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Mastering the Design History File for HF: What to Include, Why It Matters and How To Avoid Mistakes

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Introducing Gen UX Consulting

Where Research Meets Design. Seamlessly.

We design with care and research with purpose. Our team guides startups and established companies through the complex intersection of research, design, and regulatory – from concept to market. We specialize in Human Factors, UX research, and strategic design support to ensure your products are intuitive, compliant, and market-ready.

Staci Miller

Founder & Director of HF/UX

With a decade of expertise bridging MedTech & Big Tech, she demonstrated a history of consistently delivering technology innovations that enrich lives. She has achieved success in launching both B2B & B2C products, including medical devices, cementing her reputation as a dynamic force in the industry.

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Understand the Key Components of a DHF Correlating to Human Factors Best Practices

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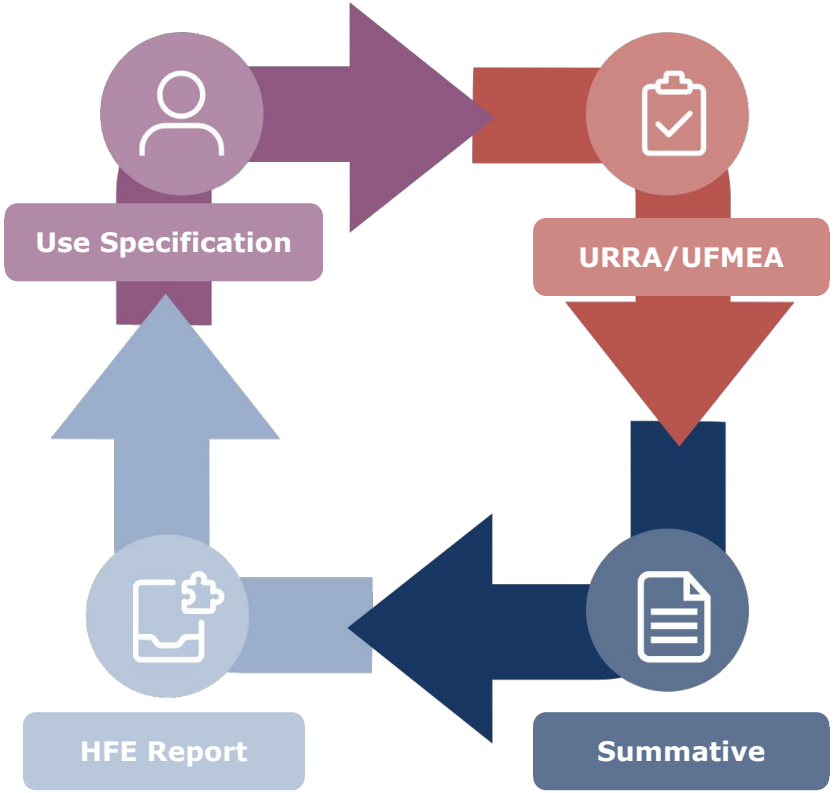
Why Design History Files (DHFs) Matter: More Than Just Compliance

In a Design History File (DHF)—especially in industries like medical devices, consumer health tech, or regulated hardware—the Human Factors (HF) documents are essential for demonstrating that the product was designed with user needs, safety, and usability in mind.

1. Use Specification
2. URRA/UFMEA with Task Analysis
3. Summative Usability Test Protocol and Report
4. Human Factors Engineering Report

Circular Nature of the DHF for HF



Lives in each Document

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Use Specification

- Intended Users
- Description of intended use environments
- Use Cases
- Intended Use
  - Indications for Use
  - Principle of Operation
- User interface Description

URRA/UFMEA

- Task, Sub Task, User, Use Error, Hazard Related Use Scenario, Critical task, Hazardous Situation, Harm, Severity, Probability and Risk Level, Mitigations
- Traceability
  - Risk ID & HZ log

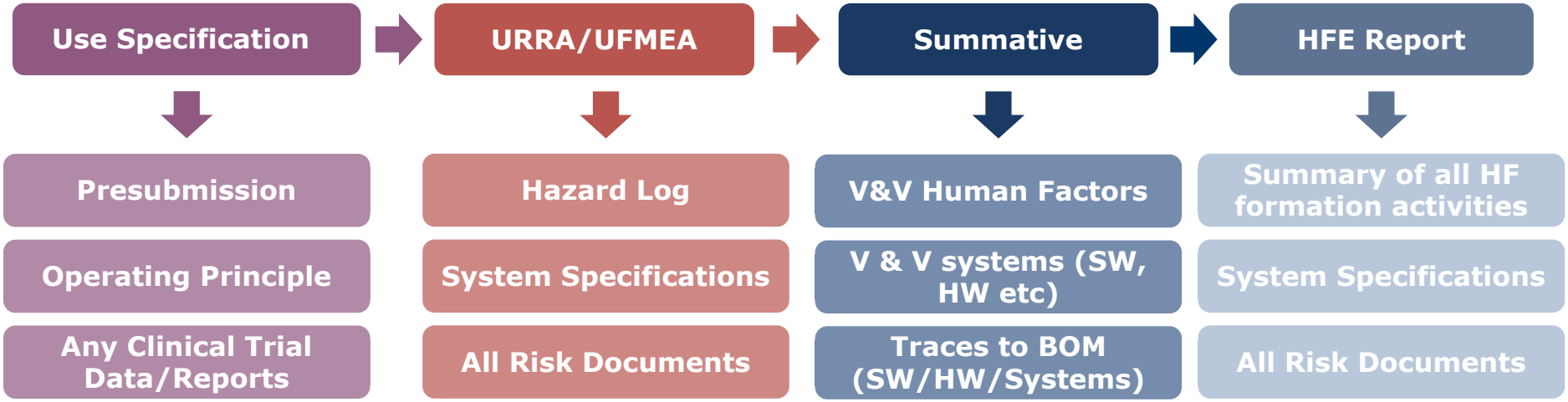
Summative

- Screens,Hardware, labeling, and packaging
- Instructions for use (IFU)
- Maude Review known use related problems
- Protocol
- Mod Guide

HFE Report

- Summarizes all HF activities involved in developing the product
- Includes summary of formative evaluations
- Any review of the interface (physical, digital and the outcomes of the discovery)

Relationship\ Traces Within the DHF



Supporting Docs: Formative & Contextual Work

Not required in the DHF, but often included in the **HF Engineering Report**:

- Formative protocols & results
- Contextual inquiries or Interface reviews (screens, IFU, partial system evaluations)

- Their Purpose:
  - Conducted during **product development**
  - Intended to **burn down risk**
  - Provide rationale for design choices and prioritization of features
    - These aren’t for validation

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Recognize Common Failures in Documentation

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Recognize Common Failures in Documentation

Common failures in human factors documentation often begin with incomplete user analysis—where teams rely on assumptions or internal perspectives instead of engaging real users early and often. This results in an unclear picture of who the users are, how they interact with the product, and what risks they face in real-world contexts. That gap then carries through to vague user needs and specs, which weaken the foundation for design decisions. Ultimately, validation studies built on this shaky input lack clear success criteria and often fail to test what matters most. The second most prevalent error in the DHF is not referencing a single source of truth from supporting documents when needed.

Common Failures in Use Specs & Needs

In design history files I've audited, user needs and use specifications are often undocumented, fragmented, or vague, leading to inconsistent use cases. This lack of clarity causes downstream issues: undefined user groups, misaligned test populations, inconsistent use cases, and system-level documentation gaps. Without a clear definition of the system or users, the foundation for usability and validation becomes unstable.

Key Red Flags:

- User needs/specs not documented or traceable
- User groups undefined or misidentified
- Use cases are inconsistent or missing
- System definition unclear—no scope for validation

Common Failures in URRA/UFMEA & Task Analysis

A common failure in documentation reviews is the absence of a comprehensive use-related risk analysis (URRA).

Teams often define tasks too narrowly—focusing on step-by-step actions instead of broader user goals. This limits the team's ability to identify plausible but non-obvious risks, and weakens the connection between hazards, potential harms, and actual use scenarios.

Over reliance on tools like DFMEA, without integrating human factors, results in risk analyses that feel disconnected from actual use.

This misalignment extends into validation, where studies may overlook key risks, lack clear success criteria, or fail to trace back to the URRA—ultimately undermining usability validation credibility.

Common Failures in URRA/UFMEA & Task Analysis

Key Red Flags:

- Too task heavy
- Not based on a happy path
- Ignores plausible outlier risks
  - Does not consider errors can lead to multiple risks not just the most critical
- DFMEA-only approach omits human factors context
- Validation not linked back to actual task-based risks

Common Failures in Validation/Summative Study

Validation studies often expose deeper issues overlooked in risk analysis and user needs. I frequently encounter incomplete datasets, especially missing key demographics needed to justify representative users. Many studies lack clear links to user needs or risks, making their purpose unclear. In some 510(k) submissions, validation is missing altogether, forcing reliance on clinical trial data instead of simulated use — undermining human factors goals and increasing regulatory risk.

Key Red Flags:

- Missing demographics in validation data
- No link to user needs or specs
- Incomplete or missing studies
- Used clinical data instead of simulated use

The Biggest DHF Mistake

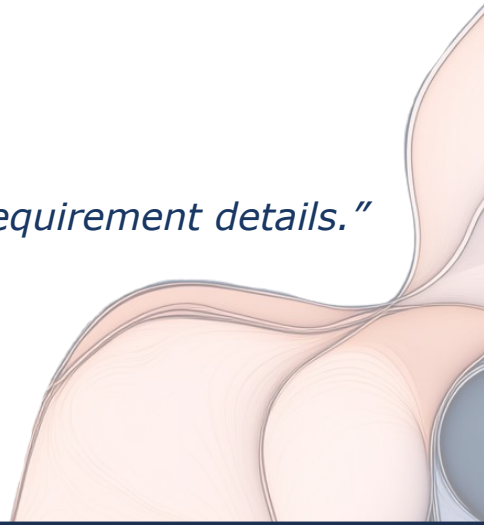
Single Source of Truth: Why It Matters in Your DHF

When referencing hazard logs, system specs, or cross-functional requirements:

- Do not copy-paste into HF documents.
- Instead, **cite the original source directly**:
  - Document name
  - Document number
  - Revision/version

Example: *"Refer to System Specification Document SS-204, Rev B for requirement details."*

- The purpose:
  - Maintains a single source of truth
  - Avoids conflicting versions
  - Stronger traceability and audit-readiness



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Preparing for Growth and/or Acquisition

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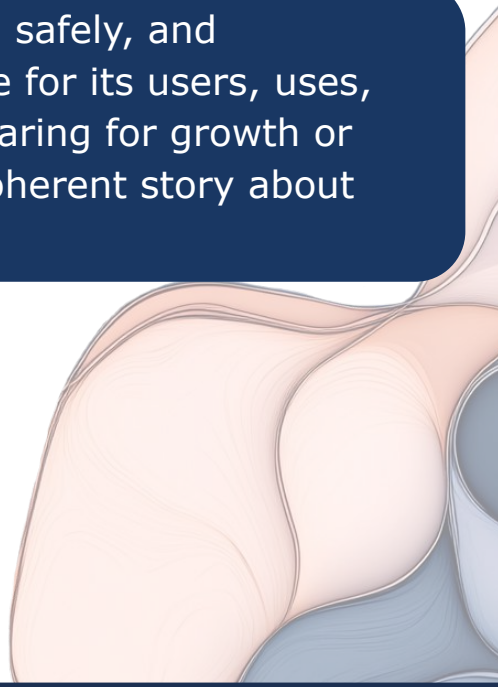
DHF Readiness for Scale, Sale, or Submission

Every section is evidence that your product was designed thoughtfully, safely, and systematically. Your always supporting the claim that the device is safe for its users, uses, and use conditions. Whether a startup or established business is preparing for growth or acquisition, it's critical that the DHF is holistic, traceable, and tells a coherent story about the product.

- A strong DHF weaves together:
  - Requirements
  - Standards, Risk ID & Risk mitigation
  - User needs & usability evidence

- Your DHF must be:
  - Holistic
  - Defensible
  - Prepared for external audit or internal handoff



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