How To Create a Class II SaMD Regulatory Strategy

A winning regulatory strategy for SaMD has five fundamental elements which reflect the key components of your future submission:

1. **The Right Regulation and Predicate**
2. **Risk Management**
3. **Software & Cybersecurity**
4. **Human Factors & Usability**
5. **Clinical Validation**

In this “How To” guide, I have listed a series of questions I would typically ask a client when creating a regulatory strategy with them along with notes throughout to help guide you in the right direction. Here is **STEP 4: Human Factors & Usability**. Happy strategy formulating!

STEP 4: HUMAN FACTORS & USABILITY

Note: Usability engineering is often tackled as just another regulatory requirement and human factors testing is seen as a regulatory checkbox. If we reframe usability engineering and human factors testing to be a development tool that helps you use data to inform the design of your product, then you can more confidently know that you’ve built a product that your customers will pay for and can use with ease and safely. The first part of usability engineering is getting to know your target user base.

- Who are your intended end users (e.g., lay user, physician)? Do you have backend users we need to consider too (e.g., hospital IT and security teams that install your system)?
    - How would you characterize the demographics of your target user groups?
    - What skill level or educational background(s) do your user groups have?
    - What other products would be your target user groups interface with that might influence how they use your device? For example, do you intend your device to modify existing clinical workflows they are using, or introduce new clinical workflows?
    - What would motivate your target users to want to use your device?

- Where is your device used and how can that influence how the user will interact with the device?
- When or how often is your device used?
- Have you been talking to potential users about the device you are building to see what features and functions they would want? *Note: This is a key step in drafting your User Needs[1].*

Note: Setting up a formal process to orchestrate usability engineering and conduct human factors testing to demonstrate compliance with the internationally recognized standard IEC 62366 is an SOP I highly recommend companies include in their QMS, even if they outsource UI/UX (User Interface/User Experience) development and UX testing. This gives your team more hands-on ownership of what your contractors should do and dictates a data driven design process, and it may even alleviate upfront work to qualify vendors. As I strategize a usability engineering process with clients, I tend to ask them these questions:

- Do your Risk Management SOP require a use-related risk assessment (often done as a uFMEA)? *Note: It is important to define the relationship between Risk Management and Usability Engineering in your QMS.*
- Where do you look to find information about competitor products or other products like yours that cause users to complain about the product or use the product incorrectly, and how often do you want to do it? *Note: This is where your "Known Use Problems Report" mentioned back in Part 1 comes in. You want to use all publicly available information about competitor products to make sure you design any applicable use-related risks out of your device.*
- Who is designing your UI/UX? How do they use user feedback to inform design? *Note: A highly accurate algorithm will flop in the market if it does not have a well thought out and well tested UI/UX. Whether you outsource UI/UX or design it in-house, I highly recommend that companies invest the time and money in people who will obsess about the UI/UX. As we think about the UI/UX and how we want to collect data to inform design or validate the final design here are some things to think about.*
- How can we include user feedback loop into the Usability Engineering SOP? While not being overly prescriptive in the SOP, we should run preliminary studies before we hit design freeze[2].
- Who is running user testing? Are they experienced in testing devices like yours? How quickly can they recruit participants? Are they willing and able to support a remote study if that makes sense for your device?

[1] User Needs: Describe a desire from the perspective of the user that help guide the design and can be objectively validated. I like to use the User Story approach: "As a [type of user], I want the [device] to [action/function], so that [benefit to user]. This not only identifies the user's desires, but it also identifies their "why" to help you prioritize design features.

[2] Design Freeze: All major design decisions are finalized, and no further changes are allowed. The design at Design Freeze is the device you run your validation testing with.

- Does your timeline allow you to run multiple user studies before a formal validation study? *Note: By the time clients come to me they are already rushing to hit the market and don't have the time to run sufficient user testing before the big validation study which is put at risk of failing because it may be the first time your team sees real users interacting with your product and finding issues with your design. Then you are left scrambling to update your design.*
- When do you plan to run a formative study[3] and what sample size do you plan to use? Will you include all user groups in your studies?
- Can you run studies remotely or does it have to be in person based on the device design?
- Is your device sold Direct-to-Consumer (DTC) or through a physician (Rx Only)? *Note: If your product is DTC then plan for a "self-selection" study. While not stated explicitly in a medical device guidance document, FDA has established an expectation for Over-The-Counter (OTC) devices to undergo "self-selection evaluations" like the Special Controls for Electrosurgical devices used for OTC use[4]. Self-selection studies prove that lay users can correctly decide if they are eligible to use the device according to its labeling and marketing information.*

Note: Back in part 2 of this How To series, we talked about risk-based decision making and how it can help inform design. This absolutely applies to your UI/UX. It is important to systematically think through each step a user need to take to use your device and imagine everything that could go wrong – what could they miss visually? What could they misunderstand? What could they not do or do wrong?

- With each task the user completes (make sure to list all mandatory and optional tasks), what could go wrong? I like to use the PCA approach:
  - What could they not **p**erceive?
  - What could they not **c**omprehend?
  - What **a**ction could they do incorrectly?
- For each task and risk, what is the potential harm to the user?
- For each task/risk, what type of risk control measures do you plan to implement? Types of risk control measures include:
  - Safety by design – designing the risk out of the device thereby eliminating or significantly reduces its possibility of occurring.
  - Protective measures – implement features that would reduce the occurrence of harm such as an alarm.

[3] Formative Study: a smaller sample sized precursor to your validation study (sometimes referred to as a "Summative Study") have a two-fold purpose: (1) identify any must-have changes to design, and (2) identify any changes that need to be made to the validation protocol and study design (e.g., logistics, moderator script, questions asked to participants).

[4] Over-the-Counter (OTC) Medical Devices: Considerations for Device Manufacturers | FDA

    - Information for safety – providing users with warnings, instructions, and training material to identify and mitigate risks associated with using the device.

  Note: As you can imagine, no one wants to design a UI/UX that solely depends on Information for safety risk control measures. Identifying, implementing, and testing out the appropriate balance of risk control measures is the cornerstone of user testing.

- As you collect human factors data, how will you investigate the tasks completed incorrectly or where users struggled? *Note: A Root Cause Analysis (RCA) is a key step in user data analysis to help inform any design iterations. This is where we assess the potential causes of any use errors, close calls, and use difficulties and reevaluate our risk control measures to decide what needs iterations or what can be justified to stay as-is.*
- Could your users benefit from device specific training before usage? *Note: For SaMD products, this is often a tutorial like module that educates the user on the product and how to navigate it. This helps to familiarize users with your UI/UX and often decreased use error.*