

International Filings (Japan, Canada, WHO)

Prepare the regional quality summary for Japan, Canada or WHO prequalification from one set of product data: the Japanese approval matters, the Health Canada Certified Product Information Document (CPID) or the WHO Quality Information Summary (QIS).

WRITES

Module 1 2.3
3.2

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

Japan: approval matters and partial/minor change notifications (MHLW); Canada: Health Canada Quality guidance for NDS/ANDS and CPID template; WHO: TRS 970 Annex 4, TRS 1010 Annex 10 and the QIS template

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You choose the agency and enter the sites, the manufacturing steps with their parameters, the specification and the stability data. The tool writes the document in the layout that agency expects.

For Japan, critical parameters become approval items (a change needs a partial change application) and the rest are marked 『 』 as minor change notification items. The tool checks stability against the climatic zone (25 °C/60% RH for Japan and Canada, 30 °C/75% RH for WHO), the pharmacopoeias the agency accepts, the master file and the site registrations.

What you get

- A Word or PDF document: Japan approval matters (Module 1), Health Canada CPID, or WHO QIS.

2. Before you start

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

- Manufacturing sites with their accreditation, DEL listing or inspection status.
- Process steps with the critical parameters and ranges.
- The specification, stability data and the drug substance master file or CEP.

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/international-filings.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 the agency

Choose Japan, Canada or WHO prequalification, the submission type and the drug substance reference.

CMCfy

International Filings (Japan, Canada, WHO)

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.

Module 1

2.3

3.2

Save project

Open project

Start blank

Load example

Prepare the regional quality summary for Japan, Canada or WHO prequalification from your product data. The tool writes the Japanese approval matters (with partial-change and minor-change items marked), the Health Canada CPID or the WHO QIS, and checks stability against the climatic zone, the pharmacopoeias accepted, master files and site registrations.

Guidance: Japan: approval matters and partial/minor change notifications (MHLW); Canada: Health Canada Quality guidance for NDS/ANDS and CPID template; WHO: TRS 970 Annex 4, TRS 1010 Annex 10 and the QIS template

1 · SUBMISSION

Agency

WHO prequalification

Product

CMX-101 tablets 50 mg

Drug substance

CMX-101 hydrochloride

Submission type

Generic (ANDS in Canad.

Document number

INTL-101-01

RESULT

Quality Information Summary (QIS) ready for WHO prequalification

WHO prequalification: zone IVb long-term 30 °C/75% RH, 24 months on 3 batches; 7 specification tests; 9 process parameters.

AGENCY

WHO prequalification

ZONE

IVb

LONG-TERM

24 months

SITES

3

2 Enter sites, process and specification

One row per site, per process parameter and per test. Write "yes" in the last process column for critical parameters.

3 Read the result

The headline gives the outcome: "Quality Information Summary (QIS) ready for WHO prequalification".

AGENCY REQUIREMENTS		
ITEM	REQUIREMENT	STATUS
Long-term stability	30 °C/75% RH	24 months
Pharmacopoeia	Ph. Int., Ph. Eur., USP, BP or JP	ok
Drug substance	APIMF (WHO API master file) or CEP, or a prequalified API	referenced
Sites	GMP inspection or recognised inspection outcome for each site	ok

Agency requirements.

4

Resolve alerts and download

Missing long-term data at the zone condition is critical. Pharmacopoeias the agency does not accept, missing site registrations and a foreign reference product for Canada are flagged. Then preview and download.

One row per step and parameter. Critical: yes for parameters that affect

Devices with AI

Report to rule-based test

Preview and review before download

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 preview 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

QIS Quality Information Summary (QIS)

CMX-101 tablets 50 mg · INTL-101-01

FPP	CMX-101 tablets 50 mg
API	CMX-101 hydrochloride
Document	INTL-101-01
API source	CEP R1-CEP 2019-123-Rev 01
Comparator product	CMX-101 50 mg tablets (Innovator Ltd., purchased in the UK)

2.3.5 Drug substance (API)

API information: CEP R1-CEP 2019-123-Rev 01.

2.3.P.3 Manufacture

Role	Name and address	Registration
Drug substance	Apex Chemicals Ltd, Plot 12 Hyderabad India	WHO PQ inspection 2025 (compliant)
Drug product	Acme Pharma Raleigh NC USA	FDA inspection 2025 (NAI); WHO desk assessment
Release testing	Acme Pharma Raleigh NC USA	FDA inspection 2025 (NAI)

Step	Parameter	Target or range	Critical
Dispensing	Materials	As per formula	No
Granulation	Impeller speed	150–250 rpm	Yes
Granulation	Granulation liquid	Purified water 30% w/w	Yes
Drying	Outlet air temperature	45–55 °C	No
Drying	Loss on drying	1.5–3.0%	Yes
Drying	Drying time	40 min	Yes

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 • Submission

FIELD	WHAT TO ENTER
Agency	Choose one: Japan (PMDA / MHLW); Canada (Health Canada); WHO prequalification.
Product	Type it in.
Drug substance	Type it in.

FIELD	WHAT TO ENTER
Submission type	Choose one: New drug; Generic (ANDS in Canada; multisource FPP for WHO).
Document number	Type it in.
Drug substance master file or CEP reference	Type it in.
Reference or comparator product (generics)	Type it in.
when it applies	

2 · Sites

FIELD	WHAT TO ENTER
Manufacturing sites	A table. Columns: Role Name and address Registration (accreditation, DEL, inspection). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Manufacturing method

One row per step and parameter. Critical: yes for parameters that affect quality (these become partial-change items in Japan).

FIELD	WHAT TO ENTER
Process	Critical parameters become partial-change items in the Japanese approval matters. A table. Columns: Step Parameter Target or range Critical (yes/no). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

4 · Specification and stability

FIELD	WHAT TO ENTER
Drug product specification	A table. Columns: Test Method Acceptance criterion. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

FIELD	WHAT TO ENTER
Long-term stability	Write the condition as "30/75" or "25/60". A table. Columns: Condition (°C/% RH) Months available Batches. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Proposed shelf life (months)	Type a number.
Container closure	Type it in.

5. Checks and alerts

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

- Long-term stability at the zone condition, months and batches.
- Pharmacopoeias accepted by the agency.
- Master file or CEP, site registrations and the reference product.

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: Summary. 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.

- 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).
- Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
- 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.
- 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
Module 1 (JP)	Approval matters
CPID	Certified Product Information Document
QIS	Quality Information Summary

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 US/EU switch does not apply here: choose the agency in the tool. Japan follows the PMD Act and MHLW notifications; Canada the Health Canada Quality guidance for NDS and ANDS; WHO the TRS 970 Annex 4 dossier guideline.

8. Working with other modules

- US and EU Module 1 items are prepared in Regional Information (3.2.R and Module 1); post-approval changes in Post-approval Filings.

9. Common pitfalls

- Filing for WHO with only 25 °C/60% RH long-term data.
- Putting every Japanese parameter in 『 』 , which the PMDA will not accept for critical parameters.

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. Switch to Japan

Choose Japan as the agency.

EXPECTED RESULT

The headline shows that the methods citing Ph. Int. are not accepted in Japan.

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.