

Change Control

Write the GMP change control record: the change and its reason, current and proposed states, an impact assessment across ten areas, a risk score, the US and EU regulatory route, actions with owners and dates, and the effectiveness check.

WRITES

Report

PRODUCT TYPE

Small molecule and biologics

**GUIDANCE IT
FOLLOWS**

ICH Q10 (3.2.3) and Q9(R1); ICH Q12; EU GMP Part I Chapter 1 (1.4 xii) and Annex 15 (11); 21 CFR 211.100(a), 211.160(a), 314.70 and 601.12; ICH Q7 13

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You describe the change, assess its impact on quality, validation, methods, stability, equipment, computerised systems, documents, training, supply and safety, and score severity, occurrence and detectability. The tool classifies the change (minor, major, critical) from the risk score, or uses your own classification and flags it if it is lower than the score suggests.

It checks the regulatory route against whether registered details are affected, flags implementation before a prior approval or within 30 days of a CBE-30, and checks that every action has an owner and a date and that validation, training and stability actions exist where the impact calls for them.

What you get

- A Word or PDF record: Change control record, with sign-off lines for the initiator, department head, regulatory affairs and QA.

2. Before you start

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

- The change number, title, description and reason, and the current and proposed state of each item.
- An impact assessment for each area, and the risk scores.
- The regulatory route agreed with Regulatory Affairs (the Post-approval Change Classifier module can suggest one).
- The actions with owners, due dates and status, the implementation date and the effectiveness check.

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/change-control.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 change

Enter the product, markets, change number, initiator, date, type and title. Describe what changes and why, and list each item as it is now and as proposed.

CMCfy Change Control 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 change control record: what changes and why, the impact assessment across quality, validation, methods, stability, systems and documents, a risk score, the regulatory route, the actions before and after implementation, and the effectiveness check. The tool flags actions without owners or dates, a change to registered details with no filing, and implementation before prior approval.

Guidance: ICH Q10 (3.2.3) and Q9(R1); ICH Q12; EU GMP Part I Chapter 1 (1.4 xii) and Annex 15 (11); 21 CFR 211.100(a), 211.160(a), 314.70 and 601.12; ICH Q7 13

1 - CHANGE

Product(s) affected

CMX-101 Tablets, 50 mg

Markets

US and EU

Change control number

CC-2026-118

Initiator and department

J. Patel, MSAT

Date raised

09/14/2026

Change type

Equipment

Title

RESULT

Major change · US CBE-30 supplement · EU Type IB

2 actions must be closed before implementation.

RISK SCORE (RPN)	HIGH-IMPACT AREAS	ACTIONS OPEN
12	3	3 of 6

IMPLEMENTATION

2027-01-12

IMPACT ASSESSMENT

AREA	IMPACT	ASSESSMENT
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2 Assess the impact and the route

For each area give none, low or high with a short assessment. Say whether registered details are affected and choose the US and EU routes. Score severity, occurrence and detectability from 1 to 5.

3 Read the classification and actions

The headline gives the classification and route: "Major change · US CBE-30 supplement · EU Type IB". The tables show the impact by area and the actions with their status.

IMPACT ASSESSMENT

AREA	IMPACT	ASSESSMENT
Product quality	low	Same design and force range; hardness and dissolution expected unchanged. Confirmed by 3 PPQ batches.
Process or cleaning validation	high	PPQ on 3 batches at the new speed (protocol PPQ-P-101-02); cleaning verification on TP-07.
Analytical methods	none	No change.
Stability	low	First commercial batch on TP-07 added to the annual stability programme.
Equipment and qualification	high	IQ/OQ/PQ of TP-07.
Computerised systems	low	Press HMI validated as part of OQ.
SOPs and batch records	high	MBR-101 and SOP-EQ-018 updated.
Training	low	Operators trained on TP-07.
Supply and inventory	none	–
Safety and environment	low	Guarding reviewed by EHS.

Impact assessment and actions.

4

Resolve alerts and download

A registered change with no filing is critical. Missing owners or dates, open pre-implementation actions, implementation before approval and a missing effectiveness check are flagged. Then preview and download.

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.

FIELD	WHAT TO ENTER
Product(s) affected	Type it in.
Markets	Choose one: US; EU; US and EU.
Change control number	Type it in.
Initiator and department	Type it in.
Date raised	Type it in.
Change type	Choose one: Manufacturing process; Equipment; Facility or utility; Specification; Analytical method; Supplier or material; Packaging; Site; Document only; Computerised system.

FIELD	WHAT TO ENTER
Title	Type it in.
Description and reason	Type or paste text.
Current and proposed	A table. Columns: Item Current Proposed. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

2 · Impact assessment

FIELD	WHAT TO ENTER
Impact by area	Keep the area names as listed; the impact is none, low or high. A table. Columns: Area Impact (none / low / high) Assessment. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Registered details affected	Choose one: No; Yes; Not sure.
US regulatory route when it applies	Choose one: None (managed in the PQS); US annual report; US CBE-0 supplement; US CBE-30 supplement; US prior approval supplement; To be decided by Regulatory Affairs.
EU regulatory route when it applies	Choose one: None (managed in the PQS); EU Type IA; EU Type IA_IN; EU Type IB; EU Type II; To be decided by Regulatory Affairs.
Regulatory assessment	Type or paste text.
Severity (1–5)	Type a number.
Occurrence (1–5)	Type a number.
Detectability (1–5; 5 = hard to detect)	Type a number.
Classification	Choose one: From the risk score; Minor; Major; Critical.

3 · Actions and approval

FIELD	WHAT TO ENTER
Actions	Mark actions that must be closed before the change is implemented with "yes" in the fourth column. A table. Columns: Action Owner Due date Before implementation (yes/no) Status (open / done). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Planned implementation date	Type it in.
Regulatory approval date (optional; prior approval only)	Only needed for a prior approval supplement or an EU Type II variation. Type it in.
Effectiveness check	Type or paste text.
QA approver	Type it in.

5. Checks and alerts

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

- Description, reason and current and proposed states present.
- Every impact area assessed; high impact explained.
- Risk priority number (severity × occurrence × detectability); a classification lower than the score suggests is flagged.
- Registered details affected with no filing (critical); route not decided; implementation before prior approval or within 30 days of a CBE-30 submission.
- Actions with owners and due dates; overdue actions; validation, training and stability actions where the impact needs them.
- Effectiveness check for non-minor changes; QA approver named.

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: Change summary and justification. 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	Change control record

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

Choose US, EU or both. The US route options are annual report, CBE-O, CBE-30 and prior approval supplement (21 CFR 314.70 or 601.12); the EU options are Type IA, IA_IN, IB and II (Regulation (EC) No 1234/2008). Changes not affecting registered details are managed in the PQS (ICH Q12).

8. Working with other modules

- Get a suggested route for each change from the Post-approval Change Classifier module.
- Validation actions are reported in the Process Validation Report or Cleaning Validation Report module.
- Changes are reviewed in the Annual Product Review.

9. Common pitfalls

- Marking an area "none" without a reason when it is not obviously unaffected.
- Setting the implementation date before the regulatory approval date.
- Leaving the effectiveness check for later: define it when the change is approved.

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. Plan no filing for a registered change

Set `Markets` to US and `US regulatory route` to None.

EXPECTED RESULT

A critical alert says the change affects registered details but no filing is planned.

2. Raise the risk

Set `Occurrence` to 5 and `Detectability` to 4.

EXPECTED RESULT

The headline says the change 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.