

# 10 | *Tips for Leading Successful Medical Device Development Projects*

*Overseeing the development of a new medical device is a challenging undertaking. There are many moving parts involved in the process and risks and pitfalls to navigate.*

*Based on our years of experience in helping life science businesses transform strategies into sustainable results, here are our top 10 recommendations for steering a medical device development project to successful completion.*



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## **1** Share the product vision with all team members.

A unified product vision sets the appropriate expectations for stakeholders and provides a singular target for the product development team. This vision is the basis for defining the marketing requirements. Confirm that the key executives and stakeholders are aligned on the product vision. Include the Lifecycle Management strategy and document it in the project charter. Revisit this with the team throughout the project to ensure that the project scope and the vision are always aligned.

## **2** Build a sound business case.

Ensure there is a clear business case with buy-in from senior leadership and that the medical device is not simply a “cool concept” dreamed up by R&D or Marketing. The business case, and thus the product itself, should also fit within the organization’s overall business strategy. The business case should be at a high level early in development (Ideation/Phase-0); refine and iterate it to include better information and hard data as the project proceeds through development to focus the scope and ensure the product remains viable for the marketplace. Include a clear definition of the economic value and the reimbursement model and update it to reflect consequential changes that occur in the market during development.

## **3** Appoint a project manager with strong leadership skills.

A high-functioning device development team requires a dedicated project manager with outstanding leadership skills. Not all project managers possess the necessary leadership skills. Good leaders must be able to communicate a clear vision of success, influence cross-functional team members without direct authority, make difficult or unpopular decisions, motivate others, listen and influence, build the team, anticipate and solve problems, establish and maintain a sense of urgency, and interface confidently with all leadership levels within the organization—all while sustaining a positive attitude and maintaining integrity. The project’s success depends on the team’s success—and the team’s success depends on the leadership.

## **4** Keep an eye on the big picture.

Each medical device development project has specific deliverables which must be completed, not merely for the sake of completing them, but to move the product towards a successful commercial launch. As the project is underway, always maintain the big picture perspective. Focus on the end goal and why the company has undertaken the project and keep team members aligned on the big picture. Project team members often have only the limited perspective of their own functional areas, so it’s not enough to only share the product vision at project initiation. It’s the project manager’s responsibility to ensure all elements of the project are working in concert to achieve the big picture.

## **5** Keep the manufacturing and production functions in the loop.

Address manufacturability and product scale-up from the onset and throughout product development – rather than as a late activity or worse, an afterthought. Remediating unexpected problems in these areas becomes more costly and time-consuming as the project approaches transfer-to-manufacturing. Involving the manufacturing and production teams early in the process will lower both project- and product-related risks, reducing unexpected project costs and minimizing delays to product launch.

## **6** Fail fast, learn fast.

Identify those elements of design that represent major challenges and/or are reliant on technological breakthroughs. “Dissect” these to better understand the feasibility of overcoming these obstacles. Perform rapid design iterations during the feasibility or early research phase of product development, before entering the formal design control phase. Provide Marketing with mock-ups and functional device prototypes to test with potential users or focus groups to provide real data for decision making before locking down user needs and design inputs.

## **7** Keep the design history file focused.

If your product development process doesn’t already do so, ensure that your organization’s business process documents are maintained separately from the formal Design Control documents. Limiting the design history file to only the essential documents applicable to the device’s design and development will keep regulators focused on the most relevant information during potential audits.

## **8** Keep most decision making at the core team level.

Always present options for solutions to risks or issues; never approach management with a newly identified project or product risk or other issue connected with the scope, schedule, or budget without one or more potential solutions. This proactive approach to problem-solving will retain more decision-making power within the team and confirm to management that the team is responsive and in control.

## **9** Stay true to the user needs.

The user needs and marketing requirements are most effectively translated into product requirements (or device or engineering specifications) through periodic reviews. During development, as requirements from various functions (e.g. regulatory, manufacturing, etc.) are more clearly understood, append or elaborate them in the specifications as required. This keeps the design on track with the user needs and marketing requirements and embeds the product requirements in the design verification and user validation protocols to come, which will themselves be iteratively elaborated. Using a model such as the “V-Model” of systems development can help to effectively map the user needs and marketing requirements to the final product requirements and device specifications through verification and validation.

## **10** Escalate only when required.

Develop a detailed communications management plan that defines how the complex flow of project communications will be managed, ensure it is followed, and update it as required. The plan must outline a clear escalation path to ensure that issues are remedied or elevated in an efficient and timely manner. However, the project manager should use diplomacy and negotiation to resolve issues internally before resorting to escalation. When escalation is warranted, the presence of a clear path, agreed upon in advance, provides the means to resolve issues and save time without immediately raising to higher levels of authority.

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