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A Proven Approach to Developing Complex Medical Devices

Traditional approaches to developing new medical devices do not work well for complex medical devices. In this whitepaper we explain an alternative approach, organized into a set of proven concepts and methods, for managing the special challenges product teams face in developing complex medical devices. We begin by analyzing those special challenges and then describe the crucial pre-development work that needs to be done in Phase Zero before beginning commercial development. A second part, to be published later in 2025, will continue describing concepts and methods to address challenges throughout product development. These challenges are fundamentally a human problem and therefore leadership and good management are key to making any of the methods successful.

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The story, all names, characters, and incidents portrayed in this whitepaper are fictitious. No identification with actual companies, persons, or products is intended or should be inferred.

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1 What Makes Complex Medical Devices Different?

The (fictional) Eagle Project, aiming to develop a complex surgical robotic system, faces a critical delay issue. The CEO is frustrated by the repeated setbacks undermining the planned product launch. The company has successfully developed simpler medical devices already. Why is this project different? We will describe why the Eagle Project was destined to fail and how to set up a product development organization, with key concepts and methods, to maximize every product team's chances for success.

1.1 A Project in Crisis

There was a deafening silence in the conference room. The project manager had just announced to the executive team that the Eagle Project—to develop a new surgical robotic system—would be delayed by another six months. The silence was finally broken by the CEO shouting, "This is unacceptable! I promised the board that we would ship the product by Q2 of next year. We cannot delay the Eagle Project again!" The CEO didn't know the product team had spent the previous week desperately trying to figure out a way to minimize the delay. Unfortunately, the roots of this problem started three years earlier when the project started. The hapless project manager could only pursue a costly fix to the new robotic system. What caused this latest project delay and the previous delays? The company had already successfully developed and commercialized previous medical devices. Why was this project such a disaster?

This new surgical robotic system was the first time the company had developed a truly complex product. They knew it would cost more to develop and had budgeted accordingly. However, they didn't anticipate the particular challenges of developing a complex system and didn't adjust their product development approach. Their approach, which was successful in developing single-use medical devices, was overmatched by the challenges of developing a significantly more complex medical device.

In this whitepaper, we will examine what is different about the development of complex medical devices, how project risks are multiplied, and why different methods are required to maximize the chance of successful development. This discussion focuses on new product development (NPD) of complex medical devices and especially how to avoid traps that teams may fall into. By "new," we are distinctly separating the kind of development that is incremental or "me too" in nature and focusing on products that involve new applications, technology, or science. By "complex," we generally mean development that includes hardware, software, and perhaps other modalities such as optics (Table 1). Further, these development projects require a large team of individuals from diverse specialties working together to achieve an outcome. The issues we discuss may crop up with simpler medical devices or non-medical products, but they are particularly challenging for complex medical devices.

Table 1: A general comparison of non-complex and complex medical devices

Non-Complex Medical Devices	Complex Medical Devices
Intravascular catheter (stent) Surgical instrument Implantable knee joint	Capital equipment such as a radiation therapy system, medical imaging system, surgical robotics system, or laboratory diagnostic equipment Complex disposables with software such as a wearable combined with a mobile app and cloud software (IOT architecture) Software-only products (SaMD)
Product BOM: Dozens of components Design requirements: 50 to 150	Product BOM: Hundreds or thousands of components Design requirements: Hundreds or thousands

The Eagle Project initially showed promise as a team of nearly 40 people, led by an experienced project leader and guided by a retired surgeon, embarked on developing a new surgical robotic system. They efficiently defined product requirements and organized the work into electrical, mechanical, software, and manufacturing streams. A detailed project schedule was established, aiming to culminate in a system integration milestone followed by verification and validation testing and transfer to manufacturing.

The product team followed the company's well-established product development process consisting of five phases (Table 2). With this process, the team conducts a design review at the end of each phase using a detailed checklist defining exactly the required documents to be completed for the phase. This detailed framework is intended to ensure every project completes all necessary deliverables, complies with all applicable regulations and standards, and stays on schedule. The Eagle product team completed Phase 1: Planning successfully on time.

Table 2: The company's product development process

Phase 1: Planning	Phase 2: Development	Phase 3: Verification	Phase 4: Validation	Phase 5: Transfer
• Development planning • Hazard analysis • Requirements & architecture • Regulatory strategy	• HW & SW design • Detailed risk analysis • Prototyping • System integration • Test method development • Mfg. process development	• Design freeze • Design verification testing of HW & SW • Mfg. process development	• Usability testing • Clinical testing • Mfg. process development • Regulatory submission	• Mfg. process validation • Launch readiness activities

However, the project encountered significant setbacks after Phase 1. The anticipated two-week system integration phase stretched into a 10-month ordeal due to persistent issues integrating hardware and software components. After finally achieving a working prototype, usability testing revealed serious shortcomings—ergonomic flaws and the lack of some important features that surgeons expected. This discovery prompted contentious redesign meetings, costing the company additional time and money. Design engineers, who had moved on to other projects, were brought back to address the issues, exacerbating delays. Adding to the frustration and delays was a mountain of documentation that had to be painstakingly updated and re-released to capture all the changes.

As these challenges mounted, the CEO grew concerned that the Eagle Project's protracted issues could jeopardize the company's broader product launch roadmap with a cascade of delays. The project, initially a beacon of hope, had turned into a costly and time-consuming ordeal.

1.2 Common Problems and Causes

The problems of the Eagle Project are not unique. We have seen many of the same problems across dozens of NPD projects:

- Launching directly into development without much or any customer insight
- Waiting to truly understand the customer's needs until a working product is ready for evaluation
- Discovering design flaws late in development, leading to expensive delays
- Schedule overruns with software development
- Underestimating the development time from a working breadboard to a commercial product (just a matter of implementation)
- Selecting a project lead who has product development experience with non-complex medical devices but has no systems experience or insight
- Planning only a single major integration milestone to combine subsystems developed in silos
- Lackluster sales of a new product after launch without a good understanding of why
- Compliance problems with meeting design controls (one of the most common FDA audit findings)

Phase-gate structures are a common way to provide a framework for new product development and are intended to act as checkpoints to ensure alignment with the program's business and technical objectives. However, no matter how carefully the phases and gates are designed, these structures cannot compensate for misguided concepts and methods or an incorrectly structured product development organization. We believe the concepts and methods we will describe in this whitepaper are more important to the success of product teams than the nuances of various phase-gate structures. In other words, a perfect phase-gate structure (or any process) is less important than the right people, culture, and leadership in the organization.

1.3 Challenges for Developing Complex Medical Devices

Why does developing a complex medical device require a different approach than developing other medical devices? Following are the primary factors resulting from product complexity that drive new challenges and, therefore, new methods for new product development (NPD) and new approaches for medical device companies.

Resource Intensive Projects

Developing a complex medical device can require a very large budget as well as more development partners and suppliers.

Challenges:

- Project failures entail much greater business risks, measured in wasted money and time
- Much harder and more expensive to change direction
- More expensive to resolve design flaws late in development
- Siloed development of various modules or subsystems

Large Product Teams

Coordinating the work of a product team of only a dozen people is very different from that of a product team with 150 people or more (often spread across multiple organizations).

Challenges:

- Coordination and communication among a large number of people
- Maintaining alignment and focus over a long-duration project
- Turnover of team members leading to loss of knowledge

No Hole-In-One

In the situation where no market currently exists, companies need to realize the first product launched may not be optimal and will need to be refined. Trying to launch with the "perfect product" may be counterproductive; launching sooner with a good product and then revising it based on customer feedback may be advantageous.

Challenges:

- Understanding what is a sufficient level of completeness for the first version of the product where there is no existing market
- The organization needs to respond to customer feedback rapidly to launch a follow-on version of the product. This needs to be part of the financial model for the product.

Interdependencies of Different Technologies

Complex medical devices frequently consist of multiple technologies (mechanical, electrical, software, optical, etc.) that must be tightly integrated.

Challenges:

- Difficult to predict system performance and behavior without modeling studies or building a prototype system
- Difficult to understand design tradeoffs and optimal system design
- Need multiple iterations to complete the system design

Complex Human Factors

The more complex the product's behavior and user interface, the more likely there will be use errors and the greater the need for human factors engineering and testing.

Challenges:

- Need to visit customer sites to understand customer use cases and usage environment
- Optimizing the user interface and workflow (extensive human factors/usability engineering)
- Demonstrating usability for safe and effective operation
- Identification of all users (e.g., customers and field service)

Complexity of Product Information

Complex medical devices involve a large amount of product data, often orders of magnitude more than simple medical devices. For example, instead of managing 50-60 requirements, the product team needs to manage 500 or 1,500 requirements, or instead of managing a product bill of materials (BOM) with 15 components, managing a product BOM with 1,000 components.

Challenges:

- Defining and prioritizing product features (not obvious and team may not be able to achieve all of them)
- Safety risk analysis and management of risk controls
- Management of design requirements
- Management of product BOM and supply chain
- Magnitude of verification and validation testing
- Volume of DHF documentation to comply with design controls

Multiple Upgrades Throughout the Product Lifetime

Most complex medical devices, especially those with significant software components, will be upgraded repeatedly after the initial product launch.

Challenges:

- Rigorous control of product design changes years after initial product launch
- Maintaining design controls and DHF documentation across multiple upgrades
- Backwards compatibility with earlier configurations
- Designing an architecture and subsystems to support future upgrades

1.4 Managing Project Risks

New product development is inherently risky. Companies that try to avoid the risks of product development only tackle incremental projects—low-risk, low-ROI projects (at the cost of not growing the top line). Companies that want truly innovative new products must accept that those projects will be risky and structure their product development around managing risks. The development of complex medical devices involves even greater risks. Companies need systematic ways to manage project risks and reduce them as early as possible to maximize the chance of success.

Innovation = Project Risk

Complex Products = Increased Project Risk

1.5 Categories of Project Risks

Product development organizations need to think broadly about the different categories of risk for new product development and how they will mitigate all of them for each project:

Technical Risk—Will the technology work (engineering/scientific challenges)? Are we trying to violate the laws of physics or biology?

Marketing Risk—Do we have the right product? What is the job to be accomplished? Does the product add enough value that customers are willing to pay for it?

Business Risk—Can we produce this new product and be profitable? What are the basic assumptions on ranges for cost of goods and margin targets?

Clinical Risk—Will the new product be clinically effective? Will the benefits of using it outweigh the costs of switching to a new product?

Safety Risk—Will patients be harmed by the new product?

Intellectual Property Risk—Do we have the freedom to operate?

Resources Risk—Do we have enough money and the right people with the right skills to develop the new product?

1.6 Problems Track Back to the Beginning

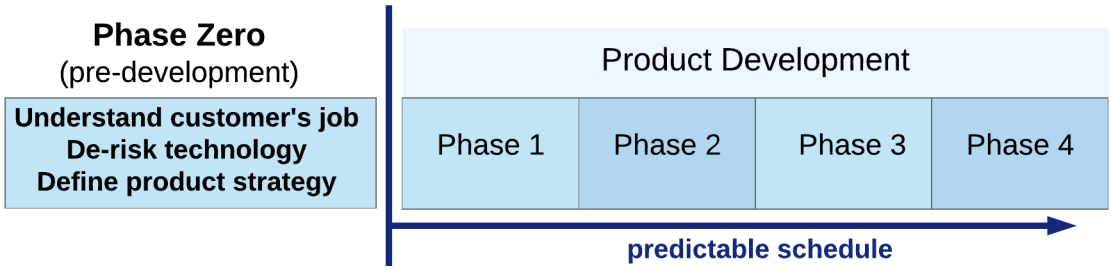
Most of the problems of the ill-fated Eagle Project trace back to the beginning of the development project, where risks were not adequately identified and mitigated (root cause). The team proceeded optimistically as if there were no uncertainties, and the hidden project risks blew up in their faces later in development. The project was missing an important set of initial activities before proceeding down the development path.

Successful development of innovative new products depends on critical work before development during a discovery/invention phase. This pre-development phase (Phase Zero) must be resourced and managed differently than development.

2 Phase Zero on Steroids

The traditional approach of marching head-first into development—with Gantt charts, project planning software, and sophisticated CAD models—does not work for complex medical devices. For teams developing complex products, there needs to be a market definition, invention, and learning phase before actual development—a period of time before proceeding with "Phase 1" in the company product development process. Driving off into the sunset becomes much harder when you don't know where the sun sets.

Phase Zero is your compass, a crucial front end to new product development that ensures the company is heading in the right direction. While the concept of Phase Zero has existed for decades and many companies include some form of it in their "Phase-Gate" processes, it is often not executed effectively or at all. Fundamentally, Phase Zero is a safe space for focused exploration and failure (where upper management is not hovering over the team's every move). "Phase Zero on Steroids" refers to investing the time and resources to fully leverage this crucial project stage.



The primary focus is to determine whether or not there is a product that can be developed to match the customer's problem to be solved. It is also an evaluation of the product opportunity and its alignment with the company's business strategy. It enables the organization to make decisions about whether the product concept has merit and should be funded. The nature of Phase Zero is dependent on the complexity of the problem to be solved and the maturity level of the technology or market understanding. It is particularly important for new technologies or new market opportunities.

Phase Zero is typically led by the product champion and a very small team; it can also be augmented by consulting experts within the company who facilitate the evaluation. For example, a team may consist of a market leader, a clinical leader, engineers who can complete the invention, and a regulatory professional to resolve the clearance or approval pathway. This is a cross-functional effort consisting of different disciplines from within engineering, as well as key personnel from other segments of the company.

An organization should complete the invention part (science, research, etc.) in Phase Zero before starting commercial development. Intensive activity in Phase Zero should not be misinterpreted as a way to avoid design controls (an unfortunate habit in some medical device companies). Phase Zero is a way to efficiently proceed through subsequent design controls by first focusing on fully understanding the customer's job to be accomplished and by project risk reduction before product development starts.

During Phase Zero, the team focuses on three main areas to set the stage for development: the customer's job, taking the invention out of development, and the product strategy.

3 CONCEPT 1: Understanding the Customer's Job

At the start of a project, when it's just a concept in someone's mind or "a napkin sketch," the first priority is understanding what is the customer's job to be done and how the new product will fit into their use cases (and what knowledge, science, technology, and logistics are needed to fulfill those expectations). At this point, it is critical to get a sound definition of the customer's problem to be solved. (The concept of "The Customer's Job" was described in Competing Against Luck by Clayton Christensen.) A key problem in the aforementioned, ill-fated Eagle Project was the team launched directly into development without much or any customer insight.

Understanding the customer's job to be accomplished is not about getting a list of features and benefits. It is getting true insight into it. Further, it is to identify where the gaps are in your customer's ability to meet the needs of their customers. This is not about defining the UX (user experience) in detail; That work is to be done at the beginning of product development. Here, we are trying to understand whether our customer's user experience needs to change—and how—for them to do their job.

Understanding the customer's job truly necessitates visiting the customer's place of work or facility where they do their job, stepping into their environment, and engaging in meaningful conversations with potential users. Effectively conversing with these prospects demands the presence of a proficient scouting team capable of asking pertinent questions and comprehending the customer's perspective.

3.1 The Role of a Scouting Team

A competent scouting team typically consists of at least two individuals: a technologist or engineering leader and a clinical marketing leader well-versed in the specific domain of the customer. One of these team members should assume the "product champion" role—the one who possesses a deep understanding of the proposed product and serves as its primary advocate within the company. The engineering and marketing leaders should grasp each other's domains, meaning the engineering leader should possess some understanding of the market and the marketing leader should have some understanding of the proposed product technology.

When engaging with customers, the primary objective is for the leaders of the proposed development to understand customers' challenges and envision an effective solution. By "solution," we mean a product concept strawman, not a fully designed solution (that will happen much later). This entails a profound understanding of the customer's unique use case. For example, in surgery, it necessitates comprehending the key issues surgeons face for a particular procedure, identifying tools to enhance their efficiency, and illustrating how your product could seamlessly integrate to address these concerns. This might even entail constructing mockups for demonstration purposes.

3.2 Brainstorming Customer Questions

To ensure productive customer visits, meticulous planning is paramount. In our experience, this is best achieved through a series of brainstorming sessions involving the scouting team. The outcome of the brainstorming sessions is a detailed list of questions to be addressed and a list of customers to be visited. The purpose of these customer visits is to understand the customer's job, any unmet or under-met user needs, and how a proposed product could help the customer in their job.

The way to accomplish this is to put together the elements of a business plan. Keep in mind, this is a new venture, and the product being developed is creating a new market or augmenting an existing one. There are a set of questions that need to be asked and answered in this process. Some of these will be addressed during the customer visits, and some can be answered by the team after the visits. They will, of course, include what the product is and the technology involved. But as importantly, they will identify and describe the business model, the cost structure, the product buyer, the financial premise, etc.

Brainstorming aims to flesh out the details of the questions to be answered by a small team. These meetings should include whomever else in the organization could contribute to asking the right questions, including members of sales, finance, and other technology members not part of this development. The outcome of the brainstorming sessions is a detailed list of questions to be addressed and a list of customers to be visited. This may sound like the team is forming a model to be tested. That is correct; the customer visits are not a fishing expedition but a validation of the product concept or to disprove it.

3.3 Understanding "The Customer's Job" in Action

At one small company in which one of us worked, the team had successfully completed development of a new product line and brought in a new general manager to lead this business (semiconductor manufacturing equipment). Sales weren't taking off the way they had hoped. To fix this, the general manager did something fairly radical; he pulled four leaders in marketing and engineering, as well as himself, out of their day-to-day responsibilities to focus on this new product's market requirements.

The main problem was the business hadn't done a robust job of understanding the customer requirements the first time. There was a desperate need for new marketing insight that would outline exactly what the product needed to be. They picked ten customer sites to contact for feedback and sent travel scouting teams (composed of at least one engineer and one marketeer) to physically go out and visit these target customers with a kind of "straw man" in the form of a presentation of the proposed next-generation product.

The scouting teams learned the business was heading in the wrong direction. The outcome of the customer visits forced the company to change its whole approach to the market and re-invent the product. The original product

was essentially a "Swiss army knife" of various features and capabilities. What the customer needed, however, was a single-function system that performed that task extremely well to enable the customer to accomplish their job. The key was defining a product based on the customer's job, not a list of features. From there, definition, development, and manufacturing of the next generation system became a more straightforward effort. When the company introduced the new system, it took the market by storm and fundamentally changed the way the customers performed their jobs. The company grew 10x over time and this product market became the largest in the company.

3.4 Customer Visits

Among the first matters to resolve are to decide which customers to visit (hospitals, clinics, etc.), identify the roles within the customer's organization to include, and determine who will visit them. These visits must be vetted by the sales personnel (if in an existing business) who maintains a relationship with the customer.

One mechanism we have used to show customers our thinking is to create a "strawman" PowerPoint model of the product to be developed based on prior input on the unmet need or job to be done. A presentation should be prepared for showcasing the planned product to the customers, and teams comprising two to three individuals should be designated for each customer visit. The duration of a customer visit can vary from an hour to several hours, encompassing site tours and comprehensive explanations from the customer about their role and the challenges they encounter in their work.

During customer visits, one team member should lead the questioning, while another should be the scribe. These roles can be rotated between team members for different customers. Additionally, it is essential to have at least one team member with technical expertise and one with market knowledge.

Following the customer visit, typically on the return journey, the team should convene for a debriefing session to review the questions posed and the responses received from the customers. Different customers may provide varying answers and insights. The purpose of multiple visits is to formulate a market model that can anticipate how a specific customer might respond to inquiries. The teams must persist with customer visits until they develop a market model that accurately predicts customer responses.

Sometimes, ranking the importance of specific features can be employed during customer visits, enhancing the information collection process. However, the true advantage of face-to-face customer visits lies in the ability to gauge body language, discern customer reactions, identify points of frustration or enthusiasm, and witness the customer's job in action. This is more than putting a statistical survey together to be answered by customers, using tools such as conjoint analysis. It requires face-to-face engagement with customers by members of the team.

Depending on the nature of the business, this process can span several weeks to a couple of months and may require significant travel. Ensuring each customer feels appreciated and valued for their time is vital, often accompanied by "thank you" lunches or dinners.

After the customer visits, the team should convene to summarize and agree on the conclusions of the visits. The work here is to convert the understanding of the customers' "jobs to be done" to outcomes/unmet needs as well as clinical and market needs. It will greatly inform the team whether the proposed product solution envisioned in the strawman hits the mark or needs to be modified or radically changed. This activity also creates a template for informing the team on product requirements/market requirements that would be delineated in the beginning of product development.

4 CONCEPT 2: De-Risking Technology in Phase Zero

The ability to innovate products involves the invention of new technology to address the gaps in your customer's job to be done to meet the needs of their customers. Likely, all the technical feasibility of what is needed is not complete. To reduce the risk of significant delays with product development later in the schedule, it is important to first complete the science and engineering of new technologies or areas that are incomplete.

Some teams assume this technical feasibility work can be tackled during the "development" phase. This is a serious mistake. Trying to unravel difficult technical problems during development or even later, such as during transfer to manufacturing, can be very expensive. This can result in huge amounts of time and money wasted in repeating tasks and dead ends. Even more alarming is discovering technical problems after the product has been launched. Multiple design flaws discovered late in development plagued the ill-fated Eagle Project described earlier, leading to expensive delays.

4.1 Take the Invention Out of Development

The objective is to prove the feasibility of a new technology by developing a breadboard or prototype. It is acceptable if breadboards or prototypes are high-cost and not manufacturable since their purpose is to get the unknowns vetted out. They are just for learning. If an invention is needed to complete the technology, then Phase Zero is the time to do that invention or demonstrate that it cannot be done. If the invention cannot be done, the team needs to determine an alternative to the invention, otherwise the product cannot be developed. This work must be accomplished in Phase Zero and not postponed to the development phase; the failure in development would be much more costly to the company.

Not all new product development needs invention. In one company one of us had worked in, the VP of engineering led the Phase Zero team of a next-generation medical device through a brainstorming process in which they invited outside vendors to attend. To get the product to market as fast as possible, the team established a technology roadmap in a way that minimized the amount of invention required. It was a multi-day process that resulted in a product roadmap and plan. This eventually led to an extremely successful product launch and growth of market share!

5 CONCEPT 3: Defining the Product Strategy

How you define your product strategy depends on multiple factors, such as the competitive landscape, maturity of your market, whether the product is disruptive, etc. In this context, product strategy refers to something analogous to a business plan presented to investors. However, instead of investors, senior management is receiving the presentation. The proposal should capture all of the typical elements of a traditional business plan but in a concise format for this product concept. Following are examples of questions to be addressed in a product strategy:

- Does the technology work?
- How much risk is involved with the proposed new product?
- Will the product win against competitors?
- What is the market size?
- Have we identified the right leadership and team for success?

5.1 Project Risk Analysis

High-level assessments should be conducted for all types of project risks, including safety considerations, marketing challenges, and manufacturing concerns. Are there any development aspects, such as sterilization strategy that will be difficult to define? Are there other technical risks, although not new, which are new for the team? Will the new product be clinically effective? Will the benefits of using it outweigh the costs of switching to a new product? Will safety risks to patients be outweighed by the benefits of the new product? Is there enough funding or money to develop the product? Are the right people identified to develop the technology?

5.2 Intellectual Property Assessment

Whether the product incorporates new or existing technologies, the team must assess existing patents related to the technology. A Freedom to Operate (FTO) analysis is essential to confirm the product concept does not infringe on existing intellectual property. Does the new product have defensible barriers in the intellectual property (IP)

landscape? What technologies, procedures, logistics, or manufacturing processes are needed for the product concept and to avoid infringing on existing IP? We have found creative brainstorming methods conducted in a secluded or even off-site area to be an effective way to do this.

Apart from individual technologies, the team must identify potential interdependencies within the product concept and assess if they could be subject to intellectual property protection or if existing IP already covers them. The complexity of this process may vary based on the product and competitive landscape. If issues arise, the team must seek alternatives or explore licensing options to avoid potential legal disputes. Neglecting any of these aspects can spell failure for the product.

5.3 Regulatory Strategy

Just as critical as assessing IP is determining the best regulatory pathway for product approval within the target market's regulatory body. In the United States, a straightforward pathway—such as FDA 510(k)—is much shorter and cheaper than pathways such as de novo or PMA (pre-market approval). The latter can significantly extend development timelines and costs, potentially making the project unviable. See below for more details on developing a regulatory strategy and particular considerations for complex medical devices.

5.4 Launch Strategy

With truly innovative products, perhaps first in kind and even in the absence of direct competition, there is an urgency to get the product into the market for multiple reasons (e.g., generating income, potentially being first, and getting customer feedback). The last reason should be the first reason. It may be that you have nailed understanding the customer's job, but do not know if there will be market uptake because there is no existing product market. Then, the market strategy would be to go "lean" into the market, using a very small sales force and keeping business costs low until you know there will be market uptake (see The Lean Startup by Eric Reis). As the challenge identified as "No Hole in One" above, the first product may not be optimal and the business should be prepared to refine it after the initial launch. Trying to launch with the "perfect product" may be counterproductive. Launching sooner with a good product and then revising it based on customer feedback may be advantageous.

In this case, it is imperative to get your product to market as fast as you can. This is not accomplished by adding lots of developers or inventing time accelerators. Rather, you must cut down the specifications you elicited from your customer to the bare minimum—a minimum viable product. This is an involved process requiring lots of open communication and objectivity; it can also sometimes be a painful experience. Without this focus and understanding, the team can become disconnected from the problem and greatly delay the time to market.

In one situation, we had been asked to work with a cross-functional team that was late in the development of its first medtech product. They were late in the sense they were supposed to be close to submitting for clearance, and late in the sense they were more than a couple of years behind schedule. Further, the technology was incomplete (see Concept 2: De-Risking Technology). Essentially, there were too many deliverables for a first-release product. We led the team through a prioritization process from several hundred items down to a handful of deliverables and a pathway where we could visualize an endpoint. We bucketed those items not in the first release to be worked on for subsequent releases. This, and solving the technical issues, enabled the team to get the product submitted for clearance and, soon after, successfully released to the market.

5.5 Completing Phase Zero

By the end of Phase Zero, the small team should be able to write a concise business plan or initiation plan that summarizes the estimated cost, time, and risks to fully develop the proposed new product. Business management should review this plan to determine whether to proceed with funding and development. If it is deemed too expensive, it may be that straightforward changes could be made to the technology or market fit to lower development costs. Conversely, it could be decided not to fund the project further (avoiding much greater costs of shutting down the project at a later point).

If the company decides to proceed with development, it now has the knowledge required to plan the full development of the new product. The next steps produce the following key outputs:

- Product development plan: a plan covering all activities needed to bring the new product to market, with enough detail to support the allocation of all the necessary resources (within the company and from partners/service providers).
- Regulatory strategy
- Reimbursement strategy
- Clinical testing strategy
- High-level schedule with key dependencies
- Product architecture
- Hazard analysis: a summary of safety risks and key mitigations

5.6 Summary of Phase Zero

Phase Zero is a period of invention, exploration, and discovery that outlines the parameters of your product. Those parameters, in turn, dictate the nature of your product development process (or whether development should proceed at all). Phase Zero is the time before development starts to take risks and evaluate the approach with the "new" product ideas. The regulatory strategy you develop during Phase Zero plays a key role in the overall product strategy and determines many aspects of the entire development project.

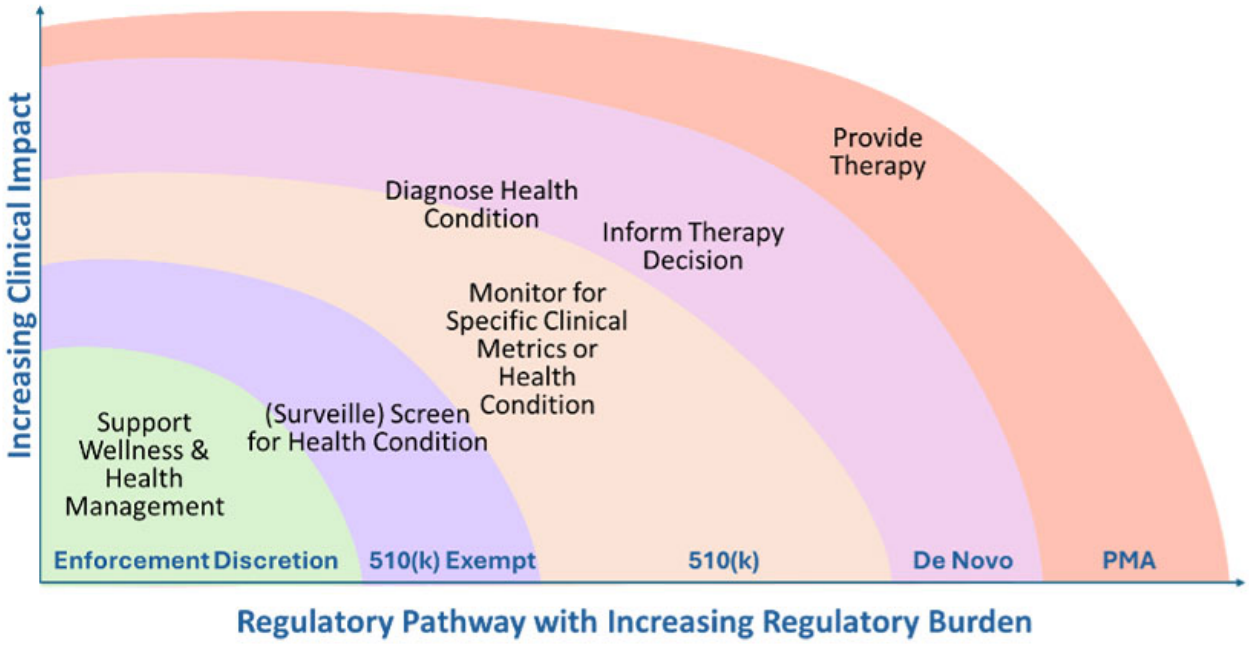
6 Your Regulatory Strategy Is Your Market Strategy

By Geetha Rao, PhD • CEO, Springborne Life Sciences

Gaining regulatory approval is a necessary milestone for most medical devices. Regulatory considerations affect the product roadmap and having a clear list of regulatory milestones is critical in planning development activities.

6.1 Key Considerations for FDA Approval

The degree of FDA oversight of a medical device depends on the risk presented by the device. This is correlated in large part with the potential clinical impact of the device, which in turn, depends on the intended clinical use of the device. Thus, one of the first regulatory decisions is to establish the "intended use" of the device (i.e., how the device will be used and by whom—a clinician or a patient). It is also important to specify for which patient populations the device can be used, including those for whom it may be contraindicated (e.g., pediatric patients), as well as the device use environment (e.g., a clinic, operating room, or in the home). These details comprise the formal "Indications for Use," which determine the scope of FDA approval or clearance. Upon receiving the FDA's OK, the company is restricted to marketing the device only for its indications for use or risk regulatory action. Thus, your regulatory strategy is your market strategy.



The FDA classifies device risk primarily into three classes—Class I (low), Class II (medium), or Class III (high). In rare cases, devices may be "unclassified" or have special classification status, such as a wellness device subject only to "enforcement discretion." The approval process, also known as the "regulatory pathway" depends on the risk classification.

Most Class I devices are exempt from pre-market review requirements and, in some cases, are also exempt from specific quality management requirements. This is described as the 510(k) Exempt pathway. These devices are typically subject only to "general controls," which include company registration and a listing of the product with the FDA.

Class II devices and some "reserved" Class I devices are subject to additional "special controls." These typically consist of specific performance and safety tests, such as those demonstrating electrical safety or biocompatibility, required for a particular type of device. The two most common regulatory pathways for Class II devices are the easier 510(k) pathway (named after the regulation number) and the De Novo pathway. In the more typically used 510(k) pathway, the device needs to be shown to be "substantially equivalent" in terms of safety and effectiveness to a previously approved device (called a "predicate" device). In cases where no suitable predicate is available (such as for novel devices), the De Novo pathway must be used. This consists of demonstrating that the clinical benefits of the device outweigh its risks and typically requires some degree of clinical testing.

Class III devices are subject to general and special controls similar to Class II devices but also require more rigorous clinical validation. The regulatory pathway used is known as the PMA (pre-market approval) pathway.

The graphic above illustrates how clinical uses with greater clinical impact are subject to a greater regulatory burden.

While 510(k) and De Novo pathways may typically be completed within a year or two of development effort, the PMA pathway can take five to seven years. Thus, very serious consideration needs to be given to the implications for the product development timelines and costs involved.

6.2 Engaging with the FDA

Gaining an FDA OK for a complex device typically requires compiling and submitting a significant amount of information about the product design, testing, and clinical use—an expensive and time-consuming endeavor. As such, it is important to de-risk the FDA review process to the extent possible. The FDA offers the opportunity to have pre-submission meetings with them. This is a formal process where the company sends the FDA a "Q-Sub" documentation package with preliminary information about the product along with specific questions. The FDA will review the Q-Sub and provide written feedback, typically within eight to 10 weeks. The company can accept the feedback as provided or request a videoconference to get further clarification. Records are kept of all feedback and enable both the company and FDA to refer to them in the future. This is very helpful in maintaining a consistent understanding of the regulatory requirements as the product development proceeds. Good questions to ask the FDA using the pre-submission process include:

- Suitability of proposed indications for use and appropriateness of associated labeling, including marketing language
- Appropriate regulatory pathway; if attempting a 510(k) pathway, the suitability of a proposed predicate device
- Adequacy of a proposed clinical testing plan, including the trial size, randomization scheme, number of sites, etc.
- Specific concerns about demonstrating product performance or safety

A special type of Q-Sub is a request for a "Breakthrough Device Designation" (BDD)—granted to a novel product with potentially high clinical impact. Gaining a BDD allows for expedited review by the FDA, which can shorten the approval timeline by years. Additionally, a BDD device is currently eligible for six months of transitional reimbursement under Medicare, which can be valuable when fundraising for novel product development.

A key requirement for all medical products is they must be designed, developed, and manufactured under a quality management system with records that are subject to audit at a later time.

Once the required information is compiled, a pre-market submission is made for FDA review. Upon successful completion of the review, the FDA will grant marketing authorization for the product. Any modifications made to the product following this must be carefully evaluated to ensure they do not require a new submission. Records of modifications and evaluations must be kept and are subject to audit. Key considerations in determining device modifications originate from feedback or complaints received about the product. Specifically, any information that

implies an actual or potential safety concern requires timely follow-up, including potentially reporting adverse events to the FDA.

6.3 Considerations for Complex Medical Devices

For complex devices, there are additional special considerations for ensuring safety and effectiveness. Complex devices are often built on a technology platform that supports multiple allied products. For example, technology for cardiac function monitoring may be commercialized in a product line addressing atrial fibrillation, heart failure, and coronary artery disease. Separately, the products may be used at different points in the care workflow, such as for screening, diagnosing, or monitoring. From a regulatory perspective, each of these use cases represents a different indication for use and will need its own regulatory approval. Depending on the market opportunity in addressing each of these conditions, the business strategy and the regulatory roadmap will need to be aligned. One approach is to first introduce the product with the lowest regulatory bar (i.e., the minimal viable regulated product) and then introduce products with higher clinical claims. A different approach may be to develop the product with the easiest market entry first and sequence the required regulatory activities accordingly.

In addition, since variants are built on a common technology platform, they share functionality. As product development proceeds, the functional modules can vary widely in their maturity. For example, standard "utilities" such as user authentication and patient demographic information recording may be shared. These modules may already be well developed when a new product development project is initiated, while other more variant-specific modules may need to be developed from scratch. However, as each new module is added to the platform, there is an increased risk of adverse emergent conditions, where there are unsafe interactions or those producing errors. These are additional risk considerations for regulatory authorities and updates required for products already on the market.

A good regulatory strategy is also useful in optimizing a product roadmap and establishing realistic and efficient product development timelines. It is critical to identify key regulatory milestones early in the product lifecycle and develop a regulatory strategy that is consistent with the business goals of the product line.

7 Market Validation of a Complex Medical Device

By **Amir Lev** • President, ALEV Ventures

For companies working on complex medical devices, obtaining customer input early in the development cycle is essential. By collaborating with customers during the market validation process, companies can ensure they are heading in the right direction before committing significant resources. The primary goal of market validation is to determine whether there is a genuine market need for the product, helping to guide development efforts and minimize risks, specifically addressing the question: "Will anyone want to buy the new product we're developing?"

7.1 Assembling the Market Validation Team

The first step in the market validation process is assembling a cross-functional team. This team should include marketing, application, and technology experts who will work together to develop a strategy for market validation and define the key questions to ask customers. The team's role is to gather and document market feedback continuously and ensure that insights are integrated into the product development process.

It is critical to include a customer representative in the team, such as a practicing physician or clinical expert, to ensure the feedback is relevant and actionable. In addition to customer representatives, the team should include an application expert who is familiar with the product's intended use and a technical expert who understands the product's implementation and the trade-offs associated with its key performance attributes.

7.2 Identifying Key Questions

A critical component of market validation is asking the right questions. Rather than attempting to ask every possible question, companies should focus on a small set of three to five key inquiries for each customer interaction, typically no more than 10 questions in total. These questions should center around specific use cases and encourage customers to talk about their current processes and how the new device could improve outcomes. It is important to emphasize measurable benefits and quantitative insights rather than qualitative opinions.

The key questions should address several important areas. First, the team must understand how the user currently conducts the specific medical procedure and whether the new device can improve the process. Second, the team should determine the critical attributes of the product that would make it useful and beneficial for the customer. Discussions should also explore trade-offs around key product performance attributes, such as form factor, speed, complication rates, cost, and reimbursement. These "attribute tensions" will help the team understand what customers are willing to compromise on and prioritize features for the minimum viable product.

By focusing the discussion on how the product will impact patient outcomes, the team can gain clarity on the device's potential value. This process of understanding trade-offs and refining priorities will guide decisions about the product's development.

7.3 Conducting Customer Interviews

Customer interviews are the next critical step in the market validation process. One challenge companies often face is that customers may not have a direct reference product to compare with the new device, making it harder for them to envision its use. To address this, it is important to guide customers through a "virtual journey" of how the product would fit into their workflow. This can be done through mock-ups, prototypes, video demonstrations, and other visual aids that help the customer imagine the product in action.

The focus of the interview should be on gathering feedback about how the device would integrate into the customer's existing workflow. It's essential to avoid defending the product if feedback doesn't align with expectations. Instead, the goal should be to listen and gather insights that can be used for further refinement. Collecting feedback from a variety of customers is also critical to ensure that the insights gathered reflect broader market trends, rather than just individual opinions.

When selecting customers for interviews, it's important to consider whether they represent organizations with the knowledge and purchasing power to influence the market. It's also beneficial to engage with customers who could generate buzz around the product and establish long-term relationships that could improve patient treatment outcomes.

7.4 Integrating Market Validation Feedback into Product Design

After conducting the customer interviews, the next step is to analyze the feedback and identify actionable insights. The team should look for patterns in the data, drawing conclusions that will inform the next steps in product development. It is helpful to quantify the conclusions and integrate them into the product's design strategy. Regular interactions with executive management are essential to ensure buy-in and to align the product development efforts with customer feedback.

Customer information is often the most influential factor in moving projects forward, especially when it comes to securing funding and making key product development decisions. Integrating customer feedback into the product design process is an ongoing effort that continues throughout the product lifecycle. While initial feedback from interviews is critical, continuous engagement with customers is necessary to refine the product and ensure that it meets their needs.

The timing of these customer interactions is also key. They should align with important decision-making milestones throughout the product lifecycle. These milestones typically include determining whether the product is viable, understanding if it solves a critical unmet need, defining key performance features, and assessing whether the

product is ready for market introduction. Additionally, as the product moves toward scale-up, feedback from customers should continue to inform decisions on production and market readiness.

7.5 Case Study: Shifting Focus Based on Market Validation

Consider the case of Company A, which was developing a capital equipment solution designed to assess tissue abnormalities. Initially, the company targeted pathology labs, with the pathologist as the primary user. However, early discussions with customers revealed that the most effective use case for the product would be in the operating room, where the surgeon would be the primary user. This feedback prompted the company to pivot, adjusting the form factor of the device to a "handheld" solution better suited to the operating room environment.

By engaging in market validation early, Company A was able to refine its product strategy, avoid a costly misdirection, and ultimately create a more effective solution that met the needs of its target users.

7.6 Summary

The market validation process is an essential tool for any company developing complex medical devices. It helps refine product strategy, identify key market needs, and ensure that development resources are allocated efficiently. By following a structured approach to market validation, companies can better align their products with customer needs, reduce risk, and increase the likelihood of a successful product launch.

8 Final Thoughts

Developing a complex medical device involves risks and challenges that are different than developing simpler medical devices and therefore demands an approach that can manage the scale and complexity of these projects. The recommended approach for these types of projects can be described as a set of concepts that the product development organization must embrace. We have presented here the first three concepts needed:

- Concept 1: Understanding the Customer's Job – actively seeking to understand what is the customer's job and how the new proposed product will fit into their use cases
- Concept 2: De-Risking Technology in Phase Zero – proving the feasibility of a new technology upfront by developing a breadboard or prototype and taking the invention out of the subsequent development phases
- Concept 3: Defining the Product Strategy – fully addressing all project risks (technical, clinical, safety, resources, etc.), analyzing the IP landscape, and defining the regulatory strategy and the product launch strategy

These three concepts all apply to the pre-development phase (Phase Zero). They are intended to bring project risks down to a manageable level and to ensure that the product team heads off in the right direction with the right resources. In future updates to this whitepaper we will describe the remaining concepts and a set of methods, applicable to all phases of development, that together will maximize the chances of success for every product team. These recommendations are not just about process. Success depends upon how the entire product development organization is structured and its leadership.

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