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 3: SOFTWARE & CYBERSECURITY**. Happy strategy formulating!

STEP 3: SOFTWARE & CYBERSECURITY

Note: We want to understand how your team approaches software development.

- What does your software development process look like?
- How does your team incorporate security by design principles into your design and development process?
- What development tools do you use?
- Is your team actively following a process reflected in a Standard Operating Procedure (SOP) from your Quality Management System (QMS)?
  Note: Design Controls[1] can begin at different stages for different companies. The line between research and development is blurry. We want to start following design controls once we have decided to develop a product, which often happens after you've conducted research that proves you have a product that meets a market need.
- Has your team drafted a Design and Development Plan (DDP)?
  Note: DDPs are required per ISO 13485 and FDA's QMSR and are meant to be updated throughout the design lifecycle. This can be a really helpful cross-functional alignment tool rather than just a compliance artifact if you add in risk control checkpoints, define strategies for interfacing with internal and external teams, and map out development milestones.

[1] Design Controls – outlined in 21 CFR 820.30 and ISO 13485 as the set of practices and procedures that define and manage your design and development process

- *o* Does your DDP align with your business timeline?
  Note: Often business timelines are misaligned development timelines. When executive leadership understands the development timelines, especially what is feasible to accelerate and what your team cannot control (like FDA's review timeline), you will have more success setting and managing expectations.
- Has your team used machine learning techniques to develop your algorithms? If so, has your team established data governance to ensure Good Machine Learning Practices[2] are followed?
  NOTE: No matter how simple your ML techniques may be FDA will want to understand how you're following GMLP so consider mapping FDA's GMLP to your team's practices to make this easy to communicate to FDA.
- *o* How is your team using or planning to use risk-based decision making to design your device?
  Note: This is a philosophy that can help your team design software architecture that is safer, leaner, and more resilient by using risk to inform architecture decisions rather than using risk assessment solely as a post-design assessment. For example, structuring the architecture into distinct layers can isolate risk-prone components which can minimize the impact of potential failures and streamline the verification process. This will also help justify your code coverage strategy.
- Has your team conducted a Threat Model for your device?
  Note: By identifying attack paths and mapping threats to functional failures, we can prioritize what must be tested, how rigorously, and why.
- Have you developed a product roadmap for target markets, indications, features and functions, and product improvements? What is the level of commitment to each of these projects?
- Which projects are high priority for your business? Which are nice to have but not need to have?
- Do we have a strong sense of how we will design, develop and test high priority projects?
- Then we ask: To PCCP or to not PCCP?
  Note: If your team already has improvements or changes to your device in the pipeline then we can consider pursuing a Predetermined Change Control Plan (PCCP), which provides FDA with the blueprint you will follow to modify and test your device so they can grant you prior authorization to implement those changes without having to resubmit to FDA. This is certainly a path worth considering if your product roadmap is well defined. Consider submitting your draft PCCP to FDA in a pre-submission.

[2] Good Machine Learning Practice for Medical Device Development: Guiding Principles | FDA