

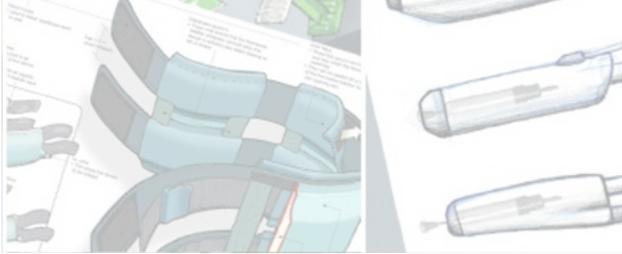
## USABILITY ENGINEERING FRAMEWORK FOR MEDICAL DEVICES

The intent of this Framework is to aid in informing the Usability Engineering component of your medical device development process. Use the questions within to assess how well you have considered the usability needs for your Medical Device.

### USABILITY ENGINEERING

*Usability Engineering has always been an integral component of design, but the dynamic around the topic has changed significantly as a result of the implementation in 2007 of IEC 62366. This standard for the Application of usability engineering to medical devices has changed the landscape from recommending user needs be considered, to requiring the implementation and role of usability engineering throughout the design process.*

*Though usability engineering is often considered to be highly intuitive, it is a component of design that is not well perfected; Use errors are the cause of a large proportion of medical device failures. Here is a Framework to keep in mind when addressing usability during conceptualization, detailed design, and user validation.*



## Conceptualization

During the conceptualization phase, it is vital to engage in thorough client interactions which help you build a picture of how a device will be used and identify potential upcoming design challenges.

Review customer requirements

Observe use environments and evaluate user workflows

Perform detailed interviews with key stakeholders/users

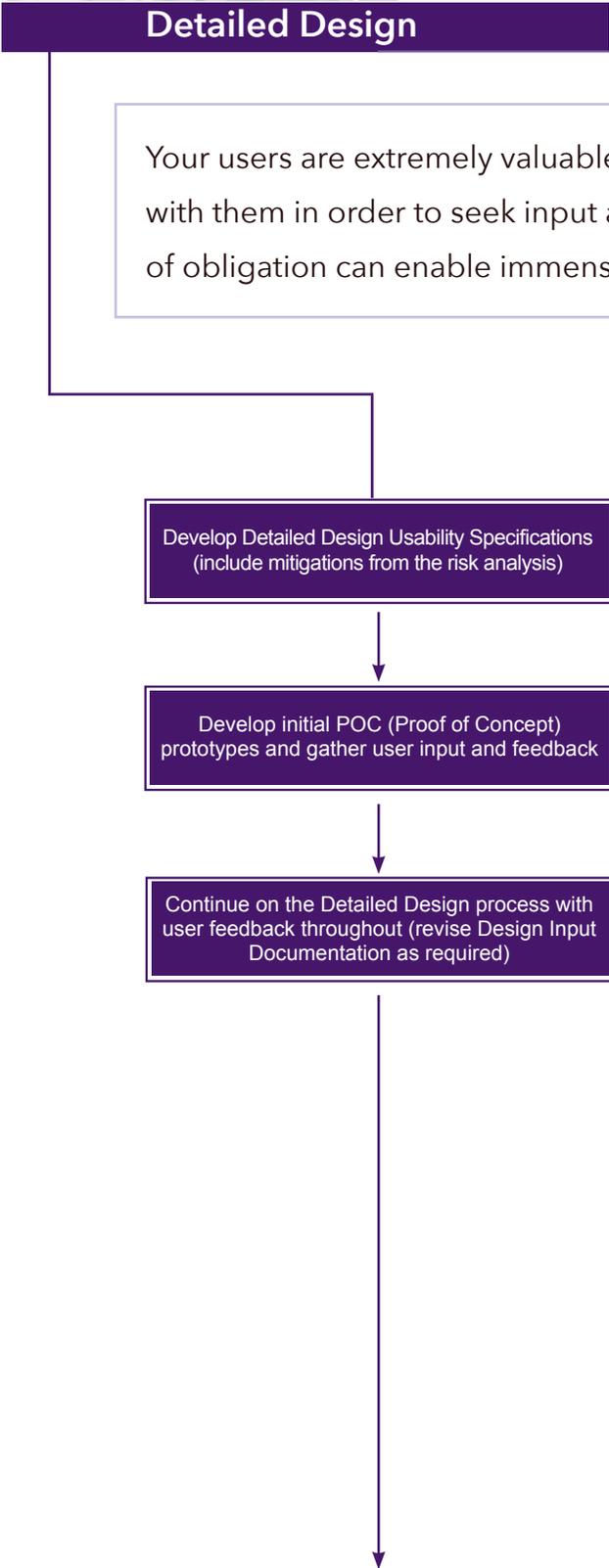
Develop Usability Product Requirements

Identify known or foreseeable hazards

Perform detailed risk analysis with clinical expert(s) and identify foreseeable misuses

### *Important items to consider are:*

- What is the intended use of the device?
- What are the characteristics of a typical user? Do they have any limitations or particular training requirements? What kind of user demographic are you working with (age, height, gender, etc.)?
- What does the intended use environment look like? Keep in mind that home-use and hospital-use pose very different challenges.
- How would existing user workflows be affected by this device?
- What risks can you think of in using the device? Are there any foreseeable off-label uses?



## Detailed Design

The diagram is a vertical flowchart with three main rectangular boxes connected by downward-pointing arrows. The top box is titled 'Detailed Design' and contains a quote about user engagement. The middle box is 'Develop Detailed Design Usability Specifications (include mitigations from the risk analysis)'. The bottom box is 'Develop initial POC (Proof of Concept) prototypes and gather user input and feedback'. A final box at the bottom is 'Continue on the Detailed Design process with user feedback throughout (revise Design Input Documentation as required)'. A long arrow points downwards from the bottom box.

Your users are extremely valuable resources in this time, and engaging with them in order to seek input and value-add rather than engaging out of obligation can enable immense success!

Develop Detailed Design Usability Specifications  
(include mitigations from the risk analysis)

Develop initial POC (Proof of Concept)  
prototypes and gather user input and feedback

Continue on the Detailed Design process with  
user feedback throughout (revise Design Input  
Documentation as required)

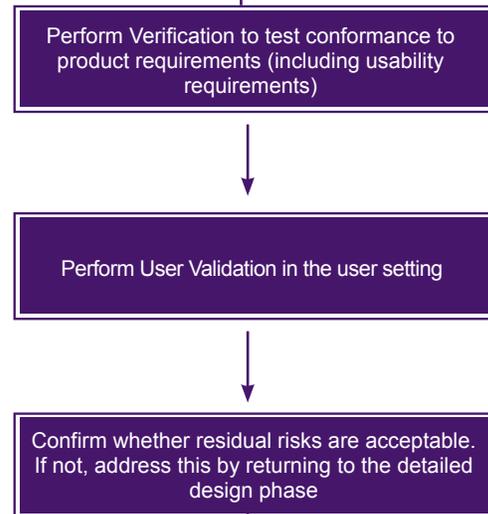
### *Important items to consider are:*

- Does all of your Design History File documentation include usability considerations?
- Have you designed according to the requirements and specifications that pertain to usability?
- Have you tested out your prototypes with all of your potential users?
- Have you tested your prototypes in your use environment to identify potential interferences?
- Are there any risks that haven't been addressed and how will you either minimize or justify them?



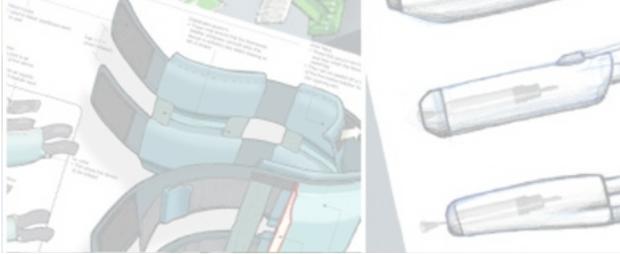
## Usability Testing (Validation)

The final user engagement opportunity is during validation, and is a crucial opportunity to identify any device flaws or failures that were not captured during verification testing in the detailed design phase. Testing should be done in environments that most closely represent end use conditions.



### *Important items to consider are:*

- Have you developed a comprehensive plan to validate the device design with users?
- In the case of home-use: is the device intuitive enough that without having read the user manual the user would not cause any harm to themselves or others?
- Did user testing uncover any new risks that weren't identified in the risk analysis?
- Have the worst case scenarios been tested?



## Next Steps

*This Usability Engineering Framework provides you with starting points. However, comprehensive review of IEC 62366 and (and IEC 60601-1-6 as applicable) as well as performing a comprehensive usability analysis are crucial to the success of a Medical Device. **Request our free one hour consultation** for expert insights and feedback on your medical device.*



**Learn How Clinical Input  
Can Improve Your Medical  
Device Success  
in 5 Minutes**

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