

# Design History File Summary

Use this template to dHF summary for [device\_name] and design control evidence.

## Template Metadata

Field	Details
Category	Medical Devices
Owner	[Team or owner]
Version	[Version number]
Effective Date	[Date]
Review Cycle	[Monthly / Quarterly / Annual / Event-based]
Status	[Draft / In Review / Approved]

## Device Overview

Identify device name, model, intended use, classification, markets, and design project scope.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Design Inputs

Summarize user needs, regulatory requirements, standards, safety requirements, and performance requirements.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

### Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Design Outputs

List drawings, specifications, software items, labeling, manufacturing instructions, and packaging outputs.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

### Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Verification

Summarize verification activities proving design outputs meet design inputs.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Validation

Summarize clinical, usability, simulated-use, or production-equivalent validation evidence.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Design Reviews

Record major review milestones, participants, decisions, and open items.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Traceability

Explain how inputs, risks, outputs, verification, and validation are linked. Use tables and keep claims traceable to controlled records.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]