Enzyme

Path to Market Guide

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Introduction

Welcome to the Path to Market Course!

This guide contains information and recommendations for medical device and software as a medical device (SaMD) companies to get their product to market.

This guide divides the process into 4 phases, and outlines activities and deliverables for each phase. Ultimately, the specifics of each company's path to market will vary based on their unique products and circumstances.

Phase 1: Product Planning and Product Strategy

Before your 50th, 20th or even 5th prototype iteration, it is important to have a strategy for how your product will create value (safe, effective, or less expensive) and how you will get it to market.

Your strategy may evolve over time but it's important to assess **how** the product, design and development, production and the sustaining/maintenance processes meet the various applicable regulatory requirements.

During the design and development process, Phase 1 and Phase 2 often proceed in parallel, which is normal. However, Enzyme recommends the Phase 1 strategies always outpace the prototyping.

During this phase, assess the skills and expertise of your current team. Determine if these are sufficient to implement your product through all the phases. It is important to hire individuals, or consultants that can advise the company and help get the product to market.

Your overall Path to Market strategy is comprised of several functional strategies. Let’s take a closer look!

Intellectual Property (IP) Strategy

Start by performing research to determine how your product is different from those on the market. If you have an innovative product and it cannot be compared to any other products on the market, you can apply for a patent. It is vital to protect your company's intellectual property. Furthermore, this will benefit you during your pre-submission, if applicable, by demonstrating how your product is different from predicate devices.

Research & Development (R&D) Strategy

As part of your R&D strategy, it's important to document details of prototype iterations and changes as well as to study and document your product risks .

This will help address them early while you are still designing your product and avoid issues later. The best risk mitigations are those implemented *within* the design of the product. Prior to finalizing the design, it's important to be mindful of how to test the various requirements being developed. This allows for more accurate predictions for development, testing and submission milestones. Furthermore, understanding your product risk classification and product code will inform the details that need to be assessed and included in your product development, testing and submission. Read our Risk Classification guide to learn more about how to categorize your product's risk class.

Regulatory Strategy

FDA's product classification database allows you to research other similar products on the market. This helps determine the appropriate product risk classification for your device, and drives your development strategy and submission type/requirements.

It may be important to choose a Regulatory Affairs Consultant (or company) who can help with your FDA submission.

If your in-house team does not include Regulatory Affairs (RA) professional, retaining one (or a firm) on a consultant contract will help facilitate identifying product risks and best regulatory strategies to expedite the development and submission processes.The earlier this happens, the better the result. Waiting too late can lead to the need for remediation activities and cause significant delays in a planned submission. Companies have gone out of business by not adequately navigating *this* phase during their path to market.

Clinical Strategy

Intimately tied to the regulatory strategy is the clinical strategy. Some products based on their risk require mandatory human clinical trials; whereas low-risk products with clear predicates (similar devices) may not require any clinical testing. Factoring in whether your product will require a clinical trial and the costs of that endeavor are important to understand early so sufficient funding can be raised. You also have think about how clinicians and patients will use your product and how they will report results. As part of the clinical strategy, it is essential to demonstrate how your product improves the cost and standards to existing diagnosis and treatment options.

Enzyme recommends you start with small studies so you can collect data from a small population to show the efficacy of your product.

Then you can expand to include larger studies. As you are developing your protocol, you'll have to apply to one or more hospital Institutional Research Boards (IRBs) or even directly to FDA if the trial poses moderate to significant risk to patients. It is wise to consult with an IRB and/or FDA as applicable for feedback on the clinical strategy before submitting for approval.

Quality Strategy

Establishing a quality management system (QMS), and a "culture of quality", creates and aligns standard business practices and procedures. It ensure that all employees understand how they directly or indirectly impact product quality and therefore patients' lives.

It drive consistency in work steps and deliverables to facilitate predictable business results and consistently safe and effective product. It also helps your company comply with regulations and applicable regulatory standards. The QMS you implement is both a business best-practice as well as a regulatory necessity, and it is vital to ensure your company meets customer, regulatory, and investor expectations. Learn more about establishing a QMS in our Intro to QMS Guide.

Marketing and Stakeholder Strategy

Develop a plan for how to market and sell to the customer, and meet investor and shareholder expectations. Payer (insurance) coverage is not guaranteed after receiving FDA clearance or approval to market a product. Therefore, it is far easier to obtain payer coverage if the new product can be categorized within an existing reimbursement code. For novel devices/treatments, new codes may be necessary, and this requires significant reimbursement knowledge to navigate through the healthcare, including Medicare/Medicaid and private payer, system. Understanding the purchaser's (often an administrator for a hospital system or conglomerate) needs will help drive your sales and adoption. Having a strategy for this well in advance of any submission will help inform the likelihood of whether your product will be profitable.

Phase 3: Final V&V and Submission

Once the product is in its final stages of development, final verification and validation (including human factors) should occur.

Final Verification and Validation (V&V)

Verification and validation activities include testing, analysis, simulation and must have traceability to released requirements in your QMS. Validation also frequently involves user testing (e.g. physician, nurse, patient, etc.) to best replicate the environment in which the product will be used.

Since the product is now in production, you can set up your QMS for Complaints, Non-conformances, CAPA and production controls. These are in preparation for when you launch the product.

Submission

Once you have finished your final prototype and corresponding verification and validation, you can then submit to the FDA. Be sure that all your verification and validation is documented in your QMS.

Once you know your product's risk classification, it will determine the type of submission you will need. For devices there are several types of submissions:

- 510(k) (Premarket Notification)
- PMA (Premarket Approval)
- De Novo (Evaluation of Automatic Class III Designation)
- Humanitarian Device Exemption (HDE)

Premarket Approval (PMA): Most Class III devices require a PMA. The company must prove evidence that their product is safe and effective for it's intended use.

510 (K): Some Class I and most Class II products require a 510(K). The company must show that their product is substantially equivalent to a device that's already on the market.

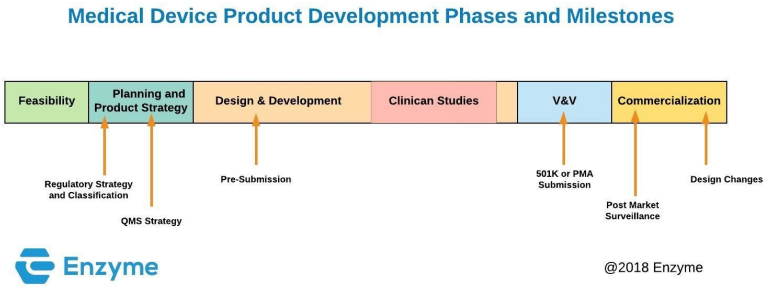
De Novo: If your product is a new device that does not have a predicate to which it can be compared, then you'll have to apply De Novo approval.

Humanitarian Device Exemption (HDE): Class III devices that are intended to benefit patients with rare diseases can submit for HDE. The company must first apply for the Humanitarian Use Device designation.

Class 1 devices generally do not require a submission. Software as a Medical Device (SaMD) products have additional classifications they need to follow. Our Introduction to FDA and Notified Bodies Guide discusses in depth what each each classification requires and what the FDA is looking for.

Phase 4: Commercialization

Once your product is on the market, you must monitor the product for issues and complaints and make product improvements to mitigate any issues.



Product Development Milestones

You can capture all customer complaints in the QMS and then determine if these complaints must be escalated to an NC or CAPA. High risk products may be audited by the FDA to ensure their safety and efficacy.

Conclusion

This guide was an overview of a device's path to market.

If you do not have an in-house Regulatory or Quality , we highly recommend hiring a consultant (or Enzyme) to help guide you through the process.

Congrats! You have completed the course and are ready to take the quiz.