

Process Validation Report

Write the stage 2 process performance qualification (PPQ) report from your batch data: every result against its predefined criterion, capability (Ppk) per attribute, process parameters against their ranges, deviations, and the stage 3 continued process verification plan.

WRITES

Report

3.2.P.3.5

3.2.S.2.5

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

FDA Process Validation: General Principles and Practices (2011); 21 CFR 211.100, 211.110; ICH Q8(R2), Q9(R1), Q10, Q11; ASTM E2709 / E2810

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You enter the PPQ batches, the quality attribute results (several results per batch where the protocol samples more than once, for example blend uniformity locations) and the recorded range of each critical process parameter. The tool checks each result and parameter against its limit and calculates the mean, standard deviation and Ppk of each attribute across all PPQ results, and the spread within each batch.

It writes the PPQ report with a chart of the attribute you choose, tables of results and parameters, the discussion, the continued process verification plan and the conclusion. A failure or excursion blocks the report until you record the investigation.

What you get

- A Word or PDF report: Process performance qualification report, with sign-off lines.
- A summary file for the QOS Composer & Dossier Assembler with each attribute's Ppk.

2. Before you start

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

- The approved PPQ protocol (number, number of batches, acceptance criteria and any capability criterion).
- Each batch: date, size, scale, yield, deviations and disposition.
- Results for each attribute and batch, and the lowest and highest value recorded for each critical process parameter.
- Deviation summaries, hold times and the continued process verification plan.

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/process-validation-report.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 study

Enter the product, the regulations (US, EU or both), the product type, the report and protocol numbers, the process and scale, and the number of batches the protocol requires. In EU mode choose the validation approach.

CMCfy Process Validation Report Projects All modules Training Security

Runs entirely on this device Training guide Protocol builder

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 3.2.P.3.5 3.2.S.2.5 Save project Open project Start blank Load example

Write the process performance qualification (PPQ) report from your batch data. Every result is checked against its predefined criterion, the spread within and between batches is summarised, process performance (Ppk) is calculated for each attribute, and process parameters are checked against their ranges. The report ends with the continued process verification plan.

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; 21 CFR 211.100, 211.110; ICH Q8(R2), Q9(R1), Q10, Q11; ASTM E2709 / E2810

1 - STUDY

Product
CMX-101 Tablets, 50 mg

Regulations Both US and EU Product type Small molecule drug proc

Report number PPQ-R-101-01 Protocol number PPQ-P-101-01

Process and commercial scale
Wet granulation, compression and film coating; commercial

RESULT

3 PPQ batches · all 66 results within criteria

Every predefined criterion is met. The process can move to stage 3 continued process verification.

BATCHES	ATTRIBUTES	LOWEST PPK
3 of 3	4	3.05 (Dissolution (30 min))

CPP EXCURSIONS
0

2 Enter batches, results and parameters

One row per batch. Results go one row per attribute and batch, with several results in one cell separated by ";". Process parameters go one row per parameter and batch, with the range and the lowest and highest value recorded. Excel, CSV, Word, PDF and scanned tables can be loaded.

3 Read the result

The headline says whether every result met its criterion: "3 PPQ batches · all 66 results within criteria". The capability table gives Ppk per attribute; values from fewer than 10 results are marked with an asterisk, because they are an indication only.

CAPABILITY BY ATTRIBUTE						
ATTRIBUTE	RESULTS	MEAN	SD	LIMITS	PPK	OUTSIDE
Blend uniformity	30	100.18	0.750	90 to 110	4.36	0
Tablet hardness	15	11.91	0.386	8 to 16	3.37	0
Assay	3	99.97	0.404	95 to 105	4.10 *	0
Dissolution (30 min)	18	92.78	1.396	80 to –	3.05	0

Capability by attribute.

4

Resolve alerts and download

A result outside its criterion is critical: record the investigation reference and outcome. Excursions, missing batches, low Ppk, blend uniformity RSD above 5% and a missing CPV plan are flagged. Then preview and download the report.

04 and 2026-05-18: wet granulation, compression and film coating, commercial batch size

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)

Assay: Ppk is based on 3 results.

With fewer than 10 results the capability estimate is uncertain; continue to assess it in CPV.

recommended · Capability · FDA PV guidance (2011) stage 3

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.

Process performance qualification report

CMX-101 Tablets, 50 mg · PPQ-R-101-01 · US (FDA) and EU (EMA)

Product	CMX-101 Tablets, 50 mg
Report number	PPQ-R-101-01
Protocol	PPQ-P-101-01
Site	CMX Pharma, Building 4, Raleigh, NC, USA
Process and scale	Wet granulation, compression and film coating; commercial batch size 500,000 tablets (150 kg)
Regulations	US (FDA) and EU (EMA)
EU approach	Traditional process validation

1. Objective

To report the process performance qualification of CMX-101 Tablets, 50 mg against the predefined acceptance criteria of protocol PPQ-P-101-01, and to conclude whether the commercial process is in a state of control.

2. Batches

Batch	Date	Size	Scale	Yield (%)	Deviations	Disposition
PPQ-01	2026-05-04	500000 tablets	commercial	98.6	none	Released
PPQ-02	2026-05-11	500000 tablets	commercial	97.9	DEV-2026-041 (minor; granulator alarm)	Released
PPQ-03	2026-05-18	500000 tablets	commercial	98.9	none	Released

3. Quality attributes

Attribute	Stage	Results	Mean	SD	Criterion	Ppk	Outside
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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 · Study

FIELD	WHAT TO ENTER
Product	Type it in.
Regulations	Choose one: US: FDA (21 CFR 211, PV guidance 2011); EU: EU GMP Annex 15 and EMA PV guideline; Both US and EU.
Product type	Choose one: Small molecule drug product; Drug substance (API); Biological drug substance or product; Sterile product.

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FIELD	WHAT TO ENTER
Report number	Type it in.
Protocol number	Type it in.
Process and commercial scale	Type it in.
Manufacturing site	Type it in.
Number of batches in the protocol	Type a number.
EU validation approach when it applies	Choose one: Traditional (3 consecutive batches); Continuous process verification; Hybrid.
Ppk criterion in the protocol (optional)	Only set this if the protocol has a capability criterion. Type a number.

2 · PPQ batches

FIELD	WHAT TO ENTER
Batches	A table. Columns: Batch Date of manufacture Batch size Scale (commercial / pilot) Yield (%) Deviations (reference or none) Disposition. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Yield criterion (%)	Type a number.

3 · Quality attribute results

One row per batch and attribute. Put several results for the same batch in one cell separated by ";" (for example blend uniformity locations). Leave a limit empty if there is none.

FIELD	WHAT TO ENTER
Results	Put several results for one batch in the same cell, separated by ";". Leave a limit empty when there is only one. A table. Columns: Attribute Batch Results (separate with ;) Lower limit Upper limit Unit Stage (blend / in-process / release). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

FIELD	WHAT TO ENTER
Attribute to chart	Type it in.

4 · Process parameters

FIELD	WHAT TO ENTER
Critical process parameters	The range can be written 1.0–1.4, 38–45, NLT 10 or NMT 16. A table. Columns: Step Parameter Range Batch Lowest recorded Highest recorded. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

5 · Deviations, hold times and continued verification

FIELD	WHAT TO ENTER
Deviations and their impact	Type or paste text.
Hold times covered	Type it in.
Continued process verification plan	Type or paste text.

5. Checks and alerts

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

- Every result against its lower and upper limit; a failure is critical and must be recorded with its investigation.
- Mean, standard deviation and Ppk per attribute across all PPQ results; Ppk below 1.0 (major) or below the protocol criterion (minor); fewer than 10 results noted.
- Within-batch spread per batch; blend uniformity RSD above 5% flagged (ASTM E2709 / E2810 practice).
- Each critical process parameter against its range in every batch.
- Number of batches against the protocol (three consecutive for EU traditional validation), commercial scale, yield criterion, disposition, deviations with references and a discussion.
- Continued process verification plan and hold times present; HCP and DNA results for biologics; sterility assurance referenced for sterile products.

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: Results and discussion; 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	Process performance qualification report, with chart, results, parameters, CPV plan and conclusion

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 the FDA Process Validation guidance (2011): stage 2 process qualification and stage 3 continued process verification. EU mode follows EU GMP Annex 15 and the EMA process validation guideline: traditional validation on at least three consecutive batches, continuous process verification, or a hybrid, followed by ongoing process verification.

8. Working with other modules

- Write the protocol first in the Protocol Builder (Process validation (PPQ)); the approved protocol is compared with this report in the preview.
- The summary of validation for 3.2.P.3.5 or 3.2.S.2.5 is written in the Process & Controls Writer or the Biologics Process Writer module.
- A failure is investigated in the Investigation Studio (OOS, deviation, CAPA).
- The PPQ data feed the trends in the Annual Product Review.

9. Common pitfalls

- Entering only the batch mean for attributes sampled at many locations: Ppk then rests on three numbers.
- Leaving the limit empty for an attribute that has one.
- Treating Ppk from three results as proof of capability; continue to assess it in CPV.

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. Introduce a failing result

In the results table, change the assay of PPQ-02 from 100.4 to 94.5.

EXPECTED RESULT

The headline shows one result outside criteria.

2. **Raise the capability criterion**

Set Ppk criterion in the protocol to 3.5.

EXPECTED RESULT

The result note says Ppk for tablet hardness and dissolution is below 3.5.

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.