

QOS Composer & Dossier Assembler

Bring the summary files from every module together: write the Quality Overall Summary (Module 2.3) and 3.2.R, check that the same facts agree across sections, see which Module 3 sections are still missing, and build the eCTD folder.

WRITES

2.3 3.2.R

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

ICH M4Q(R1)
Module 2.3; ICH
eCTD Specification
v3.2.2; FDA
regional 3.2.R

TIME TO LEARN

About 20 minutes
with the example

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

1. What this module does

Each module has a [Download summary for QOS](#) button that saves a small .cmcfy.json file with the facts that other sections depend on. The Composer reads those files and writes the QOS from them, so 2.3 always says what Module 3 says.

It also cross-checks the sections: the same impurity limit in the specification and the batch analysis, the same active quantity in 3.2.P.1 and the batch formula, stability batches that appear in the batch analyses, a storage statement that matches light and moisture sensitivity, and summaries made for the same region.

What you get

- Word or PDF files for 2.3 Quality overall summary, 3.2.R Regional information, and a cross-section consistency report.
- An eCTD folder (.zip) with the QOS and your section files placed in the eCTD v3.2.2 structure.

2. Before you start

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

- The summary file from each module you have used (.cmcfy.json).
- Proprietary and nonproprietary names, applicant, dosage form and strength, route and proposed indication.
- The eCTD folder names you use for the drug substance and drug product.
- The labelled shelf life and drug substance retest period.
- Regional information: for the US, executed batch records, method validation package and comparability protocols; for the EU, process validation status, CEP or ASMF, TSE certificates and any device (Article 117).
- Optionally, your finished section files to place in the eCTD folders.

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/qos-composer.html. The example loads the summaries from every module's example data, so you can see a full cross-check before adding your own files.

1 Enter the product

Enter the names, applicant, dosage form, route, indication and the eCTD folder names, and choose the region.

CMCfy | QOS Composer & Dossier Assembler | 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.

2.3 3.2.R Save project Open project Start blank Load example

Add the summary files saved from each CMCfy tool. The Composer writes the Quality Overall Summary, checks that the same facts agree across sections, shows which Module 3 sections are still missing, and builds the eCTD folder structure with your section files.

Guidance: ICH M4Q(R1) Module 2.3; ICH eCTD Specification v3.2.2; FDA regional 3.2.R

1 - PRODUCT (2.3 INTRODUCTION)

Proprietary and nonproprietary name

CMX-101 Tablets, 50 mg

Submission region US: FDA (NDA, ANDA, BL Drug substance (INN) Cimexafen hydrochloride

Applicant CMX Pharma Inc. Dosage form and strength Film-coated tablets, 50 mg

Route Oral

Proposed indication [Proposed indication]

eCTD folder name for the drug substance eCTD folder name for the drug product

RESULT

8 summary files · 23 Module 3 sections still missing

7 cross-section findings.

SECTIONS COVERED	TOOLS USED	SHELF LIFE (STABILITY)
29	batch, composition, container, development, impurity, process, spec, stability	30 months

FILES TO PLACE

0

MODULE 3 COVERAGE

SECTION	TITLE	STATUS
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2

Add the summary files

Press Add files under Summary files (.cmcfy.json) and pick the summaries saved from each module. Enter the labelled shelf life and retest period. The headline counts the files and the Module 3 sections still missing: 8 summary files, 23 sections still missing, 7 cross-section findings.

RESULT

8 summary files · 23 Module 3 sections still missing

7 cross-section findings.

SECTIONS COVERED	TOOLS USED	SHELF LIFE (STABILITY)
29	batch, composition, container, development, impurity, process, spec, stability	30 months

FILES TO PLACE

0

3 Read the Module 3 coverage

The coverage table shows every Module 3 section and which module covers it. Missing sections are minor alerts, so you can file in stages.

MODULE 3 COVERAGE		
SECTION	TITLE	STATUS
3.2.S.1.1	Nomenclature	Covered
3.2.S.1.2	Structure	Covered
3.2.S.1.3	General properties	Covered
3.2.S.2.1	Manufacturer(s)	Missing
3.2.S.2.2	Description of manufacturing process and process controls	Missing
3.2.S.2.3	Control of materials	Missing
3.2.S.2.4	Controls of critical steps and intermediates	Missing
3.2.S.2.5	Process validation and/or evaluation	–
3.2.S.2.6	Manufacturing process development	Missing
3.2.S.3.1	Elucidation of structure and other characteristics	Covered
3.2.S.3.2	Impurities	Missing
3.2.S.4.1	Specification	Missing
3.2.S.4.2	Analytical procedures	Missing
3.2.S.4.3	Validation of analytical procedures	Missing
3.2.S.4.4	Batch analyses	Missing
3.2.S.4.5	Justification of specification	Missing
3.2.S.5	Reference standards or materials	Missing
3.2.S.6	Container closure system	Missing
3.2.S.7.1	Stability summary and conclusions	Missing
3.2.S.7.2	Post-approval stability protocol and stability commitment	Missing
3.2.S.7.3	Stability data	Missing
3.2.P.1	Description and composition of the drug product	Covered
3.2.P.2.1	Components of the drug product	Covered
3.2.P.2.2	Drug product	Covered
3.2.P.2.3	Manufacturing process development	Covered
3.2.P.2.4	Container closure system	Covered

Module 3 coverage by section.

4 Resolve the cross-section findings

The example has seven major findings, for example the batch analysis using "NMT 0.20%" for the unspecified degradation product while the specification says "NMT 0.3%", and 55.07 mg of active per unit in 3.2.P.1 but 54.8 mg in 3.2.P.3.2. Fix the source module, save its summary again and replace the file here.

ALERTS TO RESOLVE

7 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

Any unspecified degradation product: the batch analysis uses "NMT 0.20%" but the specification says "NMT 0.3%".

Consistency - ICH M4Q 3.2.P.5.1 / 3.2.P.5.4

Batch results must be judged against the proposed specification.

Justification Accept justification Proceed without it

MAJOR

Identification (UV) is in the specification but has no batch results.

Consistency - ICH M4Q 3.2.P.5.4

Add results for every test in the specification.

Justification Accept justification Proceed without it

MAJOR

Uniformity of dosage units is in the specification but has no batch results.

Consistency - ICH M4Q 3.2.P.5.4

Add results for every test in the specification.

Justification Accept justification Proceed without it

MAJOR

Microbial limits is in the specification but has no batch results.

Consistency - ICH M4Q 3.2.P.5.4

Add results for every test in the specification.

Justification Accept justification Proceed without it

MAJOR

Cimexafen hydrochloride: 55.07 mg per unit in 3.2.P.1 but 54.8 mg in 3.2.P.3.2.

Consistency - ICH M4Q

Use the same quantity.

Justification Accept justification Proceed without it

MAJOR

Batches marked as stability batches in 3.2.P.5.4 have no stability data: Q1A.2, Q1A.1, Q1A.2

5 Complete regional information

Fill the regional panel for the chosen region; it writes 3.2.R. Optionally add your section files: each file name must start with its section number (for example "3.2.P.5.1 Specification.docx") so it lands in the right folder.

6 Preview, download and build the eCTD folder

Preview 2.3, 3.2.R and the consistency report, read the review and download. The last item builds the eCTD folder (.zip).

PREVIEW AND DOWNLOAD BY CTD SECTION

One file per eCTD granule, with ICH M4Q headings, ready to drop into your Module 3 folder. Each file opens in a preview first, with a review of gaps in the data, gaps in the report and differences from your protocol; then download it as Word or PDF. Also save the summary file: the QOS Composer reads it to write Module 2.3 and check consistency across sections.

3.2.R	Regional information	Preview
2.3	Quality overall summary	Preview
Report	Cross-section consistency check	Preview
eCTD	eCTD folder with the QOS and your section files (.zip)	Download

Preview and download all

Download summary for QOS

Fix or justify the 7 blocking alerts before downloading. You can preview the draft now.

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 (2.3 Introduction)

FIELD	WHAT TO ENTER
Proprietary and nonproprietary name	Type it in.
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Drug substance (INN)	Type it in.
Applicant	Type it in.
Dosage form and strength	Type it in.
Route	Type it in.

FIELD	WHAT TO ENTER
Proposed indication	Type it in.
eCTD folder name for the drug substance	Type it in.
eCTD folder name for the drug product	Type it in.

2 · Summary files from the tools

Each tool has a "Download summary for QOS" button. The example below uses the summaries from every tool's example data.

FIELD	WHAT TO ENTER
Summary files (.cmcfy.json)	Saved from each module with Download summary for QOS . Press Add files and pick summary files (.cmcfy.json) saved by other modules.
Shelf life on the proposed label (months)	Type a number.
Drug substance retest period (months)	Type a number.

3 · Regional information (3.2.R)

FIELD	WHAT TO ENTER
US: executed batch records for the exhibit batches are included when it applies	Tick the box if it applies.
US: method validation package is included when it applies	Tick the box if it applies.
US: comparability protocols when it applies	Type it in.
EU: process validation of the drug product when it applies	Choose one: Completed; data in 3.2.P.3.5; Not complete; process validation scheme in 3.2.R; Not addressed yet.

FIELD	WHAT TO ENTER
EU: certificates of suitability (CEP) or ASMF when it applies	Type it in.
EU: TSE certificates when it applies	Type it in.
EU: medical device (Article 117) when it applies	Type it in.
Section files to place in eCTD folders (optional)	Optional. Each file name must start with its section number. Press Add files and pick your finished section files.

5. Checks and alerts

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

- Summary files are present and were made for the same region as this dossier.
- Cross-section consistency: specification criteria against batch analysis criteria, specification tests with batch results, active quantity in 3.2.P1 against the batch formula, stability batches against batch analyses and stability data, the Q3D status in the specification against the impurity assessment, light and moisture protection against the storage statement, shelf life against stability.
- Every Module 3 section is covered, or listed as still missing.
- Regional information: EU process validation addressed and consistent with the process file; CEP or ASMF status; US method validation package.
- Section files are named with their section number.

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: 2.3 Introduction; 2.3.S Drug substance; 2.3.P Drug product. 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
2.3	Quality overall summary
3.2.R	Regional information
Report	Cross-section consistency check
eCTD	eCTD folder with the QOS and your section files (.zip)

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 QOS follows ICH M4Q in both regions. In US mode, 3.2.R covers executed batch records, the method validation package and comparability protocols. In EU mode it covers the process validation scheme when validation is not complete, CEPs or ASMFs, TSE certificates and medical devices under Article 117. Summaries made for a different region raise a major alert, because references differ.

8. Working with other modules

- Every module feeds this one: start with Composition & General Info, Process & Controls Writer, Specification Builder, Batch Analysis & CoA, Stability Studio and the others you need.
- Upload sections written outside CMCfy to the Report Reviewer for a gap check before adding them here.

9. Common pitfalls

- Mixing summaries from old and new versions of a module: save the summary again after every change.
- Summaries made for the US in an EU dossier, or the other way round.
- Section files without the section number at the start of the name.
- Treating "not covered yet" as an error: it is a reminder of what is still to write.

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. Leave EU process validation open

Set `Submission region` to EU, then set `EU: process validation of the drug product` to "Not addressed yet".

EXPECTED RESULT

A major alert says EU process validation is not addressed.

2. **Remove all summary files**

Press **Remove all** under the summary files.

EXPECTED RESULT

A major alert says no summary files are added.

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.