HFE In-Practice: Bridging Cross-Functional Collaboration for Greater Success

GODDARD PRODUCT DEVELOPMENT

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What HFE hats do you wear? SCAN ME

The High Cost of Misalignment

In medical device development, misalignment between Human Factors, Product, Engineering, and Risk Management teams creates expensive redesigns and regulatory risk. When communication fails or design change criteria are ambiguous, time-to-market suffers due to rework.

A Dual Approach

An adaptive communication style and a tactical assessment tool can foster earlier cross-functional alignment, reduce submission risk, and accelerate the delivery of safe and effective products.

- **Human Factors Assessment**: A structured documentation tool (aligned with IEC 62366 & FDA Guidance) that uses decision logic to determine if design changes require HF Validation or if there is existing evidence to justify no additional HF Validation.
- **Three Hats Framework:** A model for HFEs to adapt their communication style (i.e., Explorer, Architect, Investigator) to match the product lifecycle phase to maximize influence.

Human Factors Assessment: Goddard's Tool

Challenge

Managing human factors across parallel projects, CAPAs, and design changes requires consistency. Changing project timelines and resources often leads to discontinuous oversight, making it difficult to maintain a cohesive safety narrative.

Solution

Serving as a tactical bridge between design evolution and regulatory evidence, the HF assessment:

- Gathers information on UI modifications and their impact on use, use errors, and usability.
- Streamlines the HF assessment of design changes across multiple projects.
- Enables direct collaboration with Risk Management to maintain traceability.
- Documents the systematic logic behind HFE decisions to ensure all conclusions are supported by objective evidence without any gaps.

Impact

The HF Assessment provides a structured framework and tool for evaluating design changes that:

- Provides visible rationale for HF involvement, fostering trust between cross-functional teams.
- Uses objective data to determine whether changes require new validation or simple justification.
- Streamlines regulatory review with standardized, defensible HFE due diligence records.

Three Hats Framework

	Phase 1: Concept & Definition Define the Right Product	Phase 2: Design & Development Build the Product Right	Phase 3: Validation & Regulatory Prove Product Safety and Efficacy
HFE Hats	**The Explorer** **Empathic Strategist** *"How might we...?"*	**The Architect** **Logical Translator** *"The system shall..."*	**The Investigator** **Objective Advocate** *"The evidence shows..."*
Traits *Thinking Focus*	**Divergent** / Translational / Convergent **User Needs** / Requirements / Safety	Divergent / **Translational** / Convergent User Needs / **Requirements** / Safety	Divergent / Translational / **Convergent** User Needs / Requirements / **Safety**
Primary Allies *Motivation*	**The Visionary (Marketing)** *Market differentiation & adoption*	**The Builder (Engineering)** *Feasibility, specifications, logic*	**The Protector (Regulatory)** *Compliance, traceability, evidence*
Alignment Strategies	Translate Observations → Opportunities • Present issues as "Barriers to Adoption". • Storytelling (qualitative and visual narratives) — more persuasive alongside data.	Translate Feelings → Concrete Concepts • Objective language: binary logic ("If/Then") and constraints ("Must/Shall"). • Specify measurable parameters (force, size).	Translate Performance → Defensibility • Root cause analyses, traceability matrices. • Prioritize evidence over opinions on risk mitigation.
HF Assessment	Identify safety gaps by reviewing legacy tasks and use errors, feeding findings into early design requirements.	Evaluates design modifications via a decision matrix to objectively determine if changes impact critical tasks.	Provides formal, documented rationale used by Regulatory teams to justify the final validation scope.