 CFR 314.70, 314.81(b)(2) and 601.12, and the FDA guidance on changes to an approved NDA or ANDA. EU follows Regulation (EC) No 1234/2008 and the classification guideline (2013/C 223/01).

8. Working with other modules

- Classify planned changes first in the Post-approval Change Classifier module.
 - GMP change assessment is done in Change Control.
-

9. Common pitfalls

- Listing a change implemented under IB or II before approval.
 - Missing the 14-day window for an IA_IN.
-

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. **Change the packaging site to a Type II**

In the changes table, change the category of the new secondary packaging site from IA_IN to II.

EXPECTED RESULT

A critical alert says a Type II change has an implementation date.

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.