MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY

Product Development Insight

Blazing a Safe Trail to Market

A project management approach can help prevent missteps along the product development path.

MALLY ARAD AND MONROE HATCH
Integrated Project Management Company, Inc.

When climbing a mountain peak, you don't simply lace up your boots and charge up the path. To arrive successfully, you prepare first. What provisions do you need based on the length and difficulty of the climb? What's the terrain like—relatively even or strewn with boulders? Will you know what to do if you run into trouble?

The product development path is fraught with risk. A project management approach helps to make the journey more predictable and more direct with fewer costly detours and do-overs (see Figure 1). This method also facilitates decision making and smooth regulatory reviews. Creating an objective process to guide development helps ensure that projects stay on course, even when things go wrong.

Small Errors, Big Problems

Without an effective process in place, inadvertent oversights can start toppling the dominoes. Let's say a company has great plans for a next-generation implantable defibrillator that is one-third smaller than the current state-of-the-art device. It spends a lot of money creating a robust design-control dossier and prototype, which it fields to prominent cardiologists for feedback. They love it, and request 15 whiz-bang changes to make the defibrillator even better. However, these changes would make the device four times more expensive to manufacture. Because the company hasn't yet explored what payers are willing to reimburse, it can't determine which enhancements it can make while also remaining profitable. In addition, incorporating even the most critical suggestions means expensive backtracking and rework. The clock is ticking. Cash is running low. Do these concerns sound familiar? A clear development process and project roadmap, prepared in advance, can prevent such headaches.

Arad

Hatch

Prepare for the Journey

The project management approach to an airtight development process consists of determining company and project requirements, establishing a process to meet those requirements, and driving projects through the process day by day (see Table I). Although this is easier said than done, the following five project-management best practices provide a guide.

Assign a Dedicated Project Manager. You wouldn't ask your chief engineer to do the building's plumbing. In the same vein, managing the daily activities of a complex cross-functional development project requires specific capabilities. An effective project manager is highly organized, has exceptional interpersonal skills, and can lead a team with authority. He or she becomes the project's fulcrum, leading planning, driving execution, and resolving conflict objectively and apolitically.

Ask the Critical Questions Early. First and foremost, is the product commercially viable? Do customers want it? Will payers reimburse it? Does it stand apart in a crowd of competitors? Determining a product's business requirements, including whether it fits into the company's overall strategy, is essential. If it doesn't meet the mark, it's a nonstarter. Technical, regulatory, and resource requirements demand equal scrutiny, as do risks. Do you have a backup plan if your manufacturer goes bust? What if your investors pull out? Think the worst. Contingency planning enables a swift, efficient response should a disaster occur.

Create a Robust Process. Identify each step needed to bring a product to fruition across functions and third parties. Doing so provides the fodder for con-

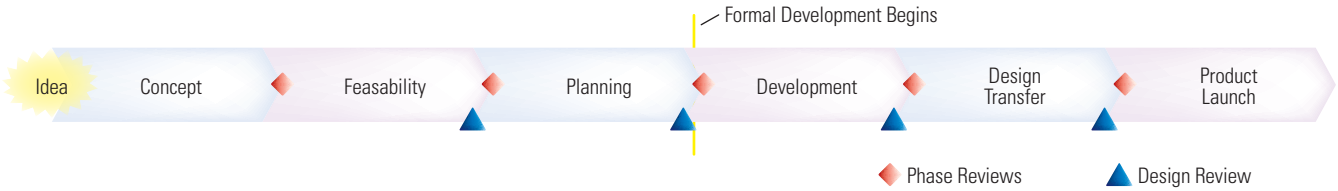

Figure 1. Having an organized development process in place can help prevent a snowball effect in the event that problems occur. Figure adapted with permission from Integrated Project Management Company, Inc.

structing a detailed process (which must comply with regulation) to guide project activities such as daily tasks, monthly reviews, and go/no-go decision points. The process should

- Identify which activities must precede others for the project to succeed, such as evaluating the competitive landscape before signing a binding contract with suppliers.
- Define the roles and responsibilities of the team.
- Provide a structure for communicating project information, so the team can stay abreast of progress and problems.
- Be thoroughly documented and available to all team members, so everyone understands his or her part.

Execute Vigorously but Thoughtfully. Even the best process will fail if execution falls short. It is important to close the loop on every critical activity every day. The project manager's chief responsibility is to keep the project on track, even if, for example, the statistician gets pneumonia just before filing. Effective execution requires navigating real-world twists and turns, not just blindly following a plan.

Stick to the Facts. When hit with a problem, solve it objectively. What are the options, what do they cost, and what will they each deliver, in measurable terms? In the high-stakes game of product development, decision-making based on fact—not hunches or passion—best protects a nascent product. Metrics can be used to assess everything from project risk to project issues to project success. Numbers provide a clear, impartial picture, and can help prevent finger-pointing when tensions run high.

Learn How Others Skirted the Crevasses

The following examples illustrate how three companies used a project management approach to create well-defined product development processes and avert disaster.

Traveler No.1: Small, Smart, and Overwhelmed

A fledgling start-up applies structure to chaos, enabling it to meet new FDA regulations and create a template for future product development efforts.

An effective project manager is highly organized, has exceptional interpersonal skills, and can lead a team with authority.

The Challenge. A small molecular diagnostic company launched its first product, which had been developed based on innovative science and excellent intuitive skills. Success drove excitement as the staff started working on four additional products. Although the company could manage its first project well as a unified group, people began to find themselves struggling as they juggled multiple projects across multiple teams. To make matters worse, FDA had recently initiated more stringent regulations governing the company's market niche. It had minimal compliance infrastructure in place, no formal processes to guide product development, and no one accountable for schedules and budgets. As a result, timelines slipped, costs multiplied, and investors complained.

Imposing Structure. To get matters under control, the company regrouped and initiated a project management approach, which was led by a skilled project manager. The first step was to impose a basic structure on the firm's daily operations. Meetings had agendas with defined action items, followed by reports that tracked progress against goals and issues to be resolved. A communications plan defined who needed to know what and when, and how that information was to be conveyed. People started working more efficiently, because they no longer had to weed through inboxes cluttered with periphery or waste time on unnecessary meetings. Roles and responsibilities were clearly defined, establishing personal accountability, which in turn helped to stabilize timelines and spending.

Rigorous Self-Assessment. Creating a solid product development process required first understanding the methods that had been in place. The project manager facilitated a cross-functional exercise to document the company's previous approach. How had the team approached development? Were there steps it should retain, or should it start completely anew? Next, the company performed a gap analysis, mapping its process against FDA requirements. Where were the holes, and how could they be filled?

What	Who	When
▪ Design and development plan ▪ Deliverables matrix by stage ▪ Design file	▪ Roles and responsibility matrix	▪ Detailed project schedule ▪ Critical path assessment ▪ Opportunities for project acceleration
Cost	**Risks**	**Feedback Sources**
▪ Detailed budget assessment	▪ Risk managment process	▪ Voice of customer ▪ Intellectual property ▪ Regulatory ▪ Phase reviews ▪ Design reviews

Table I. There are several tasks involved when beginning the product development journey.

Constructing a Process. Based on the team's findings, the project manager led the creation of a formalized phased-review process. Each phase was well-defined and required specific deliverables before the company could proceed to the next phase. Had the company assessed customer need? Was its product risk analysis complete? Did it have a viable reimbursement strategy? Had it finished the clinical validation plan? At defined junctures, the cross-functional team would conduct both technical and business reviews. Status and recommendations would be presented to executive management, who could then make educated business decisions. Was this still the right investment? Should it move forward or cut its losses?

Managing Risk. The product development process included establishing a system for identifying all potential project risks. What if a supplier couldn't deliver a critical component on time? What if the clinical sample collection was slower than anticipated? What if FDA changed regulations again? The system included quantifying and qualifying each relevant potential risk (how likely is the risk to occur, and how damaging would that be?), and then creating a Plan B, and C, as necessary, to protect both the product and the company.

Right-Sizing. Every company's product development process should fit its business and maturity level. Although a large corporation may require a standard operating procedure of 60, 70, or 100 pages, this start-up needed less than eight. The project manager helped the team create a document that was flexible enough to be efficient but detailed enough to be effective, without bogging down the process with unnecessary bureaucracy. It was a delicate balance.

Results. Armed with a well-defined and rigorously executed phased-review process, the company started meeting its milestones and ultimately filed a successful 510(k) with FDA. More importantly, it had a template for future product development efforts.

Traveler No. 2: The Price of Innovation

A global corporation launches a new version of an old device, using a metrics-driven approach to understand the skepticism of its customers and then win them over.

The Challenge. The technology of a parenteral delivery system marketed by a major life sciences firm needed drastic updating. The new system, used primarily by hospitals, would be state of the art and represent a vast improvement over the old one. The project was expensive. To recoup its investment, the company needed to raise the price of the new technology; this was a hard sell, and customers balked. The company also needed to standardize its sales process for new products to better control its income stream.

Measuring Value to the Customer. Led by a project manager, the company initiated a pilot launch of the updated delivery system to a small group of key customers.

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The goal was to measure the value of the new technology to the customer and then tweak the sales process as necessary. The project manager first built a process map of all the functions that had a role in the launch, including sales, regional marketing, global marketing, technical support, and clinical support. The company tracked events from the very first customer pitch through one month of satisfied usage. How long did it take the customer to approve a purchase proposal? Twelve days? Twenty-two days? In this case, a delay was defined as more than 30 days.

Persistent Root Cause Analysis. The number of delays in responding to a proposal was unacceptably high, which was slowing down sales. Why? Upon probing, the team discovered the root cause—a lack of clarity. Customers didn't say they wouldn't pay the price, they just didn't understand the reasons to pay it. They were generally happy with the old technology, so why should they pay more? Dropping the price was an obvious solution for the company, but it was also financially unsustainable.

Using Metrics to Solve Issues. The project manager and marketing team began working on a mathematical tool that would demonstrate the new technology's ROI. By plugging in the customer's historical monthly usage data and entering assumptions based on published reports of costs related to adverse drug events, incorrect prescriptions, and other relevant factors, customers could see that adopting the advanced system would generate savings that exceeded costs.

Results. Approval delays were cut in half. The overall time to approve a proposal dropped 34%. There was an improvement in cycle efficiency. The company saw a 14% increase in customers passing through the approval process. Most importantly, the company achieved 100% of the system's average selling price target, and no price cuts were required. The process was so successful that it has been replicated across the company and is now cited as a company best practice.

Traveler No. 3: If We Build It, They Might Not Come

A life sciences giant restructures the way marketing and R&D collaborated on the product development process after losing millions of dollars in failed or lackluster launches.

The Challenge. A global company that made medical devices for the consumer market had launched several products that fell flat. It had also sunk more than $10 million into a new product before killing it in late-stage development, when it found that the cost of production would eradicate profits. The R&D department had always driven the product development process—it had the engineers with the innovative ideas. But something was clearly going wrong. The company realized that its products were becoming increasingly commodified in a highly competitive marketplace. To turn around a struggling sector, the firm needed to take a more market-driven, project-management approach to product development.

Setting the Stage. The company focused on the following areas for its process redesign:

- Separate business from design control. The company created a two-pronged interactive product development process—one prong focused on design control and the other on business requirements. Giving business its own area of focus would

help prevent excitement over a new technology from drowning out its commercial realities, whether good or bad.

- Build a strong customer focus. From the beginning, and at defined steps along the way, the development team had to demonstrate a valid business case for pursuing development. Is there solid market demand? Is the product worth the continued investment?
- Make the process repeatable. A new product development process had to be replicable for all new products entering the pipeline, which meant building in both stability and flexibility.

Trading Places. To create a customer-driven process, the marketing department took the lead in early product development rather than R&D, which was a major procedural shift. To jumpstart the redesign effort, the project manager performed an extensive stakeholder analysis. More than 50 people were interviewed across all functions involved in product development, including vice presidents and and those in positions further down the line. Then, gathering a cross-functional team that included members of the departments of R&D, clinical, regulatory, quality, finance, operations, marketing, and legal, the company mapped out the process flows and responsibilities for each phase of a development project. It was a difficult transition, but because all parties involved had participated in a transparent, collaborative effort, the unified team could take ownership of the new process.

Focusing on the Customer. Ongoing market research was a key element in the business prong of the product development process. Did potential customers like the feel or color of the product? Did they like the way the buttons worked? Because consumer input was solicited and incorporated early in the process, the company could develop a customer-focused design up front. If the needs of the marketplace changed drastically during the development process, the company would know sooner rather than later. Management could decide quickly whether to kill the project or switch gears—whichever made the most business sense.

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A Metrics-Driven, Phased-Review Process. Spend a little money when there's a lot of risk; spend more as risks recede. At each phase, the company set metrics for both business and technical goals. In an early phase, for example, the cost of manufacturing should be known with 75% accuracy and the technical likelihood of success within 60%; closer to launch, surety must near 100% for both. Failure to measure up should raise a red flag and catalyze an investigation process by the company.

Results. With its redesigned product development process, the company could better ascertain the business case for each potential new product. It also had a well-defined process guiding collaboration between marketing and R&D. Moreover, executive management was now in a position to consider go/no-go decisions based on objective information rather than intuition, enthusiasm, or wishful thinking.

Conclusion

The project management process can help companies create a repeatable, consistent approach to product development. It reduces the guesswork, the wrong turns, and the blind spots. It provides a structure for sound reasoning and objective decision-making. Taking a product to market is an arduous trek, but skillful project management can reduce the hazards of the journey. M

Mally Arad is a regional manager at Integrated Project Management Company (IPM). She has 15 years of experience in project management and business process optimization with both domestic and international companies. She holds a degree in business administration from the University of California at Berkeley and an MBA in marketing and entrepreneurship from the California State University, Hayward, and is a certified Project Management Professional (PMP). Ms. Arad can be reached at marad@ipmcinc.com.

Monroe Hatch is a project manager at IPM, where he works on process improvement and project management initiatives for life sciences companies. He is a certified Six Sigma Black Belt and has over 25 years of experience leading process improvement efforts in multiple functions and industries. He holds a BS in chemical engineering from the University of Virginia. Mr. Hatch can be reached at mhatch@ipmcinc.com.

Integrated Project Management Company is a project management consulting firm that serves the life sciences and other industries. For more information, visit www.ipmcinc.com or call 630.789.8600.