The dilemma of task prompt wording in HF validation:

HISTORY, CHALLENGES, AND STRATEGIES FOR SUCCESS

INTRODUCTION

Designing effective task prompts for usability testing is a critical yet challenging aspect of medical device evaluation.

Regulatory guidance and industry best practices emphasize the importance of prompts that reflect real-world scenarios without leading participants toward specific actions. However, **the balance between avoiding leading language and maintaining clarity can be difficult to achieve.**

This presentation will explore the history, challenges, and best practices for task prompt phrasing, highlighting the implications for medical device safety and usability.

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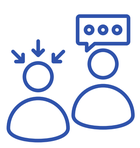
HISTORY



The FDA has identified **overly leading task prompts as a recurring issue with manufactures.**

Manufacturers either:

1. Go straight into validation, don't discuss this with FDA ahead of time, and get comments in the submission period.
   or
2. They follow FDA strict guidance and end up with overly vague task prompts.

CHALLENGES

Overly leading task wording results in an unrealistic task for participants in which they are directed to a specific feature or function to address the simulated scenario.

Using exact FDA language may be overly vague.

Overly vague task wording results in participants being tested on **medical knowledge**,

rather than on

specific **features or functions of the device.**

STRATEGIES FOR SUCCESS

1 Determine the sweet spot to ensure adequate real-life context & applicability to the device

Clearly articulate the scenario that the participant is walking into with enough granularity or detail to ensure that a specific feature or function is required to address it and/or is being evaluated. Example: "I'd like you to imagine that..."

2 Negotiate & collaborate with regulatory authorities

- **2a:** **Propose** language with rationale for specific task prompt phrasing.
- **2b:** **Negotiate** final task prompt phrasing to address regulatory concerns.
- **2c:** **Set expectations** for results regarding artifacts and/or other suboptimal outcomes.

3 Detailed HFE report

- **3a:** Include a detailed discussion of the development of task prompt wording.
- **3b:** Analyze and discuss the extent to which the study results match the expectations from 2c.

Note: These strategies do not account for internal FDA initiatives in respect to consistency among similar products. (First to file sets precedent. Then, the FDA mandates it for all others in that space.)

	Too leading	Too Vague	Balanced
Case Study 1: Rescue Autoinjector	"Demonstrate how to administer the medication using the autoinjector." **(Assumes the correct action.)**	"You encounter someone having an allergic reaction. Show what you would do." **(Scenario not tied to device.)**	"Imagine your friend is having a severe allergic reaction and needs your help to take their medicine. Please proceed as you would in real life to help them." **(Provides context without being overly directive, allows natural decision-making.)**
Case Study 2: Insulin Pump	"Imagine you need to suspend insulin delivery for 2 hours. Please show how you would do that." **(Lacks real-world context, overly directive.)**	"Imagine you will have increased physical activity for the next two hours. Please show what you would do in this situation." **(Not tied to the device, could lead to unrelated responses.)**	"Imagine you are going to a 2-hour exercise class. Please show on this pump how you would account for your increased activity level." **(Provides relevant context while focusing on device interaction.)**
Case Study 3: Electronic Health Record (EHR) System	"Demonstrate how to review and update a patient's medication list in the EHR system." **(Too task-specific, assumes correct action.)**	"A patient has been admitted. Show what you would do in the EHR." **(Lacks real-world context, overly broad.)**	"A patient has been admitted from another facility. Upon reviewing the chart, you notice potential discrepancies in their medications. Show how you would proceed in the EHR system." **(Scenario-driven, supports usability focus.)**

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