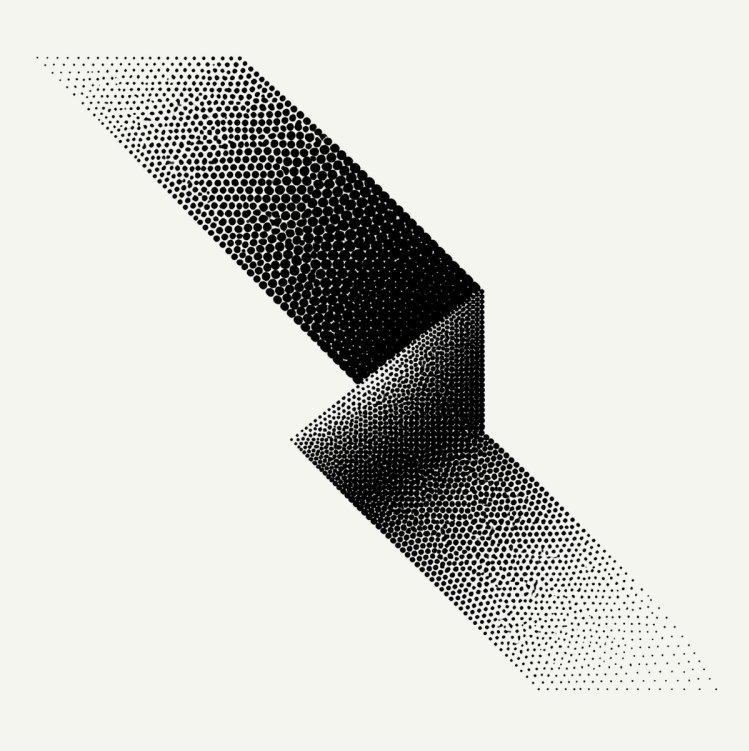




GUIDE 03

DESIGN DOCUMENTATION

Understanding waterfall design

Design controls from user needs to a finished device, the records they leave, and what to look for when you review them.

AD

ABOUT

Every medical device starts as a set of needs. Design controls turn those needs into a device, and leave a record that shows how it was done.

This guide explains the waterfall model of design controls, the records it produces, and how to trace a requirement from a user need to the test that proved it. It closes with what to look for when a design record is reviewed in litigation or in an audit.

FOR

Legal counsel who review design records in discovery.
Manufacturers — engineering and quality teams preparing for an audit.
Hospitals — clinical engineering teams who evaluate design evidence.

CONTENTS	01	Why the design record matters	03
	02	From user needs to a finished device	05
	03	Three records, three questions	07
	04	Traceability	08
	05	What to look for in litigation or audits	09
		Checklist and sources	10
		How Alpha Devices helps	11

This guide is general technical information. It is not legal or regulatory advice. Confirm which version of the regulation and which standard editions apply to the device and the dates in question.

01

Why the design record matters

FDA requires manufacturers of Class II and Class III devices, and of some Class I devices, to control their design process. The idea is simple: plan the design, define what the device must do, show that the design does it, and show that the finished device meets the needs of its users.

The result is a design record that can be read years later. In an investigation, it is often the best evidence of what the manufacturer intended, what it tested, and what it knew.

QMSR

On February 2, 2026, FDA's Quality Management System Regulation (QMSR) took effect in 21 CFR Part 820. It incorporates ISO 13485:2016 by reference. The design and development requirements are now mainly in clause 7.3 of that standard.

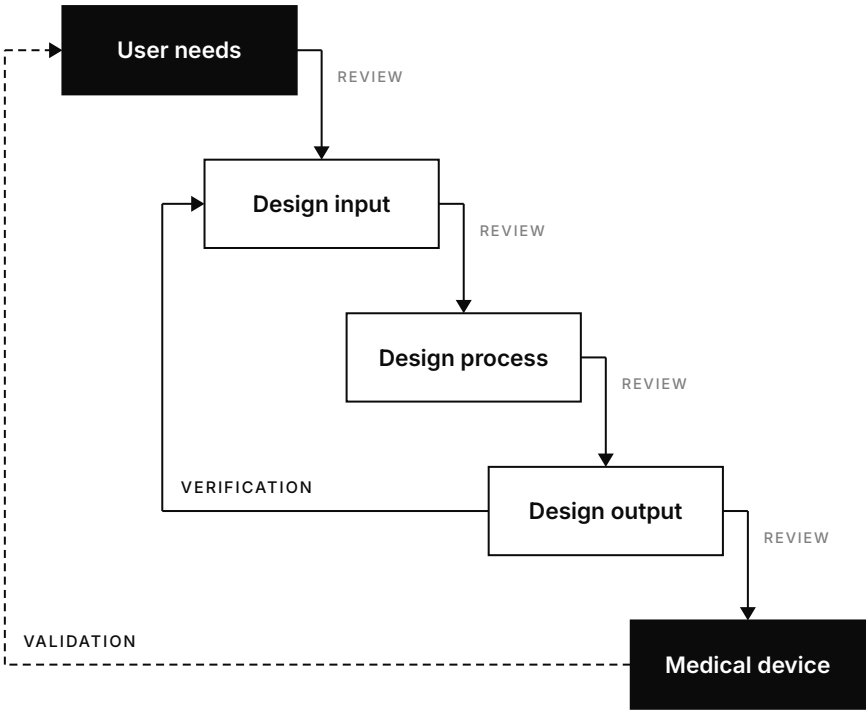
EARLIER

Design work done before that date was subject to the former Quality System Regulation, including its design control section, 21 CFR 820.30. Read each record against the requirements that applied when it was made.

NOTE

The waterfall is a teaching model, not a required process. FDA's 1997 design control guidance uses it to show how the elements relate. Real projects iterate; the record should still show each element.

FIGURE **The waterfall model**



VERIFICATION Did we build the device right? The design output meets the design input. Solid line.

VALIDATION Did we build the right device? The finished device meets the user needs and intended uses. Dashed line.

REVIEW Formal, documented reviews at planned stages of the design.

FIG 01 Application of design controls to the waterfall design process, after FDA's Design Control Guidance for Medical Device Manufacturers (1997).

02

From user needs to a finished device

01

User needs

What the device must do for the people who use it, in their words and in their environment: the intended use, the users, the use environment, and the clinical need.

02

Design input

The physical and performance requirements of the device, written so that each one can be verified. Inputs include requirements from standards, regulations, and the risk analysis. The process must resolve incomplete, ambiguous, or conflicting requirements.

03

Design output

The drawings, specifications, software, labeling, and acceptance criteria that define the device. Outputs essential for the proper function of the device are identified, and each output can be checked against an input.

04

Design review

Formal, documented reviews at planned stages. Under the former rule, each review included at least one person without direct responsibility for the stage under review.

05

Verification

Objective evidence that the design output meets the design input: tests, inspections, and analyses, each traced to the requirement it covers.

06

Validation

Objective evidence that the device meets user needs and intended uses. Validation is done on initial production units, lots, or their equivalents, under actual or simulated use conditions, and includes software validation and risk analysis where appropriate.

07

Transfer and change

The design is transferred into production specifications. Later changes are identified, documented, verified or validated as appropriate, reviewed, and approved before they are put into effect.

NOTE

Software and usability have their own life-cycle standards, IEC 62304 and IEC 62366-1, which FDA recognizes as consensus standards. Their plans, requirements, and test records belong in the same design file.

03

Three records, three questions

Three records describe a device from design to delivery. Each answers a different question, and an investigation often needs all three.

RECORD	QUESTION	TYPICAL CONTENTS
DHF Design history file	How was the device designed?	Plans, inputs, outputs, reviews, verification, validation, risk file, design changes
DMR Device master record	How is the device made?	Specifications, drawings, production and test procedures, labeling, acceptance criteria
DHR Device history record	How was this unit or lot made?	Dates, quantities, acceptance records, labels, and the device identifier for each unit or lot

QMSR The QMSR does not keep the DHF, DMR, and DHR as defined terms. ISO 13485 requires equivalent content: the design and development file (clause 7.3.10), the medical device file (4.2.3), and a record for each device or batch (7.5.1).

IN PRACTICE Many companies still use the familiar names, and records made before February 2026 carry them. Ask for the content, whatever the record is called.

04

Traceability

Traceability links each user need to the design inputs that address it, each input to the outputs that implement it, and each output to the verification and validation that proved it.

Risk controls belong in the same chain. Under ISO 14971, each risk control becomes a requirement, and its implementation and effectiveness must be verified. A trace matrix makes the chain visible:

NEED	INPUT	OUTPUT	TEST
UN-04	DI-17	DO-32	VER-09
Alert the user when flow stops	Occlusion alarm within a defined time	Pressure-sensing firmware module	Bench occlusion test report

Example structure only; identifiers are illustrative.

KEY POINT

Verification asks: did we build the device right?
Validation asks: did we build the right device?

05 What to look for in litigation or audits

- 01 **Inputs that cannot be verified**
Words such as “robust” or “user-friendly” with no measurable criterion.
- 02 **Gaps in the trace**
Needs or risk controls with no test, or tests with no requirement.
- 03 **Verification that does not match**
Test conditions, samples, or software versions that differ from the released design.
- 04 **Validation on the wrong units**
Prototypes instead of production-equivalent units, or use conditions that leave out the real environment.
- 05 **Changes without re-verification**
Design changes after release with no record of impact assessment, testing, or approval.
- 06 **Field data not fed back**
Complaints and reports that describe a failure mode the risk file does not address.
- 07 **Records that do not fit the timeline**
Dates, signatures, and versions that do not agree with each other.

CHECKLIST

Records to request

- ☐ Design and development plans
- ☐ User needs and design input requirements
- ☐ Design outputs: specifications, drawings, software, labeling
- ☐ Design review records, with attendees
- ☐ Verification protocols and reports
- ☐ Validation protocols and reports, incl. software and usability
- ☐ Risk management file and trace matrix
- ☐ Design change and design transfer records
- ☐ DMR or medical device file; DHR for the unit or lot
- ☐ Complaint, CAPA, and MDR files for the failure mode

SOURCES

eCFR — 21 CFR Part 820, Quality Management System Regulation

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820>

FDA — Design Control Guidance for Medical Device Manufacturers (1997)

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-control-guidance-medical-device-manufacturers>

ISO 13485:2016 — Medical devices, quality management systems

<https://www.iso.org/standard/59752.html>

ISO 14971:2019 — Application of risk management to medical devices

<https://www.iso.org/standard/72704.html>



SERVICES

Design records, read against the evidence

We review the QMS, design history, risk file, and traceability matrix against how the device actually performed.

01

Design record review

The DHF, risk file, and trace matrix checked against the regulation and standards that applied.

02

Gap analysis

Where requirements, tests, and field data do not connect, and why it matters.

03

Independent testing

Tests that answer the questions the design record leaves open.

CONTACT

Tell us about the device.

Send the device name, the records you have, and the question you need answered. We will tell you what the design record can show and recommend the next steps.

EMAIL info@alphadevices.io

WEB alphadevices.io

GUIDES

- 01 A device failed. What happens next?
- 02 Searching MAUDE with purpose
- 03 Understanding waterfall design

Alpha Devices

2101 Brandywine Street, Suite 200
Philadelphia, PA 19130

Independent medical device engineering. © 2026 Alpha Devices.