

Development Studio

Write pharmaceutical development (3.2.P.2) or drug substance process development (3.2.S.2.6) from your QTPP, critical quality attributes, FMEA risk assessment and studies.

WRITES 3.2.P.2.1 3.2.P.2.2 3.2.P.2.3 3.2.P.2.5 3.2.P.2.6 3.2.S.2.6	PRODUCT TYPE Small molecule	GUIDANCE IT FOLLOWS ICH Q8(R2), Q9(R1), Q10, Q11; ICH M4Q(R1) 3.2.P.2; USP <51>	TIME TO LEARN About 20 minutes with the example
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Open the tool at <https://app.cmcfy.com/app/development-studio.html>. This guide is also online at <https://cmcfy.com/guides/development-studio.html>

1. What this module does

The module turns your development data into the story a reviewer expects under ICH Q8(R2), Q9 and Q10: the quality target product profile, which attributes are critical and why, the risk assessment, the studies that set ranges, and how each critical attribute is controlled.

It scores the FMEA (risk priority number = severity × occurrence × detectability), ranks the risks, links each critical attribute to its control, and flags gaps a reviewer would ask about.

What you get

- Word or PDF files for 3.2.P.2.1, 2.2, 2.3, 2.5 and 2.6 (or 3.2.S.2.6).
- 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.

- The QTPP: dosage form, route, strength, release profile, stability and so on, with the target and justification of each.
- The quality attributes, which are critical, why, and what controls them.

- The FMEA: factor, failure mode, severity, occurrence and detectability scored 1 to 10, and the mitigation.
- DoE or other studies with the range studied, the effect and the proven acceptable range.
- Excipient compatibility results, clinical formulations and how they bridge to the commercial one, and summaries of formulation, dissolution method and process development.

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/development-studio.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 Set the scope

Choose [Section](#): drug product (3.2.P.2) or drug substance process development (3.2.S.2.6). For a drug product choose the dosage form type and the BCS class, and tick [Multi-dose or preserved product](#) if it applies. Tick [Design space claimed](#) only if you claim one.

CMCfy Development Studio 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.P.2.1](#) [3.2.P.2.2](#) [3.2.P.2.3](#) [3.2.P.2.5](#) [3.2.P.2.6](#) [3.2.S.2.6](#)
[Save project](#) [Open project](#) [Start blank](#) [Load example](#)

Write pharmaceutical development from your QTPP, CQAs, risk assessment and studies. The tool scores the FMEA, links each critical attribute to its control and flags gaps a reviewer would ask about.

Guidance: ICH Q8(R2), Q9(R1), Q10, Q11; ICH M4Q(R1) 3.2.P.2; USP <S1>

1 - PRODUCT

Section: [Drug product \(3.2.P.2\)](#) Submission region: [US: FDA \(NDA, ANDA, BL\)](#)

Product or substance name: [CMX-101 Tablets, 50 mg](#)

Dosage form type: [Solid oral](#) BCS class of the drug substance: [Class 2](#)

☐ Multi-dose or preserved product
☐ Design space claimed

Specification from Specification Builder (optional) Used to check that each critical attribute is controlled.

No files added.

[Add files](#) [Remove all](#)

RESULT

5 critical quality attributes · 2 high risks

Highest risk: Granulation water amount on Dissolution (RPN 160).

SECTIONS	QTPP ELEMENTS	RISK FACTORS SCORED
3.2.P.2.1, 2.2, 2.3, 2.5, 2.6	7	5

STUDIES: 3

RISK ASSESSMENT RANKED BY RPN

CQA	FACTOR	S	O	D	RPN	MITIGATION
Dissolution	Granulation water amount	8	5	4	160	Water range 28–32% from DoE; end-point by

2 Enter the QTPP and CQAs

Enter the QTPP and the quality attributes. For each critical attribute give the control (for example "Specification (assay)" or "Blend uniformity IPC").

3 Enter the risk assessment and studies

Enter the FMEA rows and the DoE results. The headline shows 5 critical quality attributes and 2 high risks, the highest being granulation water amount on dissolution (RPN 160).

RESULT

5 critical quality attributes · 2 high risks

Highest risk: Granulation water amount on Dissolution (RPN 160).

SECTIONS	QTPP ELEMENTS	RISK FACTORS SCORED
3.2.P.2.1, 2.2, 2.3, 2.5, 2.6	7	5

STUDIES
3

4 Read the ranked risks

The risk table is sorted by RPN, and the CQA table shows each critical attribute with its control. High risks without mitigation are flagged.

RISK ASSESSMENT RANKED BY RPN

CQA	FACTOR	S	O	D	RPN	MITIGATION
Dissolution	Granulation water amount	8	5	4	160	Water range 28–32% from DoE; end-point by power
Assay	Drug substance particle size	7	5	3	105	needed
Dissolution	Compression force	6	5	3	90	Force 10–14 kN from DoE
Content uniformity	Blend time	7	4	3	84	Blend uniformity IPC
Degradation products	Drying temperature	7	3	4	84	Inlet 60 ± 5 °C; LOD IPC

Risk assessment ranked by risk priority number.

5 Resolve alerts

The example has two major alerts (a critical attribute with no control, and a high RPN with no mitigation) and two minor ones. Fix them in the tables or justify them.

ALERTS TO RESOLVE

2 alerts to fix, justify, or proceed without before export. It is your call: "Proceed without it" lets you continue when the information is not available.

MAJOR Water content is critical but no control is given.

CQAs · ICH Q8(R2) 3.1.5; ICH Q10

State how it is controlled (specification test, IPC, process parameter range or design).

Justification

Accept justification

Proceed without it

MAJOR Drug substance particle size → Assay: RPN 105 with no mitigation.

Risk assessment · ICH Q9(R1) 5

Give the control or study that reduces the risk.

Justification

Accept justification

Proceed without it

MINOR Water content is critical but is not in the risk assessment.

Risk assessment · ICH Q9(R1)

Assess which material attributes and process parameters affect it.

Justification

Accept justification

MINOR Magnesium stearate: compatibility study showed a change.

Components · ICH Q8(R2) 2.1.1

Explain how the formulation manages it.

Justification

Accept justification

6

Preview and download

Preview each 3.2.P.2 section, check the review, and download Word or PDF.

Compatibility with diluents, admixtures or devices

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 to fix 2 recommended

MISSING INFORMATION (1)

Water content is critical but no control is given.
State how it is controlled (specification test, IPC, process parameter range or design).
major · CQAs · ICH Q8(R2) 3.1.5; ICH Q10 Ignore

DATA AND INPUTS (3)

Drug substance particle size → Assay: RPN 105 with no mitigation.
Give the control or study that reduces the risk.
major · Risk assessment · ICH Q9(R1) 5 Ignore

Water content is critical but is not in the risk assessment.
Assess which material attributes and process parameters affect it.
recommended · Risk assessment · ICH Q9(R1) Ignore

Magnesium stearate: compatibility study showed a change.
Explain how the formulation manages it.
recommended · Components · ICH Q8(R2) 2.1.1 Ignore

3.2.P.2.1 Components of the drug product

CMX-101 Tablets, 50 mg · US (FDA)

The drug substance is a BCS class 2 compound. Compatibility with the excipients was studied in binary mixtures: Microcrystalline cellulose (1:5, 4 weeks, 40 °C/75% RH): no change in assay or impurities; Lactose monohydrate (1:5, 4 weeks, 40 °C/75% RH): no change; no Maillard reaction (tertiary amine); Croscarmellose sodium (1:1, 4 weeks, 40 °C/75% RH): no change; Magnesium stearate (1:1, 4 weeks, 40 °C/75% RH): N-oxide increased from 0.05% to 0.12%; level kept at 0.6% w/w.

The excipients and their levels were chosen as described in 3.2.P.2.2.

Excipient	Ratio	Condition	Result
Microcrystalline cellulose	1:5	4 weeks, 40 °C/75% RH	No change in assay or impurities
Lactose monohydrate	1:5	4 weeks, 40 °C/75% RH	No change; no Maillard reaction (tertiary amine)
Croscarmellose sodium	1:1	4 weeks, 40 °C/75% RH	No change
Magnesium stearate	1:1	4 weeks, 40 °C/75% RH	N-oxide increased from 0.05% to 0.12%; level kept at 0.6% w/w

Review notes

Area	Issue	Resolution
Components	Magnesium stearate: compatibility study showed a change.	Open (minor)

Draft prepared with CMCfy Development Studio on 2026-10-29. Guidance applied: ICH Q8(R2), Q9(R1), Q10, Q11; ICH M4Q(R1) 3.2.P.2; USP <51>. To be reviewed and approved by a qualified person before submission.

Fix or justify the 2 blocking alerts before downloading. Or choose "Download anyway".

Download anyway 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

FIELD	WHAT TO ENTER
Section	Choose one: Drug product (3.2.P.2); Drug substance process development (3.2.S.2.6).
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.
Dosage form type when it applies	Choose one: Solid oral; Oral liquid; Parenteral; Other.
BCS class of the drug substance when it applies	Choose one: Not determined; Class 1; Class 2; Class 3; Class 4.
Multi-dose or preserved product when it applies	Tick the box if it applies.
Design space claimed	Tick the box if it applies.
Specification from Specification Builder (optional)	Optional. Add the Specification Builder summary so the tool can check that each attribute "controlled by the specification" really has a test. Press Add files and pick summary files (.cmcfy.json) saved by other modules.

2 - QTPP and critical quality attributes

FIELD	WHAT TO ENTER
Quality target product profile when it applies	A table. Columns: Element Target Justification. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

FIELD	WHAT TO ENTER
Quality attributes	A table. Columns: Attribute Target Critical (yes/no) Why Controlled by. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Risk assessment and studies

FIELD	WHAT TO ENTER
Risk assessment (FMEA)	Score each of severity, occurrence and detectability from 1 to 10. A table. Columns: CQA Factor (material attribute or process parameter) Failure mode or effect Severity (1–10) Occurrence (1–10) Detectability (1–10) Mitigation. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Design of experiments and other studies	A table. Columns: Factor Range studied Effect on CQAs Proven acceptable range. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

4 · Formulation and process development (3.2.P.2.1–2.3) shown when it applies

FIELD	WHAT TO ENTER
Drug substance and excipient compatibility	A table. Columns: Excipient Ratio (API:excipient) Condition Result. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Formulations used in clinical studies	A table. Columns: Formulation Used in Difference from commercial Bridging. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Formulation development summary	Type or paste text, or press Load file (Word, PDF, a scan, Excel or text).
Dissolution method development and discriminating power	Type or paste text.
Manufacturing process development	Type or paste text.

5 · Microbiological attributes and compatibility (3.2.P.2.5, 2.6) shown when it applies

FIELD	WHAT TO ENTER
Microbiological attributes	Type or paste text.
Compatibility with diluents, admixtures or devices	Type or paste text.

6 · Drug substance process history (3.2.S.2.6) shown when it applies

FIELD	WHAT TO ENTER
Process versions	A table. Columns: Process version Batches Used in Main changes. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Comparability of drug substance from different processes	Type or paste text.

5. Checks and alerts

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

- At least one attribute is critical; every critical attribute has a control and appears in the risk assessment.
- FMEA scores are 1 to 10; risks with a high RPN, or a severity of 9 or 10, need a mitigation.
- If a design space is claimed, studies are listed; each study gives a proven acceptable range.
- Drug substance and excipient compatibility data; any change seen in compatibility is flagged.
- Clinical formulations listed, with bridging for any that differ from the commercial formulation; formulation, dissolution method and process development summaries present.
- Multi-dose products need preservative effectiveness data; microbiological attributes are discussed.
- Drug substance (3.2.S.2.6): process versions listed with a comparability discussion when there are several.

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: 3.2.P.2.1 Components of the drug product; 3.2.P.2.2 Drug product (formulation development); 3.2.P.2.3 Manufacturing process development; 3.2.P.2.5 Microbiological attributes; 3.2.P.2.6 Compatibility; 3.2.S.2.6 Manufacturing process development. 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.2.1	Components of the drug product
3.2.P.2.2	Drug product (formulation development)
3.2.P.2.3	Manufacturing process development
3.2.P.2.5	Microbiological attributes

SECTION	DOCUMENT
3.2.P.2.6	Compatibility
3.2.S.2.6	Manufacturing process development (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

The development sections follow ICH Q8(R2) in both regions. In EU mode, references are cited as EMA and Ph. Eur. (for example Ph. Eur. 5.1.3 for efficacy of antimicrobial preservation instead of USP <51>). 3.2.P.2.4 (container closure suitability) is written by the Container Closure & E&L.

8. Working with other modules

- Add the Specification Builder summary to cross-check controls.
- Critical steps and parameters should match the Process & Controls Writer.
- The QOS Composer & Dossier Assembler summarises the control strategy in 2.3.P.2.

9. Common pitfalls

- Scoring every risk the same. The ranking only helps when severity, occurrence and detectability are scored honestly.
- Listing an attribute as critical but naming no control, or controlling it by "testing" without saying which test.
- Claiming a design space without the studies that define it.
- Forgetting to bridge an early clinical formulation (for example a capsule) to the commercial tablet.

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. Flag a multi-dose product

Tick **Multi-dose or preserved product**.

EXPECTED RESULT

A major alert says a multi-dose product needs preservative effectiveness data.

2. Claim a design space without studies

Tick **Design space claimed**, then clear the **Design of experiments and other studies** table.

EXPECTED RESULT

A major alert says a design space is claimed but no studies are listed.

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.