

Design History File

Write the design history file summary and traceability matrix: user needs to design inputs, outputs, verification and validation, with risk controls, design reviews and transfer checked.

WRITES

DHF

Design controls

PRODUCT TYPE

Medical devices

GUIDANCE IT FOLLOWS

21 CFR Part 820 (QMSR, incorporating ISO 13485:2016 by reference, effective 2 February 2026); ISO 13485:2016 clause 7.3; FDA Design Control Guidance for Medical Device Manufacturers (1997); ISO 14971:2019; IEC 62304; EU MDR 2017/745 Annex II

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You list the user needs with their validation, the design inputs with their outputs, verification and linked hazard, and the design reviews.

The tool builds the traceability matrix, flags needs without inputs, inputs without outputs, open or failed verification and validation, risk controls that are not verified, and reviews without an independent reviewer.

What you get

- A Word or PDF file: design history file summary and traceability matrix.

2. Before you start

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

- User needs and design inputs with their IDs.
- Verification and validation reports.
- Design review minutes.

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/design-history-file.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 project

Give the device, design project, classification, design reviews and the device master record.

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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.

DHF | **Design controls** [Save project](#) [Open project](#) [Start blank](#) [Load example](#)

Write the design history file summary and the traceability matrix for a medical device. The tool traces each user need to its design inputs, outputs, verification and validation, flags gaps and failures, checks that risk controls are verified, and checks the design reviews and the design transfer.

Guidance: 21 CFR Part 820 (QMSR, incorporating ISO 13485:2016 by reference, effective 2 February 2026); ISO 13485:2016 clause 7.3; FDA Design Control Guidance for Medical Device Manufacturers (1997); ISO 14971:2019; IEC 62304; EU MDR 2017/745 Annex II

1 - DEVICE AND PROJECT

Device

CMX FlowSense infusion monitor

Design project

DP-0042 FlowSense v1.0

Class (US) and risk class (EU)

Class II - EU class IIb

Design reviews held

Columns: Phase, Date, Independent reviewer present (yes/no)

Design inputs, 2026-01-20, yes
Design outputs, 2026-05-12, yes
Verification complete, 2026-09-02, yes

RESULT

1 critical gap in the design history file

4 user needs, 6 design inputs; 3 needs validated; 3 design reviews.

USER NEEDS	INPUTS TRACED	VALIDATED
4	5/6	3/4
REVIEWS		
3		

TRACEABILITY MATRIX

USER NEED	INPUT	REQUIREMENT	OUTPUT	VERIFICATION	RISK
		Occlusion alarm within	Firmware		

2 Enter the trace

One row per design input, with the user need it comes from, its output, verification and any hazard ID.

3 Read the result

The headline gives the outcome, for example "1 critical gap in the design history file".

TRACEABILITY MATRIX					
USER NEED	INPUT	REQUIREMENT	OUTPUT	VERIFICATION	RISK
UN-1	DI-1	Occlusion alarm within 30 s of full occlusion at 1 mL/h	Firmware module ALM v1.2	VER-11 pass	HZ-03
UN-1	DI-2	Alarm sound level 65–80 dB(A) at 1 m (IEC 60601-1-8)	Speaker assembly PCB-200	VER-12 pass	HZ-03
UN-2	DI-3	Flow accuracy $\pm 5\%$ from 0.1 to 999 mL/h	Sensor SNS-10 and algorithm FLW v2.0	VER-14 pass	HZ-01
UN-3	DI-4	HL7 export to the EHR within 60 s	Interface module EHR v1.0	VER-20 pass	–
UN-3	DI-5	Encrypted and authenticated network connection	TLS 1.3 stack and device certificates	VER-21 open	HZ-07
UN-4	DI-6	Fits tubing 3.0–4.5 mm OD	Clamp drawing DWG-310	VER-30 pass	–

Traceability matrix.

4

Resolve alerts and download

Failed verification or validation, an unverified risk control and no design reviews are critical. Open items and missing outputs 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.

1 critical

1 to fix

1 recommended

DATA AND INPUTS (3)

DI-5 is not verified and implements risk control HZ-07.

Verify the risk control is implemented and effective before release.

critical · Verification · ISO 14971:2019 7.2

Ignore

UN-3 is not validated.

Validate on production-equivalent units under actual or simulated use (including usability, IEC 62366-1).

major · Validation · ISO 13485:2016 7.3.7

Ignore

Design transfer is not complete.

Complete and record the transfer of the design to production before release.

recommended · Design transfer · ISO 13485:2016 7.3.8

Ignore

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.

DHF Design history file summary and traceability matrix

CMX FlowSense infusion monitor · CMX FlowSense infusion monitor · DP-0042 FlowSense v1.0

Device	CMX FlowSense infusion monitor
Design project	DP-0042 FlowSense v1.0
Classification	Class II · EU class IIb
Device master record	DMR-0042 rev A

Summary

The design history file for the CMX FlowSense infusion monitor (DP-0042 FlowSense v1.0, Class II · EU class IIb) records 4 user needs translated into 6 design inputs.

5 of 6 design inputs have a design output and a passing verification. Verification is open for DI-5.

3 of 4 user needs are validated. Validation is open for UN-3.

Design reviews: design inputs (2026-01-20); design outputs (2026-05-12); verification complete (2026-09-02). Design transfer is not yet complete; released outputs are in DMR-0042 rev A.

Traceability matrix

User need	Design input	Requirement	Design output	Verification	Risk control
UN-1	DI-1	Occlusion alarm within 30 s of full occlusion at 1 mL/h	Firmware module ALM v1.2	VER-11 Pass	HZ-03
UN-1	DI-2	Alarm sound level 65-80 dB(A) at 1 m (IEC 60601-1-8)	Speaker assembly PCB-200	VER-12 Pass	HZ-03
UN-2	DI-3	Flow accuracy ±5% from 0.1 to 999 mL/h	Sensor SNS-10 and algorithm FLW v2.0	VER-14 Pass	HZ-01
UN-3	DI-4	HL7 export to the EHR within 60 s	Interface module EHR v1.0	VER-20 Pass	–

Fix or justify the 2 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 · Device and project

FIELD	WHAT TO ENTER
Device	Type it in.
Design project	Type it in.
Class (US) and risk class (EU)	Type it in.
Design reviews held	A table. Columns: Phase Date Independent reviewer present (yes/no). Paste rows from Excel, type comma-separated rows, or press <button>Load file</button> (Excel, CSV, Word, PDF or a scan).
Design transfer to production complete	Tick the box if it applies.

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FIELD	WHAT TO ENTER
Device master record (medical device file) reference	Type it in.

2 · Traceability

One row per design input. Result: pass or fail. Risk ID links the input to a hazard in the risk management file.

FIELD	WHAT TO ENTER
User needs	A table. Columns: User need ID User need Validation ID Validation result. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Design inputs	Write Pass or Fail in the result, or leave it empty while verification is open. A table. Columns: Input ID User need ID Requirement Design output Verification ID Verification result Risk ID. 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:

- Every need traced to inputs, outputs, verification and validation.
- Risk controls verified.
- Design reviews, transfer and DMR.

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: Design history 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.
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
DHF	Design history file summary and traceability matrix

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: 21 CFR 820 (QMSR, incorporating ISO 13485:2016). EU: ISO 13485:2016 and EU MDR Annex II.

8. Working with other modules

- Hazard IDs come from the Risk Management Report; the summary supports the Device Submission (510(k), De Novo, PMA).

9. Common pitfalls

- Validating on prototypes instead of production-equivalent units.
- Risk controls left unverified at release.

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. **Close the cybersecurity verification**

Enter Pass for VER-21.

EXPECTED RESULT

No critical gap remains.

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.