Adding Predictability to SaMD Product Development and Launch Timelines

Getting product to market as quickly as possible means...

KNOWING ALL THE MILESTONES

Many companies fail to plan for all required milestones because they don't actually know what the are.

KNOWING WHAT YOU CANNOT CONTROL

Many companies waste time trying to cut timelines on milestones outside of their control.

KNOWING WHAT YOU CAN CONTROL

When we spend our energy and resources here we can actually accelerate timelines.

Do you have someone within your company responsible for each disciplines required to build regulated product?

Owning each deliverables and due dates internally, even if the work itself is outsourced, ensures the appropriate sense of urgency is brought to the timeline. When companies rely too heavily on their outsourced partners timelines can easily slip.

Product Design Milestones

PROJECT PHASE	MILESTONE
DISCOVERY & PLANNING	*Product & Market Research Complete*
	Product Requirements Document (PRD) Complete
	User Needs Complete (if not already included in PRD)
DATA INFORMED DESIGN ITERATIONS	*Wireframes Complete*
	Wireframe User Feedback Complete
	High-fidelity UI V.1 Draft Complete
	UI Draft User Feedback Complete
	High-fidelity UI V.2 Draft Complete
	Formative Study Complete
DESIGN VALIDATION	*High-fidelity UI V.3 Final Complete*
	Summative Study Complete
	Self-Selection Study Complete (if device is sold DTC)

AVOID THESE COMMON MISTAKES

- Did not plan for early user feedback & UI required lots of rework after testing.
- If early feedback was solicited it was not well documented.
- Did not plan for multiple formative studies putting summative study at risk of failure.
- Did not incorporate use error into early product risk management activities.

Note: This table includes major milestones. Exact milestones you may need to achieve can vary.

Software Milestones

PROJECT PHASE	MILESTONE
PROJECT PLANNING	*Draft Design and Development Plan*
	Conduct Preliminary Hazard Analysis & Threat Analysis
	System Requirements Complete
DESIGN & DEVELOPMENT	*Design Specifications for software Complete*
	Design specifications for hardware Complete (if applicable)
	Security controls for system Complete
	Core features and functions implemented
	Run initial testing and review code
	Establish traceability across requirements, design elements, test cases, and risks
TESTING	*Complete integration testing*
	Complete quality assurance testing
	Complete cybersecurity testing (penetration, fuzz, etc.)

AVOID THESE COMMON MISTAKES

- Secure-by-design is not implemented or neglecting cybersecurity entirely (scary but true!).
- Significant software development completed before any documentation.
- Poor traceability throughout software development lifecycle.
- Not budgeting time or resources for formal validation testing.

Note: This table includes major milestones. Exact milestones you may need to achieve can vary.

Clinical Milestones

PHASE	MILESTONE
PLANNING	*Design Clinical Study*
	Secure IRB Approval & IDE Approval, if needed
	Clinical Research Organization (CRO) Selected (if you choose to work with one)
	Identify Clinical Sites
STUDY EXECUTION	*Clinical Sites Activated*
	Electronic Data Capture (EDC) System Established
	First Patient In (FPI) Completed
	Last Patient Out (LPO) Completed (also referred to as Enrollment Complete)
DATA COLLECTION & ANALYSIS	*Data Collection Complete & Database locked*
	Primary Endpoint Analysis Complete
	Secondary & Exploratory Endpoints Complete
STUDY CLOSE OUT	*Trial Master File (TMF) transferred to Company (if CRO is used) or TMF Complete (if no CRO is used)*

AVOID THESE COMMON MISTAKES

- Pick clinical sites that aren't aligned with incentives, ability to enroll, experience running studies like yours.
- Did not budget sufficient time for study start up making you already behind before you even start!
- Not thinking through clinical trial tasks that your team can do effectively.

Note: This table includes major milestones. Exact milestones you may need to achieve can vary.

Regulatory Milestones

PHASE	MILESTONE
STRATEGY*	*Identify Device Class, Relevant Regulations, and Competitor Products*
	Build a testing strategy for Software, Cybersecurity, Human Factors and Clinical validation
	Initiate a Preliminary Hazards Analysis to identify known risks for your device class
EXECUTION	*Draft testing protocols & reports*
	Identify outsourced testing partners, where needed
	Engage with FDA via Pre-Submission (optional but encouraged)
	Draft Marketing submission
	Submit Marketing Submissions
	Market Authorization

***See my free resource on regulatory strategy for more insight and practical guidance**

AVOID THESE COMMON MISTAKES

- Your formal submission is your first interaction with FDA.
- Underestimate the amount of time it would take to address FDA questions during formal review.
- Draft inconsistent, incomplete, or hard to understand submissions.

Note: This table includes major milestones. Exact milestones you may need to achieve can vary.

Quality Milestones

PHASE	MILESTONE
Set Up 1	*Draft pre-market related SOPs + related templates and work instructions*
	Approve pre-market related SOPs + related templates and work instructions
	Train staff on pre-market related SOPs + related templates
DHF building	*Draft a Design and Development Plan (DDP)*
	Approve a Design and Development Plan
	Hold Design Review meeting(s) as specified in DDP
	Review and approve DHF documents (i.e. quality records related to design and development activity)
Set Up 2	*Draft post-market related SOPs + related templates and work instructions*
	Approve post-market related SOPs + related templates and work instructions
	Train staff on post-market related SOPs + related templates and work instructions
	Conduct internal audit

AVOID THESE COMMON MISTAKES

- Setting up a full QMS before you need it adding more work to your plate than necessary.
- Writing SOPs that are too restricting. You can be compliant & flexible!
- Have too many sources of truth that make maintenance of your QMS and DHF nearly unmanageable.

Note: This table includes major milestones. Exact milestones you may need to achieve can vary.

Business Milestones

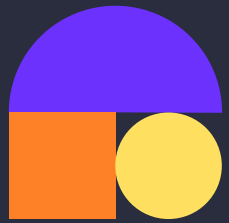
PHASE	MILESTONE
Product & Business Feasibility	*Complete market research and needs assessment*
	Outline value proposition of product/service
	Conduct feasibility analysis/interviews
Go-To-Market Strategy	*Select product pricing model and reimbursement pathways (if applicable)*
	Prepare sales and support team with approved labeling
	Design KPIs for product launch
	Identify sales and distribution channels
Launch Execution	*Coordinate marketing and distribution*
	Track KPIs
	Secure payer coverage and coding approvals (if applicable)
	Establish partnerships with KOLs to promote and advocate for product usage
	Monitor customer feedback

AVOID THESE COMMON MISTAKES

- Ignore market validation and build a product people don't want.
- Underestimate regulatory complexity.
- Do not value quality as a critical company attribute.
- Design an ineffective commercial strategy.

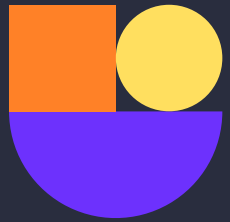
Note: This table includes major milestones. Exact milestones you may need to achieve can vary.

For each milestone we track, we ask....



WHAT CAN BE MOVED TO AN EARLIER DATE?

WHAT CANNOT BE MOVED AT ALL?



WHAT CAN WE WORK ON CONCURRENTLY?

WHAT IS A GATING ITEM FOR WHAT?

If your timeline isn’t comprehensive, you’ll start behind. Plan thoroughly. Avoid day-one set backs.