

DMF & ASMF

Prepare a US drug master file or an EU active substance master file: allocate each section to the applicant's or restricted part, check the versions, the annual update and the letters of access.

WRITES	PRODUCT TYPE	GUIDANCE IT FOLLOWS	TIME TO LEARN
Report 3.2.S	Small molecule and biologics	21 CFR 314.420; FDA Drug Master Files guidance (2019); FDA Completeness Assessments for Type II API DMFs under GDUFA (2017); EMA Guideline on Active Substance Master File Procedure (CHMP/QWP/227/02 Rev. 4); EMA ASMF worksharing procedure; EDQM certification procedure (CEP)	About 20 minutes with the example

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

1. What this module does

You enter the holder, the US DMF and EU ASMF references, the versions of each part, the sections with their part, the specification and impurity information given to the applicant, the letters of access and the changes since the last version.

The tool checks each section is in the right part, that sections the applicant must see are in the applicant's part, that both parts carry the same version, that customers are notified of changes, and gives the US annual update due date.

What you get

- A Word or PDF report: section allocation, letters of access and the change summary for the annual update or new version.

2. Before you start

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

- Holder and US agent, DMF number and date, ASMF reference and versions.
- The section list with the part and version.
- Letters of access and changes since the last version.

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/dmf-asmf.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 master file

Choose the regions, enter the holder, agent, DMF number and date and the ASMF reference and versions.

CMCfy DMF & ASMF 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.

[Report](#) **3.2.5** Save project Open project Start blank Load example

Prepare a US Type II drug master file or an EU active substance master file. Each 3.2.S section is put in the applicant's part, the restricted part or both, and the split is checked against the EMA ASMF guideline. The tool checks that both parts carry the same version, tracks the letters of access for each customer, and works out when the US annual update is due.

Guidance: 21 CFR 314.420; FDA Drug Master Files guidance (2019); FDA Completeness Assessments for Type II API DMFs under GDUFA (2017); EMA Guideline on Active Substance Master File Procedure (CHMP/QWP/227/02 Rev. 4); EMA ASMF worksharing procedure; EDQM certification procedure (CEP)

1 · MASTER FILE

Active substance

Cmxitinib

Submission region

Both US and EU

Holder and address

Chem API Ltd., Plot 12, Genome Valley, Hyderabad 500078, I

US agent (foreign holders)

RegAgent LLC, Wilmington I

US DMF number

038812

DMF submission date

RESULT

13 sections in the applicant's part · 6 in the restricted part

Both parts carry the same version. US annual update due 2027-07-01.

CUSTOMERS	DMF	ANNUAL UPDATE DUE
3	Type II 038812	2027-07-01
ASMF	VERSIONS	
EMA/ASMF/00123	AP-03 (2026-05) / RP-03 (2026-05)	

SECTION ALLOCATION

2 Allocate the sections

One row per section with AP (applicant's part) or RP (restricted part).

3 Read the result

The headline counts the sections in each part: "13 sections in the applicant's part · 6 in the restricted part". The note says whether the versions match and when the US annual update is due.

SECTION ALLOCATION

SECTION	TITLE	PART	VERSION
3.2.S.1	General information	AP	03
3.2.S.2.1	Manufacturer(s)	AP	03
3.2.S.2.2	Description of the manufacturing process: brief outline (AP) and full detail (RP)	AP and RP	03
3.2.S.2.3	Control of materials	RP	03
3.2.S.2.4	Controls of critical steps and intermediates	RP	03
3.2.S.2.5	Process validation and/or evaluation	RP	03
3.2.S.2.6	Manufacturing process development	RP	03
3.2.S.3.1	Elucidation of structure and other characteristics	AP	03
3.2.S.3.2	Impurities	AP and RP	03
3.2.S.4.1	Specification	AP	03
3.2.S.4.2	Analytical procedures	AP	03
3.2.S.4.3	Validation of analytical procedures	AP	03
3.2.S.4.4	Batch analyses	AP	03
3.2.S.4.5	Justification of specification	AP	03
3.2.S.5	Reference standards or materials	AP	03
3.2.S.6	Container closure system	AP	03
3.2.S.7	Stability	AP	03

Section allocation.

4

Resolve alerts and download

Misallocated or missing sections, a specification or impurity information missing from the applicant's part, mutagenic and nitrosamine statements, version mismatch, missing GDUFA assessment, a foreign holder with no US agent and customers not notified are flagged. Then preview and download.

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.

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 fileCompare

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

Active substance master file: section allocation

Cmxitinib - US (FDA) and EU (EMA)

Chem API Ltd. submits an amendment to Type II DMF 038812 for Cmxitinib. Version 03: tightened residual toluene limit (890 ppm to 500 ppm); added a second source of starting material SM-2 (Supplier B, same route). Customers notified 2026-05-12. Authorised customers: CMX Pharma Inc. (NDA 212345); Generic Co. (ANDA 219876). The holder commits to submit an annual update on each anniversary of the original submission and to notify each authorised customer of any change.

Chem API Ltd. submits version AP-03 (2026-05) / RP-03 (2026-05) of the active substance master file EMEA/ASMF/00123 for Cmxitinib. The applicant's part contains S.1, S.2.1, S.2.2, S.3.1, S.3.2, S.4.1, S.4.2, S.4.3, S.4.4, S.4.5, S.5, S.6, S.7; the restricted part contains S.2.2, S.2.3, S.2.4, S.2.5, S.2.6, S.3.2. Version 03: tightened residual toluene limit (890 ppm to 500 ppm); added a second source of starting material SM-2 (Supplier B, same route). Customers notified 2026-05-12.

Section	Title	Applicant's part	Restricted part
3.2.S.1	General information	Yes	
3.2.S.2.1	Manufacturer(s)	Yes	
3.2.S.2.2	Description of the manufacturing process: brief outline (AP) and full detail (RP)	Yes	Yes
3.2.S.2.3	Control of materials		Yes
3.2.S.2.4	Controls of critical steps and intermediates		Yes
3.2.S.2.5	Process validation and/or evaluation		Yes
3.2.S.2.6	Manufacturing process development		Yes
3.2.S.3.1	Elucidation of structure and other characteristics	Yes	
3.2.S.3.2	Impurities	Yes	Yes
3.2.S.4.1	Specification	Yes	
3.2.S.4.2	Analytical procedures	Yes	
3.2.S.4.3	Validation of analytical procedures	Yes	

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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 • Master file

FIELD	WHAT TO ENTER
Active substance	Type it in.
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Holder and address	Type it in.
US agent (foreign holders)	Type it in.
	when it applies
US DMF number	Type it in.
	when it applies

FIELD	WHAT TO ENTER
DMF submission date when it applies	Type it in.
GDUFA DMF fee paid and completeness assessment passed (for ANDA use) when it applies	Tick the box if it applies.
EU ASMF reference when it applies	Type it in.
Applicant's part version when it applies	Type it in.
Restricted part version when it applies	Type it in.
A CEP is held for this substance	Tick the box if it applies.

2 · Section allocation

Part: AP (applicant's / open part), RP (restricted / closed part) or both.

FIELD	WHAT TO ENTER
Sections	Part: AP or RP. A table. Columns: Section Title Part Version or date. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Specification in the applicant's part (tests and limits)	Type or paste text.
Impurity information given to the applicant	Type or paste text.

3 · Customers and letters of access

FIELD	WHAT TO ENTER
Letters of access / authorisation	Region: US or EU. A table. Columns: Customer (applicant) Application Region (US/EU) Letter date. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Changes since the last version or annual update	Type or paste text.
Customers notified of changes	Tick the box if it applies.

5. Checks and alerts

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

- Sections the applicant needs (specification, impurity profile, stability) are in the applicant's part.
- Applicant's and restricted part versions match.
- US annual update due date (one year from the DMF date or last update); GDUFA fee and completeness assessment for ANDA use; US agent for a foreign holder.
- Letters of access for each customer and customers notified of changes.

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: Cover letter text. 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
Master file report	Section allocation, letters of access and changes

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 follows 21 CFR 314.420 and the FDA DMF guidance. EU follows the ASMF procedure guideline (CHMP/QWP/227/02 Rev. 4).

8. Working with other modules

- The applicant references the master file in the Regional Information (3.2.R and Module 1) module.

9. Common pitfalls

- Updating one part without the other.

- Putting the specification only in the restricted part.

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. **Update one part only**

Set [Restricted part version](#) to RP-02 (2025-01).

EXPECTED RESULT

The note says the two parts carry different versions.

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.