

Process & Controls Writer

Turn your process steps into the manufacture sections: manufacturers, batch formula, process description with a flow diagram, controls of critical steps and intermediates, and process validation.

WRITES

3.2.S.2.1

3.2.S.2.2

3.2.S.2.3

3.2.S.2.4

3.2.S.2.5

3.2.P.3.1

3.2.P.3.2

3.2.P.3.3

3.2.P.3.4

3.2.P.3.5

PRODUCT TYPE

Small molecule

GUIDANCE IT FOLLOWS

ICH M4Q(R1) 3.2.S.2 and 3.2.P.3; ICH Q7, Q8(R2), Q11; FDA Process Validation: General Principles and Practices (2011)

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

Use this module for 3.2.P.3 (drug product manufacture) or 3.2.S.2 (drug substance manufacture). You enter the sites, the unit formula and the steps; the tool calculates the batch formula, draws the flow diagram, lists the critical steps with their controls and writes the narratives.

For a drug substance it also handles starting materials, reagents and solvents, and asks for the ICH Q11 justification of each starting material.

What you get

- Word or PDF files for 3.2.P.3.1 to 3.2.P.3.5 (or 3.2.S.2.1 to 3.2.S.2.5), with the flow diagram as a picture.
- A summary file for the QOS Composer & Dossier Assembler.

2. Before you start

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

- Names, addresses and responsibilities of each manufacturer and test site, with FEI numbers (US) or EU GMP certificate or manufacturing authorisation numbers (EU).
- The unit formula (mg per unit with overages) and the commercial batch size.
- The process steps: operation, materials added, equipment, process parameters with ranges and in-process controls with acceptance criteria. Mark which steps are critical.
- Process validation status: PPQ completed (with batches) or a PPQ plan.
- For drug substance: starting materials with supplier, number of steps to the drug substance and specification reference.

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-writer.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 Choose drug product or drug substance

In panel 1 choose [Manufacture of](#). The batch formula panel shows for a drug product; the starting materials panel shows for a drug substance. Enter the manufacturers table.

CMCfy Process & Controls Writer 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.

3.2.S.2.1 3.2.S.2.2 3.2.S.2.3 3.2.S.2.4 3.2.S.2.5 3.2.P.3.1 3.2.P.3.2 3.2.P.3.3 3.2.P.3.4 3.2.P.3.5 Save project Open project Start blank Load example

Turn your process steps into the manufacture sections: manufacturers, batch formula, process description with a flow diagram, controls of critical steps and process validation. Batch quantities are calculated from the unit formula.

Guidance: ICH M4Q(R1) 3.2.S.2 and 3.2.P.3; ICH Q7, Q8(R2), Q11; FDA Process Validation: General Principles and Practices (2011)

1 - PRODUCT AND SITES

Manufacture of Submission region
 Drug product (3.2.P.3) US: FDA (NDA, ANDA, BL

Product or substance name
 CMX-101 Tablets, 50 mg

Manufacturers
 Columns: Name, Address, Responsibility, FEI (US) or EU GMP certificate / MIA number
 CMX Pharma Manufacturing LLC, "100 Tablet Way, Raleigh, Analytica Labs Inc., "22 Lab Park, Durham, NC 27703, USA

RESULT

10 steps · 5 critical

Batch of 150000 units: 51.22 kg of materials (unit weight 340.00 mg).

SECTIONS	SITES	IN-PROCESS CONTROLS
3.2.P.3.1, 3.2.P.3.2, 3.2.P.3.3, 3.2.P.3.4, 3.2.P.3.5	2	7

VALIDATION
PPQ protocol

FLOW DIAGRAM

2 Enter the batch formula

Enter the batch size in units and the unit formula. If you saved a summary from Composition & General Info, add it under **Composition from Composition & General Info** instead of typing the formula. Any overage needs a justification.

3 Enter the process steps

One row per step. Mark **Critical (yes/no)** for each step whose parameters affect a critical quality attribute, and give ranges (for example "Impeller 150 rpm; 5 min"). The headline shows 10 steps, 5 critical, and the batch quantity: 51.22 kg of materials for 150,000 units.

RESULT

10 steps · 5 critical

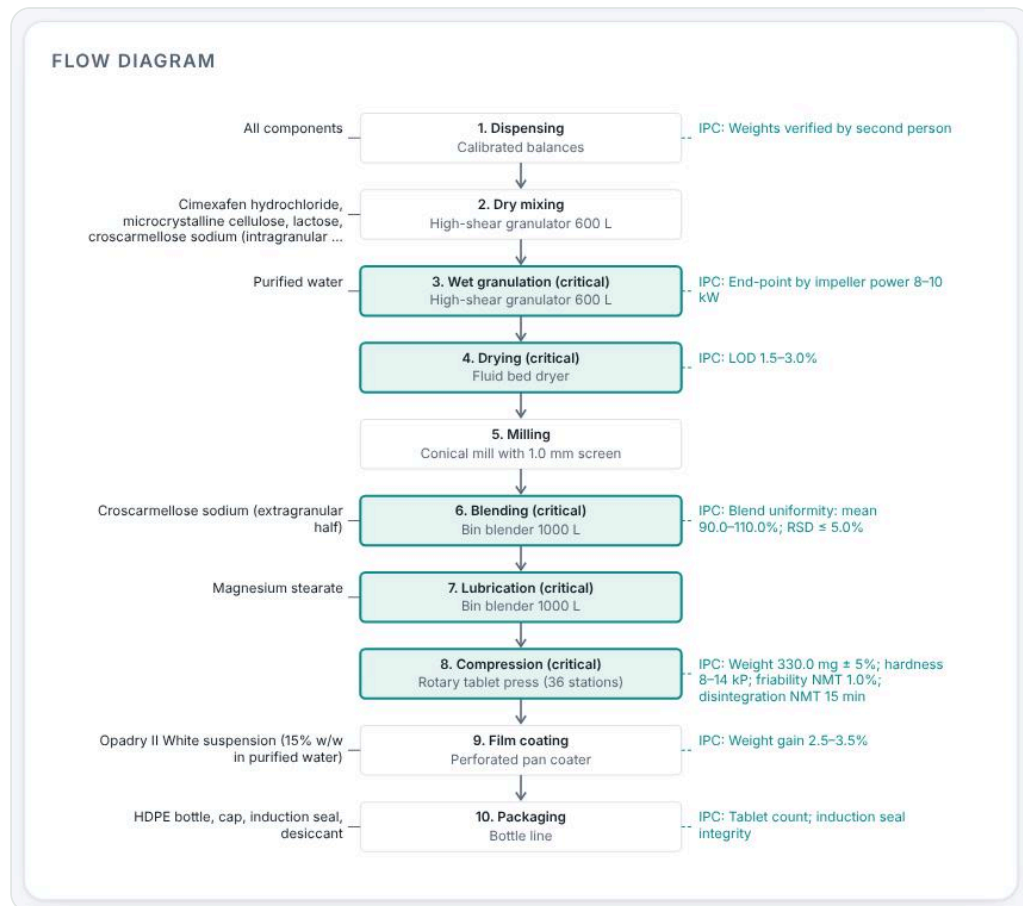
Batch of 150000 units: 51.22 kg of materials (unit weight 340.00 mg).

SECTIONS	SITES	IN-PROCESS CONTROLS
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VALIDATION
PPQ protocol

4 Check the flow diagram

The flow diagram is drawn from your steps, with critical steps and in-process controls marked. It goes into 3.2.P.3.3 as a picture.



The flow diagram drawn from the steps table.

5 Resolve alerts

In the example, one minor alert says the stability test lab has no FEI number. Switch to EU and more appear: no EU batch release site with a Qualified Person, no EU GMP certificate number, and process validation not complete at submission.

ALERTS TO RESOLVE

All blocking alerts are fixed, justified or accepted. Minor alerts are listed in the Word files.

MINOR **Analytica Labs Inc.: no FEI number.**

Manufacturers · FDA Form 356h

Give the FDA Establishment Identifier for US filings.

6

Preview and download

Preview each section, read the gap review, then download Word or PDF. The flow diagram, batch formula and critical steps tables are in the files.

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.

2 recommended

MISSING INFORMATION (1)

"PPQ batches" is empty.

Enter it in the tool, or confirm it does not apply. Empty inputs show as placeholders or gaps in the report.

recommended · Process validation

Ignore

DATA AND INPUTS (1)

Analytica Labs Inc.: no FEI number.

Give the FDA Establishment Identifier for US filings.

recommended · Manufacturers · FDA Form 356h

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

3.2.P.3.1 Manufacturer(s)

CMX-101 Tablets, 50 mg · US (FDA)

Name	Address	Responsibility	FEI
CMX Pharma Manufacturing LLC	100 Tablet Way, Raleigh, NC 27601, USA	Manufacture, packaging, release testing	3012345678
Analytica Labs Inc.	22 Lab Park, Durham, NC 27703, USA	Stability testing	

Review notes

Area	Issue	Resolution
Manufacturers	Analytica Labs Inc.: no FEI number.	Open (minor)

Draft prepared with CMCfy Process & Controls Writer on 2026-10-29. Guidance applied: ICH M4Q(R1) 3.2.S.2 and 3.2.P.3; ICH Q7, Q8(R2), Q11; FDA Process Validation: General Principles and Practices (2011). To be reviewed and approved by a qualified person before submission.

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 sites

FIELD	WHAT TO ENTER
Manufacture of	Choose one: Drug product (3.2.P.3); Drug substance (3.2.S.2).
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Product or substance name	Type it in.

FIELD	WHAT TO ENTER
Manufacturers	A table. Columns: Name Address Responsibility FEI (US) or EU GMP certificate / MIA number. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

2 · Batch formula (3.2.P.3.2) shown when it applies

FIELD	WHAT TO ENTER
Composition from Composition & General Info (optional)	Optional. Fills the unit formula from the Composition & General Info summary. Press Add files and pick summary files (.cmcfy.json) saved by other modules.
Batch size (units)	Type a number.
Unit formula	A table. Columns: Component mg per unit Overage (%) Quality standard. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Justification of overages	Type it in.

3 · Starting materials and reagents (3.2.S.2.3) shown when it applies

FIELD	WHAT TO ENTER
Starting materials	A table. Columns: Starting material Supplier Steps to drug substance Specification reference Justified per ICH Q11 (yes/no). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Reagents, solvents and catalysts	A table. Columns: Material Step Quality standard. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

4 · Process steps

Mark the steps whose parameters affect a critical quality attribute as critical. Give parameters with ranges.

FIELD	WHAT TO ENTER
Steps	A table. Columns: Step Operation Materials added Equipment Critical (yes/no) Process parameters In-process controls. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Reprocessing	Type it in.
Master batch record or process description (optional, used by AI)	Optional. Gives AI more context when you use Rewrite with AI; it is not copied into the files. Type or paste text, or press Load file (Word, PDF, a scan, Excel or text).

5 · Process validation

FIELD	WHAT TO ENTER
Status	Choose one: Process performance qualification (PPQ) completed; PPQ protocol submitted; batches before commercial distribution; Not addressed yet.
Sterility when it applies	Shown for a drug product. Choose aseptic or terminal sterilisation to open the sterilisation validation field. Choose one: Not a sterile product; Terminally sterilised; Aseptically processed.
Sterilisation or aseptic process validation summary when it applies	Type or paste text.
PPQ batches	A table. Columns: Batch Batch size Result. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
PPQ plan	Type it in.

5. Checks and alerts

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

- Every manufacturer has an address and responsibility; FEI (US) or EU GMP certificate or MIA number (EU); in EU mode, a batch release site with a Qualified Person.
- Batch size given; every overage justified; batch quantities calculated from the unit formula.

- At least one step marked critical; every critical step has parameters or controls; parameters have numerical ranges; equipment is named; each in-process control has an acceptance criterion.
- Drug substance: starting materials listed, each with a specification, supplier and an ICH Q11 justification; a starting material only one step from the drug substance is flagged.
- Process validation addressed: PPQ batches listed when marked completed, or a PPQ plan; for sterile products, sterilisation or aseptic process validation summarised, and aseptic processing justified over terminal sterilisation.

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: Description of the manufacturing process; Process validation. 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
3.2.P.3.1	Manufacturer(s)
3.2.P.3.2	Batch formula
3.2.P.3.3	Description of manufacturing process and process controls (with flow diagram)
3.2.P.3.4	Controls of critical steps and intermediates
3.2.P.3.5	Process validation and/or evaluation
3.2.S.2.1-2.5	The same sections for a drug substance

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: each site needs its FEI number, and PPQ may be completed after approval if the protocol is described. EU: each site needs its EU GMP certificate or manufacturing authorisation number, a batch release site with a Qualified Person must be named, and process validation of the drug product is normally expected at submission or a process validation scheme is given in 3.2.R. A drug substance made outside the EEA is noted for the importation and QP declaration.

Choose **Both US and EU** to collect both identifiers in one table.

8. Working with other modules

- Add the Composition & General Info summary to fill the unit formula.
- The critical steps and parameters support the risk assessment in the Development Studio.
- The QOS Composer & Dossier Assembler compares the batch formula with the composition in 3.2.P.1 and the process validation status with 3.2.R.

- For biologics drug substance use the Biologics Process Writer; for fill-finish of a protein use the Biologics Drug Product Writer.

9. Common pitfalls

- Marking no step as critical. Reviewers expect the critical steps that control the CQAs to be identified.
- Giving set points without ranges ("150 rpm" instead of "140–160 rpm").
- Entering the unit formula with a different active quantity from 3.2.P.1 (for example 54.80 mg here against 55.07 mg in Composition). The QOS Composer will flag it.
- Forgetting the test laboratories in the manufacturers table: every site with a GMP role must be listed.

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. See the EU site requirements

Set [Submission region](#) to EU.

EXPECTED RESULT

A major alert says no EU batch release site with a Qualified Person is listed.

2. Mark PPQ as completed

Set [Status](#) under Process validation to "Process performance qualification (PPQ) completed" and leave the PPQ batches table empty.

EXPECTED RESULT

A major alert says PPQ is marked completed but no batches are listed.

3. Recalculate the batch

Change [Batch size \(units\)](#) to 300000.

EXPECTED RESULT

The headline note reads "Batch of 300000 units: 102.45 kg of materials".

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.