

eCTD Dossier Planner

Plan an FDA eCTD sequence before publishing: each file placed in its CTD folder, the sections the application type needs, and the technical checks FDA's validation applies.

WRITES

eCTD sequence

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

ICH M8 eCTD Specification v3.2.2 and eCTD v4.0 Implementation Guide; FDA eCTD Technical Conformance Guide; FDA Specifications for eCTD Validation Criteria; FDA Portable Document Format (PDF) Specifications; FDA Comprehensive Table of Contents Headings and Hierarchy; FD&C Act 745A(a); FDA Providing Regulatory Submissions in Electronic Format (eCTD)

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You give the application, sequence and submission type, and one row per file with its CTD section, name, pages, size, PDF version, bookmarks and searchable text.

The tool works out the folder of each file, lists the required sections for an original NDA, BLA, ANDA, IND or DMF, and checks file names, path length, PDF version, size, bookmarks, OCR, duplicates and the sequence and application numbers.

What you get

- A Word or PDF file: eCTD sequence plan with the table of contents and the technical check findings.

2. Before you start

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

- The file list from your publishing folder.
- Page count, size and PDF version of each file.
- The application number FDA assigned.

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/ectd-dossier-planner.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 sequence

Choose the application type, submission type and eCTD version, and give the application and sequence numbers.

CMCfy eCTD Dossier Planner 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.

eCTD sequence Save project Open project Start blank Load example

Plan an eCTD sequence for FDA before it goes to the publishing team. Give the application, the sequence and the files; the tool places each file in its CTD folder, checks the sections the application type needs, and runs the checks FDA's technical validation applies to file names, path length, PDF version, size, bookmarks and searchable text.

Guidance: ICH M8 eCTD Specification v3.2.2 and eCTD v4.0 Implementation Guide; FDA eCTD Technical Conformance Guide; FDA Specifications for eCTD Validation Criteria; FDA Portable Document Format (PDF) Specifications; FDA Comprehensive Table of Contents Headings and Hierarchy; FD&C Act 745A(a); FDA Providing Regulatory Submissions in Electronic Format (eCTD)

1 - APPLICATION AND SEQUENCE

Product
CMX-101 tablets 25 mg and 50 mg

Application type
NDA

Application number (6 digits)
219876

Sequence number
0000

Submission type
Original application

eCTD version
eCTD v3.2.2

Drug substance folder name (substance-manufacturer)
cmx-101-chem-dev

RESULT

3 issues that would fail FDA validation

18 files (445.7 MB) in 12 folders; 12 of 12 required sections present.

FILES	SIZE	SECTIONS
18	446 MB	12/12

FILES WITH ISSUES
3

REQUIRED SECTIONS

SECTION	CONTENT	FILES
1.1	Form (256K 2207)	2

2 List the files

One row per file. Give the CTD section as numbered in the CTD, for example 3.2.P.5.1.

3 Read the result

The headline gives the outcome: "3 issues that would fail FDA validation".

REQUIRED SECTIONS

SECTION	CONTENT	FILES
1.1	Forms (356h, 3397)	2
1.2	Cover letter	1
1.14	Labeling	1
2.3	Quality overall summary	3
2.4	Nonclinical overview	1
2.5	Clinical overview	1
2.6	Nonclinical summaries	1
2.7	Clinical summary	1
3.2.S	Drug substance	2
3.2.P	Drug product	2
4.2	Nonclinical study reports	1
5.3	Clinical study reports	2

Required sections and file checks.

4 Resolve alerts and download

Invalid file names, PDF versions outside 1.4 to 1.7, files over 100 MB, duplicate names and missing required sections are critical. Missing bookmarks and text that cannot be searched 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.

3 critical

1 to fix

DATA AND INPUTS (4)

Specification_DS.pdf (3.2.S.4.1): File name uses characters other than lower case letters, digits and hyphens.

Rename the file with lower case letters, digits and hyphens only.

critical · Files · ICH eCTD v3.2.2 Appendix 2

Ignore

stability-data.pdf (3.2.P.8.3): 131 MB is over the 100 MB limit; split the document.

Split the document into files under 100 MB.

critical · Files · FDA PDF Specifications

Ignore

cmx-101-302-csr.pdf (5.3.5.1): PDF version 1.3 is not accepted (1.4 to 1.7 or PDF/A).

Save the file as PDF 1.4 to 1.7 or PDF/A.

critical · Files · FDA PDF Specifications

Ignore

cmx-101-302-csr.pdf (5.3.5.1): Text cannot be searched (scanned image); apply OCR.

Apply OCR so the text can be searched and copied.

major · Files · FDA PDF Specifications

Ignore

eCTD sequence eCTD sequence plan and technical check

CMX-101 tablets 25 mg and 50 mg · NDA 219876 · sequence 0000

Product	CMX-101 tablets 25 mg and 50 mg
Application	NDA 219876
Sequence	0000
Submission type	Original application
eCTD version	v3.2.2
Total size	445.7 MB

Summary

Sequence 0000 of NDA 219876 (CMX-101 tablets 25 mg and 50 mg) is the original application, in eCTD v3.2.2. It contains 18 files with a total size of 445.7 MB.

Every section required for this submission type has at least one file.

3 files need correction before publishing: Specification_DS.pdf, stability-data.pdf, cmx-101-302-csr.pdf.

Required sections

Section	Content	Files
1.1	Forms (356h, 3397)	2
1.2	Cover letter	1
1.14	Labeling	1
2.3	Quality overall summary	3
2.4	Nonclinical overview	1
2.5	Clinical overview	1
2.6	Nonclinical summaries	1

Fix or justify the 4 blocking alerts before downloading. Or choose "Download anyway".

Download anyway

Download Word (.docx)

Download PDF

Document text

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 · Application and sequence

FIELD	WHAT TO ENTER
Product	Type it in.
Application type	Choose one: NDA; BLA; ANDA; IND; DMF.
Application number (6 digits)	Type it in.
Sequence number	Type it in.
Submission type	Choose one: Original application; Amendment; Supplement; Annual report; Response to information request.
eCTD version	Choose one: eCTD v3.2.2; eCTD v4.0.

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FIELD	WHAT TO ENTER
Drug substance folder name (substance-manufacturer)	Type it in.
Study tagging files prepared for Module 4 and 5 studies	Tick the box if it applies.
when it applies	

2 · Files

One row per file (leaf). Section as in the CTD, for example 3.2.P.5.1 or 1.14.1. Pages, PDF version and size come from the file properties.

FIELD	WHAT TO ENTER
Files	File names use lower case letters, digits and hyphens only, for example cmx-101-301-csr.pdf. A table. Columns: CTD section File name Pages Size (MB) PDF version Bookmarked (yes/no) Searchable text (yes/no). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

5. Checks and alerts

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

- File names, path length, PDF version, size, bookmarks and OCR.
- Required sections by application type.
- Sequence and application number format.

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: Submission note. 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
eCTD sequence	eCTD sequence plan and technical check

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 only: FDA eCTD (Module 1 US regional).

8. Working with other modules

- Plan the application content in NDA & BLA Submission or IND Application.

9. Common pitfalls

- Scanned study reports without OCR.
- Stability reports over 100 MB that need splitting.

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. **Fix the file names**

Rename Specification_DS.pdf to specification.pdf.

EXPECTED RESULT

One fewer issue that would fail FDA validation.

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.