

Business Process Management

How Project Management Can Prevent Costly Detours During Product Development

By Monroe Hatch and Greg Kain

When you set out on a cross-country road trip, you don't just get in the car and drive. You research your route, determine your timing, decide how much money you're going to spend, etc. You make sure your auto is set for the journey. But if it breaks down along the way,

you have the wherewithal to handle it.

Taking a product to market is a road trip in the fast lane through perilous mountain passes. Using a project management process helps products travel more securely from conception to commercialization. You have less money wasted on dead ends and do-overs, and you experience safer trips through regulatory review. You also have faster launches. Asking the right questions up front followed by rigorous execution and continuous problem-solving help your products arrive on schedule.

SIGNPOSTS TO GUIDE A SUCCESSFUL DEVELOPMENT EFFORT

Prioritize. Ruthlessly. Your new idea is innovative and exciting. You're passionate about it. It's at the leading edge of science, and you bring 20 years of experience in the field. But, is your product viable?

- Does it fit your company's business strategy, or will it confuse investors and divert resources?
- Is there a market for it? Do physicians and patients need it? Want it?
- Is it approvable? Across countries? Across continents?
- Is it reimbursable?

- Can you recoup your investment — and make a profit?

Whether you're big or small, you can't afford to spend money on a nonstarter. Before sinking thousands and then millions of dollars into your new product, you need to establish an objective process to identify whether it can truly travel the distance. Go/no-go decision making takes place not just at the beginning, but at defined junctures throughout the product's development. Such a process, once established, can then be used as a template to adjudicate future product candidates.

Identify your risks. No one wants to think about what could go wrong. It's theoretical. It takes time. It's unsettling. It's also critical to preventing costly missteps, not just during development but through the approval process and launch.

What if ...

- Investigators submit sloppy documentation?
- Vendors are late with supplies?
- The FDA wants more safety data?
- Your manufacturing process is unreliable?

Objective risk planning includes identifying potential project risks, qualifying each by probability and negative impact, and then determining how to 1) mitigate the

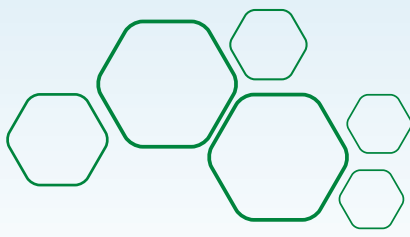


risk or 2) respond to it, should it occur. If you do hit a bump, reexamine the plan before taking action: Does the real-world situation warrant the response you prepared? Or do you need to modify it?

Plan with care. Execute with rigor. Sounds basic. But that's where the rubber hits the road. Mapping interdependent tasks and people within and across internal functions and external suppliers enables you to coordinate a complex web of activities. An airtight project plan defines what's to be done, day by day, person by person. Then — perhaps most important — driving those activities each day, managing issues promptly as they arise, keeps the project on track.

Some questions to answer:

- Now that you've mapped your process, where are the gaps? The bottlenecks?
- Where and how can you compress your timeline? What are the risks of doing so, if any?
- Are the right people on your team? (A degree or title is not necessarily the determiner.)
- Who does what, and when?
- Do you have a system in place to objectively handle conflicts?



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LAUNCHING THE RIGHT PRODUCTS DOWN THE DEVELOPMENT HIGHWAY

A global healthcare company had sunk more than \$10 million into an exciting new point-of-care product before they killed it in late-stage development when they realized their production costs would make it unprofitable. In addition, several products that made it to the market weren't doing so well. The firm knew it needed a more market-driven process to help guide product development, rather than hoping that "if we build it, they will come." In response, using a project management framework, the company built a structured but flexible process to evaluate the business case for each product candidate coming down the line.

Performing an extensive stakeholder analysis. More than 50 people were interviewed to assess the company's current product development process. Who's involved across the organization? What are their roles? How do decisions get made to advance a project, to allocate funding? How do teams collaborate across functions? What works? What doesn't?

Establishing a metrics-driven process. Using the results from the stakeholder analysis, the company better defined its product development phases (or stages). One area of focus was to incorporate more input by regulatory agencies and end users. Their feedback not only enabled the company to develop more customer-focused products, but also served as a reality check on a product's commercial demand. The firm set clear roles and responsibilities for internal players: who "owns" which activity, who contributes, and the metrics they must meet at each stage. For example, in an early phase, manufacturing costs should be estimated to 75% accuracy. But at a later stage, cost accuracy must be 90% — or alarm bells ring. At the end of every stage, if the product does not meet objectively defined marketability, manufacturing, regulatory, and other requirements, the management team can kill it and reallocate funding to more promising prospects.

SKIRTING THE POTHOLES AND ARRIVING SAFELY

A biotechnology startup had in-licensed a Phase 3 oncology biologic meant to treat some of the toughest forms of cancer. Facing considerable hurdles, the company used a project management approach to assess and mitigate its risks.

Risk #1: Lagging patient enrollment. The patient population was not only small, but the study required painful surgery, a deter-

rent to participation. In addition, other companies competed for the same patient pool.

Solution: Assessed risk/benefit of conducting trials in additional countries around the world. In the end, multiple sites across 10 countries participated in the study, boosting the enrollment rate.

Risk #2: Inaccessible data. The company required NIH data on the compound to complete its dossier. But the data were scattered across multiple repositories and difficult to locate, especially with no single NIH "owner."

Solution: Hired a physician to be placed at the NIH and work peer-to-peer with government researchers to successfully secure and compile the required study data.

Risk #3: Additional study requirement. Because a new third party, not the innovator, would be manufacturing commercial supplies, the FDA may (or may not) have required a bridging study to show process and product equivalency, making time and resource planning difficult.

Solution: Requested Type C meeting with the FDA to confirm equivalency requirements. No bridging study was required, and the meeting also served to

resolve a CMC (chemistry, manufacturing, and control) issue that had emerged in the interim.

Coordination on overdrive. To make matters even more complex, the company was "virtual," with only a handful of employees. Nearly all services were outsourced, from safety and analytical experts to the CRO and IP counsel. Teambuilding and intense hands-on coordination brought the compound successfully through to regulatory approval.

The road to successful product development is rarely straight and smooth. Project management can act as both navigator and mechanic, providing added security during a difficult journey. ●



About the Authors

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