Medical Device
Commercialization 101

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INTRODUCTION

The path from concept to commercialization is a complex process. Gone are the days where companies can simply develop a prototype, present its value proposition, and then quickly send off to a manufacturer. Today, companies must establish clearly defined requirements, asses hazards, risks, human factors and cybersecurity, implement and test the solution, and prepare a strategy and regulatory submission. Developing medical products in this highly regulated environment is a challenge and requires a deep understanding of the various protocols and current regulations for the FDA and other agencies.

For medical products, it's good to understand your regulatory strategy and make the tradeoffs on labeled claim vs. clinical study effort (cost and time) in your plan. Certainly durable vs. disposable models and margin considerations are central to a business plan for most medical devices. Based on years of experience working on FDA regulated devices, Sunrise Labs has prepared an outline of the medical device commercialization process as an overview of the business, development and regulatory efforts required.

CREATING YOUR STRATEGY

Step 1.

Define Your User Needs

Defining what your product needs to deliver begins with a market assessment from both a medical and business perspective. This investigation helps companies better understand the existing drivers for demand before entering any device development project. Typically, this research includes examining existing competitive offerings, analyst and trend reports, and convincing expert panels. For first-of-kind devices, keep in mind that it's often prudent to test the market as soon as possible with a bare-bones model that incorporates only the necessary features. Companies can also gather primary data through surveys and focus groups. Once these market needs have been assessed, they are usually compiled in a Market Requirements Document.

Step 2.

Define Your Resource Strategy

Now it's time to consider 'How' you will go about developing your idea. The initial phase of this process should focused on Time to Profit, which takes a holistic view of the upcoming commercialization effort and the product lifecycle in the context of your business model. Quality, cost, and delivery time need to be considered as part of the strategy. To achieve a product with optimal quality, at the right costs, delivered to the market at the right time.

While most medical devices have a unique and critical aspect that forms the basis for the business case (e.g.; the reagent chemistry for a point of care diagnostic, or the sensors in a monitoring device), the balance of the device often uses a combination of available technologies. A large part of the development effort, such as the graphical user interface (GUI), or cloud database connection, or data acquisition, can be executed more quickly, efficiently, and effectively by a team that has done it before.

Many companies maintain in-house expertise to develop technologies that may be patented, and are unique and critical to their products. Commercialization of technologies unique and critical to the company's offerings can also be outsourced to accelerate time to profit. A plan to capture and retain this IP within your company is vital.

Next, you need to determine how you will build the right development team. A broad range of skills is necessary to design most medical devices, particularly for devices that are part of an integrated system. You can build the development team in-house, outsource the entire development effort, or consider a combination of both. The first step is to take inventory of the available in-house talent and compare it to the expertise you will need for the project. This process will help to identify gaps between project needs and in-house capabilities which you'll need to address.

DESIGN EXECUTION

Step 3.

Assemble your Development Team – Look for Experience

It's important to establish a resource strategy that aligns best with your firm and the scope of the project. Assembling the project team could include using in-house experts, hiring additional staff, or hiring outside firms. If you need to hire outside firms, prepare a request for proposal (RFP) that includes:

- Expected deliverables and timing
- Market Requirements
- Expertise areas required to complement your in-house capabilities and provide the skills and experience you need

Step 4.

Identify & Mitigate Risk Areas

Technical risks within the development process can impact schedule, budget, and quality. Identifying and coming up with a plan to mitigate technology risks as early as possible in the project planning is critical. A focused effort on risk mitigation is best performed before engaging a full team to design a system that may require fundamental changes to address risks. For medical device development, the process of identifying and mitigating risk should start in the planning phase and be reviewed at key stages during product development, design verification, and design transfer.

Assessment of human factors, safety, and cybersecurity related risk investigations are required by the FDA. Starting these analyses early in the development effort can save costly rework and improve outcomes.

Risk and Hazard assessments begin by determining the intended use for the device and users of the device. Hazards associated with the device use should be identified and assigned a risk level based upon the severity and likelihood of occurrence. Clinical judgement is necessary to evaluate the severity of risks. Identifying appropriate mitigations to manage risk is required. Hazards, and any mitigations are then placed into categories based upon their type (energy, radiation, thermal, etc.) and characterized by the cause or sequence of events, the situation, and the level of harm.

Over the past decade, cybersecurity in medical devices has become a growing concern for medical device designers. Based on FDA Guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, there are several suggested mitigations for connected devices, such as creating user identifications and passwords or using automatic timed methods to terminate network sessions. Sunrise Labs offers a comprehensive assessment for identifying, assessing, and managing cybersecurity risks for new medical devices and those that already exist on the market

Step 5.

Derive System Requirements

Establishing clearly defined, unambiguous, and testable system requirements provides the project team with a clear plan for what needs to be developed, and the timing for development of each requirement. Requirements define what the medical device does and how it operates. Testing to requirements demonstrates that the engineers implemented the intended functions. Well defined requirements provide a robust foundation for product development. Poorly defined requirements can create frustration for developers, and increase both product risk and rework, impacting project schedule, budget and outcome.

Most devices containing electronics are Systems unto themselves that need to be architected properly to work robustly under a wide range of conditions. In step two, we mentioned that your development team should include a strong Systems Engineer. Systems Engineering bridges the traditional engineering disciplines based on the diverse elements in complex systems. For the system to perform correctly, each system element must function properly in combination with one or more other system elements. Essentially, a Systems Engineer creates the requirements that defines the device's architecture and key interfaces, with a thorough understanding of the critical functions and tradeoffs necessary to meet technical and business goals.

Step 6.

Architect the Solution Using a Systems Approach

A product architecture shows how mechanical, electrical, software, and other subsystems integrate to solve a design problem. Make sure to architect the system, including the definition of interfaces, before designing the subsystems for the medical device. As with the System Requirements, the architecture is foundational and will impact all aspects of the design that follow.

A good architecture addresses:

- All defined use-cases of the device
- All connections internal and external
- All critical performance parameters with margin
- All known and significant hazards and safety concerns (fail-safe or fault tolerant where appropriate)
- Maintenance considerations including software upgrades

Step 7.

Design the Subsystems

Now that the system is architected, each engineering discipline implements their part of the system. Electronics engineers write electrical requirements, design circuits and create circuit boards. Software developers generate the appropriate software documentation, write the code and test the code. Industrial designers create models for the look and feel and define the user interface. Mechanical engineers design the mechanisms and the enclosure. Each of the subsystems need to tie back to the System design, requiring close interaction between the engineering disciplines during this phase.

Development teams often prefer to develop new products in multiple prototype 'design-build-test' cycles. This allows the team to learn what works and iterate to optimize the design before production. Sometimes, the early prototypes can be used for testing with end users to get feedback on the design while there is still time to incorporate changes.

Step 8.

Verification and Validation

Verification is performed to confirm that the design conforms to the requirements set out at the start of development, along with any requirements that were added during development as risk mitigations. Verification methods may include analysis, demonstration, inspection, and testing. A system verification plan can identify verification tasks and responsibilities, along with documentation required to support the verification activities and results.

Validation is a field based test, or simulated-use test, to validate that the product developed safely meets the market needs with real end users. This often requires a clinical study, overseen by an investigational review board (IRB). It's efficient to have design tools to enable tracing and maintenance of the tracing to the requirements, including requirements added to mitigate risks identified during the design and development process. If you can't validate that the device meets its intended use and satisfies user needs, then it's unlikely you'll satisfy the FDA or other regulatory agencies.

REGULATORY CLEARANCE & TRANSFER

Step 9

Regulatory Submission

In the US, both “510(k) cleared” and “PMA approved” medical devices require the submission of the development dossier referred to as the Design History File (DHF). This provides evidence to the FDA that the required design controls were followed, including conformance with the appropriate industry standards.

The FDA provides specific and detailed guidance regarding medical device submission through five steps.

- **Step One:** Classify the Medical Device
- **Step Two:** Choose the Correct Premarket Submission
- **Step Three:** Prepare the Appropriate Information for your Premarket Submission to the FDA
- **Step Four:** Send your Premarket Submission to the FDA
- **Step Five:** Complete the Establishment Registration and Device Listing

A comprehensive guidance and established list of requirements can be on the FDA’s website under ‘How to Study and Market Your Device’.

For devices that will be distributed in countries belonging to the European Union, manufacturers need to obtain a CE mark. The clearance /approval process is different that the FDA’s but still relies heavily on the same international standards to define safety requirements. A report generated by a registered body (such as TUV, Intertek, UL, etc.) is used to self-declare conformance before medical devices are labeled with a CE mark and marketed in the EU countries. Countries outside the EU have other requirements and means to control distribution of devices in their markets. Fortunately, most countries depend on the same set of international standards at the core of their systems.

Step 10.

Transfer to Manufacturing

Without proper planning, medical device transfer to manufacturing can present unique challenges. It's important to research potential contract manufacturers early in the design phase. Doing so allows the selected contract manufacturer (CM) to provide Design for Manufacturing (DFM) inputs while the design is fluid. The applicable section of the DHF is given to the manufacturing enterprise, which in turn generates a Device Master Record (DMR) covering each device manufactured. Any required tooling is procured and first article parts off of the tools are inspected for conformance to the drawings in the DHF. The development team works with the manufacturer to set up the appropriate tests and if necessary, calibration steps. The manufacturing processes are validated using installation, operational, and performance qualification testing. Ultimately final devices, produced in multiple lots, are tested to an acceptance test procedure.

Attention to DFM, DFT (Design for Testing) and supply chain considerations earlier in the design phase will ensure this transfer goes smoothly, without late design changes, additional cost and time.

Step 11.

Design Maintenance

It's not uncommon for changes to be made to a product throughout it's lifecycle. These alterations could stem from component obsolescence, the addition of a new feature, or new regulatory standards that require design modifications. For this, it's good practice to use a team that is familiar with your device design to address these issues. Choose established partners that will be available to support your complete product lifecycle.

About Sunrise Labs

For over 25, clients have come to Sunrise Labs for complete product development for medical devices, combination products, and life science instrumentation, leveraging our ISO-13485 and ISO-9001 certified processes. Client success stories reflect our strengths in system engineering, project management, and a full range of technical disciplines to turn novel ideas into commercially viable products. We are known for solving tough engineering problems nimbly and with integrity. Our extensive project portfolio includes patient monitoring solutions, imaging, cardiac, neuro, and IVD applications.

Sunrise Labs' main facility is located in Auburn, New Hampshire, with a satellite office in the Bay area of California. We proudly employ over 60 dedicated employees in a high performance culture based on engineering excellence, mutual respect, ethics, and integrity. We look forward to working with you to meet your product development needs!

Visit our website at www.sunriselabs.com, or contact us to learn more.

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