

Continued Process Verification Report

Write the continued (ongoing) process verification report: a control chart, trend signals and capability for every critical quality attribute and process parameter, and a conclusion on the state of control.

WRITES

GMP 3.2.P.3.5

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

FDA Process Validation: General Principles and Practices (2011) stage 3; EU GMP Annex 15 (2015) 5.28–5.32 ongoing process verification; ICH Q8(R2), Q9(R1), Q10; ASTM E2709 and E2587; BPOG CPV guidance (2014)

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You list the attributes and parameters with their specification limits and enter the batch results in batch order. The tool draws an individuals control chart for each, with limits from the average moving range.

It flags points beyond 3σ , 8 in a row on one side of the mean and 6 in a row rising or falling, and calculates Ppk against your target.

What you get

- A Word or PDF report: Continued process verification report, with control charts.

2. Before you start

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

- The CQAs and CPPs with their limits.
- Batch results in manufacturing order.
- Deviations, changes and complaints 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/continued-process-verification.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 period

Enter the product, the period, the stage (3a heightened or 3b routine) and the Ppk target.

CMCfy Continued Process Verification Report 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 3.2.P.3.5 [Save project](#) [Open project](#) [Start blank](#) [Load example](#)

Write the continued (ongoing) process verification report. For each critical quality attribute and process parameter the tool draws an individuals control chart, checks trend signals and calculates capability, then summarises whether the process remains in a state of control.

Guidance: FDA Process Validation: General Principles and Practices (2011) / EMA Guideline on process validation for finished products (EMA/CHMP/CVMP/QWP/BWP/70278/2012 Rev1) and EU GMP Annex 15 stage 3; EU GMP Annex 15 (2015) 5.28–5.32 ongoing process verification; ICH Q8(R2), Q9(R1), Q10; ASTM E2709 and E2587; BPOG CPV guidance (2014)

1 · REPORT

Product
CMX-101 tablets 50 mg

Regulations Both US and EU Report number CPV-R-2026-02

Period 2026-01-01 to 2026-06-30 Stage Stage 3b: routine monito

Capability target (Ppk)
1.33

RESULT

In a state of control · 20 batches

Assay (%): Ppk 5.17; Dissolution 30 min (%): Ppk 3.30; Content uniformity AV: Ppk 11.23; Granulation end-point power (kW): Ppk 2.23.

BATCHES	ATTRIBUTES	SIGNALS
20	4	0

PERIOD
2026-01-01 to 2026-06-30

CAPABILITY AND SIGNALS

2 Enter attributes and results

One row per attribute with its type and limits. One row per batch and attribute.

3 Read the result

The headline gives the state: "In a state of control · 20 batches".

CAPABILITY AND SIGNALS								
ATTRIBUTE	TYPE	N	MEAN	Σ (MR)	LCL-UCL	SPEC	PPK	SIGNAL
Assay (%)	CQA	20	100.02	0.467	98.62–101.41	95–105	5.17	none
Dissolution 30 min (%)	CQA	20	93.05	1.866	87.45–98.65	80–	3.30	none
Content uniformity AV	CQA	20	3.80	0.434	2.50–5.10	–15	11.23	none
Granulation end-point power (kW)	CPP	20	18.46	0.285	17.61–19.31	17–20	2.23	none

Control charts.

4 Resolve alerts and download

Out-of-specification results are critical; trend signals and low capability 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.

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 review 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

Continued process verification report
 CMX-101 tablets 50 mg · CPV-R-2026-02 · US (FDA) and EU (EMA)

Product	CMX-101 tablets 50 mg
Report number	CPV-R-2026-02
Period	2026-01-01 to 2026-06-30
Stage	3b (routine)
Regulations	US (FDA) and EU (EMA)

1. Scope and method
 Critical quality attributes and process parameters are trended on individuals control charts (mean $\pm 3\sigma$, σ from the average moving range). Signals: a point beyond the control limits, 8 in a row on one side of the mean, or 6 in a row rising or falling. Capability target Ppk ≥ 1.33 .

2. Summary

Attribute	Type	n	Mean	Control limits	Ppk	Signals
Assay (%)	CQA	20	100.02	98.62–101.41	5.17	None
Dissolution 30 min (%)	CQA	20	93.05	87.45–98.65	3.30	None
Content uniformity AV	CQA	20	3.80	2.50–5.10	11.23	None
Granulation end-point power (kW)	CPP	20	18.46	17.61–19.31	2.23	None

3. Control charts

USL 105

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 • Report

FIELD	WHAT TO ENTER
Product	Type it in.
Regulations	Choose one: US: FDA stage 3 CPV; EU: Annex 15 ongoing process verification; Both US and EU.
Report number	Type it in.
Period	Type it in.
Stage	Choose one: Stage 3a: heightened monitoring after PPQ; Stage 3b: routine monitoring.
Capability target (Ppk)	Type a number.

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2 · Attributes and parameters

FIELD	WHAT TO ENTER
Attributes	A table. Columns: Attribute or parameter Type (CQA/CP/IPC) LSL USL. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Batch data

One row per batch and attribute, in batch order.

FIELD	WHAT TO ENTER
Results	Keep the rows in batch order: the trend rules depend on it. A table. Columns: Batch Attribute or parameter Result. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Deviations, changes and complaints in the period	Type or paste text.

5. Checks and alerts

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

- Control limits from the moving range.
- Trend rules: beyond 3σ , 8 on one side, 6 trending.
- Ppk against the target; enough batches.

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: Discussion and conclusion. 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	Continued process verification report

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 the FDA Process Validation guidance (2011) stage 3. EU follows EU GMP Annex 15 (5.28–5.32) ongoing process verification.

8. Working with other modules

- Stage 2 is reported in the Process Validation Report; yearly trends also go into the Annual Product Review.

9. Common pitfalls

- Mixing batch order, which hides trends.
- Control limits from the specification instead of the data.

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. **Shift the last assay result**

Change the assay of batch B2620 from 100.4 to 104.0.

EXPECTED RESULT

The headline shows one attribute with a trend signal.

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.