



## Reengineering medtech R&D

Innovation by medtech companies gave the world life-saving devices such as dialysis machines, pacemakers and defibrillators. Now these companies need help of their own to address several disruptive changes in the market. Their R&D models can still achieve game-changing innovations—but only if they reengineer them to respond to two new market forces.

**New customer buying behavior:** In the past, a physician's preference greatly influenced which medical devices were bought and which were not. Today, individual physicians wield less and less influence due to structural changes. Many physicians now work for hospitals or group practices that are aligned with larger medical centers. In turn, hospitals—acting as “economic buyers”—are using their purchasing clout to drive down costs, particularly in high-end product segments such as knee implants and implantable cardioverter defibrillators.

As a result, across multiple product categories, prices are starting to tumble. For example, annual price declines have reached double digits for drug-eluting stents for which hospitals perceive little product differentiation. A number of key medtech product categories suffer from the “generics effect”: the performance difference between leading products just isn't evident. Changes in payment models will likely accelerate this price pressure. Bundled payments, for example, cover full episodes of care—including device costs and doctor's fees. The consequence: physicians are increasingly motivated to preserve their income by lowering the device costs.

**Rising regulatory hurdles:** It's increasingly costly and complex to bring new medtech products to market. The US Food and Drug Administration (FDA) requires clinical trials—the pre-market approval path—only for Class III medical devices, which have higher levels of complexity and patient risk. Now the FDA is revamping its regulatory pathways and applying greater scrutiny to a much larger set of products, including products classified as Class II. The FDA is also intensively investigating quality issues, as reflected in the industry's rising number of consent decrees and product recalls. In 2001, the FDA recalled just three devices. In 2009, the number jumped to 31 (see Figure 1).

These regulatory headwinds pose a major challenge. Medtech companies must now plan and budget for longer, more stringent product development—with no guarantee of approval at the end. A stent clinical trial, for example, can cost tens of millions of dollars and stretch over several years. In effect, the cost of entering—and staying in—markets has gone up, so companies need to respond.

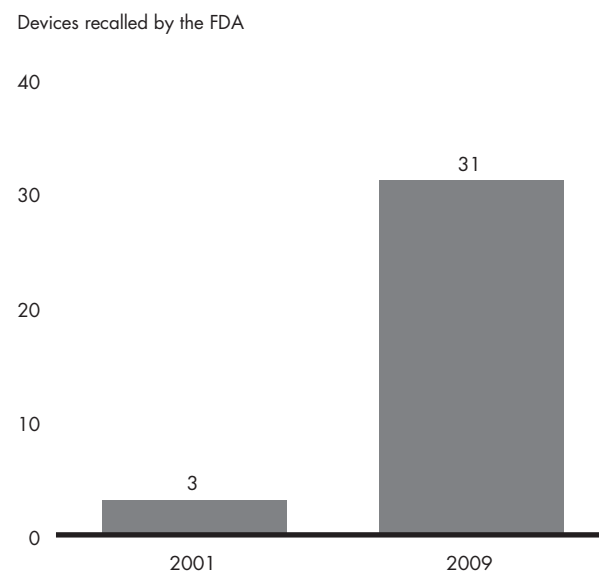
## Rethinking the “what” and “how” of R&D

Increasingly, leading medtech companies tell us that they see the need to fix their R&D models. But their challenge is: where do they start? Do they focus externally on understanding the new customer needs? Or should they concentrate on revamping processes internally? Our belief is that to lean completely into the new medtech R&D opportunity, companies will need to do both.

## Start with what customers will pay for

To thrive in this changing market, medtech companies must closely align their innovation with customer willingness to pay. For this, they must consider two steps.

Figure 1: Higher hurdles for medtech devices



Source: FDA website

The first involves a choice, as medtech companies have reached a fork in the road. One path is to step up innovation and develop products with greater value. These will not necessarily have the latest features and benefits. Rather, they'll differ in that they'll offer clinical evidence showing superior efficacy, safety and cost-effectiveness versus their competitors' products. Some will even have data demonstrating superior outcomes for patients. It's an approach similar to one taken by pharmaceutical companies. Faced with the acute threat of generic drugs at much lower prices, these companies are starting to prove—and price—the comparative effectiveness of new drugs. For example, Merck has a performance-based contract with CIGNA for its oral anti-diabetes medications Januvia® and Janumet®. Merck offers discounts to CIGNA's customers if the patients adhere to their physicians' prescriptions and their blood sugar levels improve. The other path is to step down innovation and develop products with fewer features but good-enough performance that sell at lower prices. Such value-based products are common in other industries, and they will arrive soon in medtech.

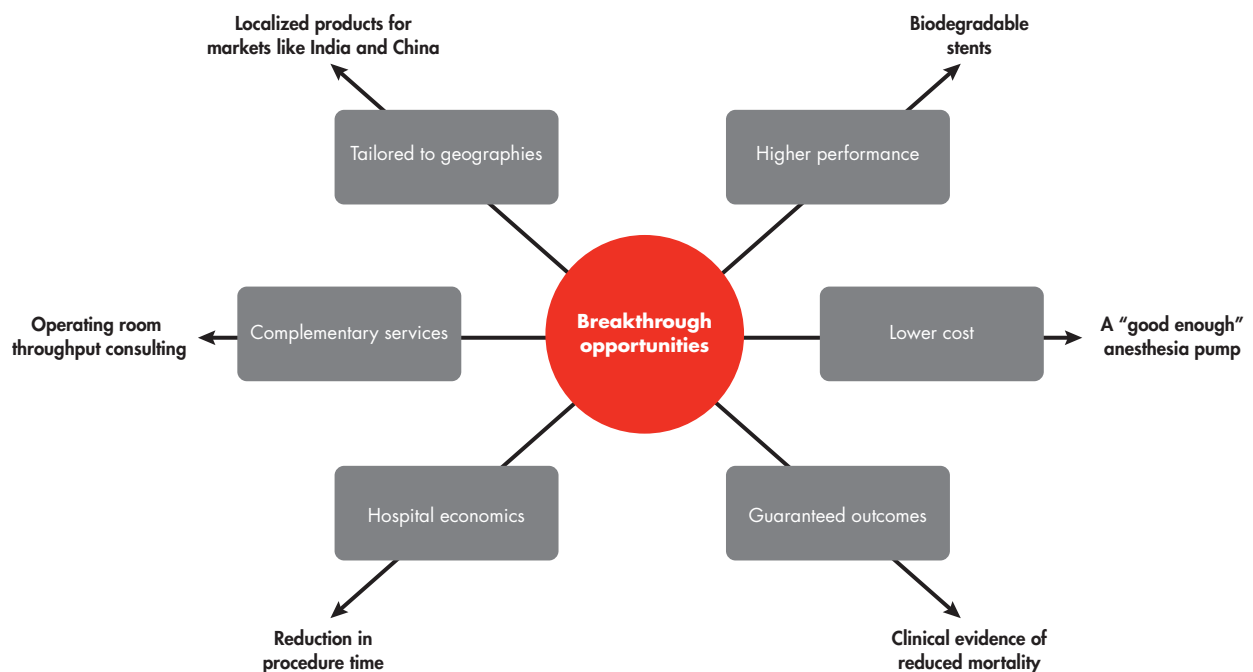
Medtech companies must choose, as staying the course—that is, investing heavily in incremental innovation—

is not an option. Going down both roads is possible, but only if the company has the resources and capabilities to win in both categories of breakthrough and good-enough innovation. What's most important is making the choice, and acting on it (see Figure 2).

The second step, a logical follow-on, is for a medtech company to X-ray its pipeline. Projects that don't fit the chosen path of innovation must be redefined or canceled. For example, some projects will be caught in the middle: derivative projects offering the promise of modest efficacy improvement, but requiring costly clinical trials to clear regulatory hurdles. They will arrive in the market as neither the innovation nor the low-cost leader.

Another critical component of the pipeline X-ray is reviewing business development issues. The hard question must always be asked: Is the company better off making or buying the next technology? The answer lies in understanding the company's distinctive competence, plus the external landscape of innovation. When working in collaboration, R&D and business development can make an informed decision about where to spend the company's innovation dollars.

Figure 2: Medtech companies can take multiple paths to breakthrough innovation



Bain experience in helping medtech companies X-ray their pipelines indicates that up to 25 percent of projects typically must be reconfigured or stopped. These actions free up scarce funds to double down on projects that do survive the rigorous scrutiny.

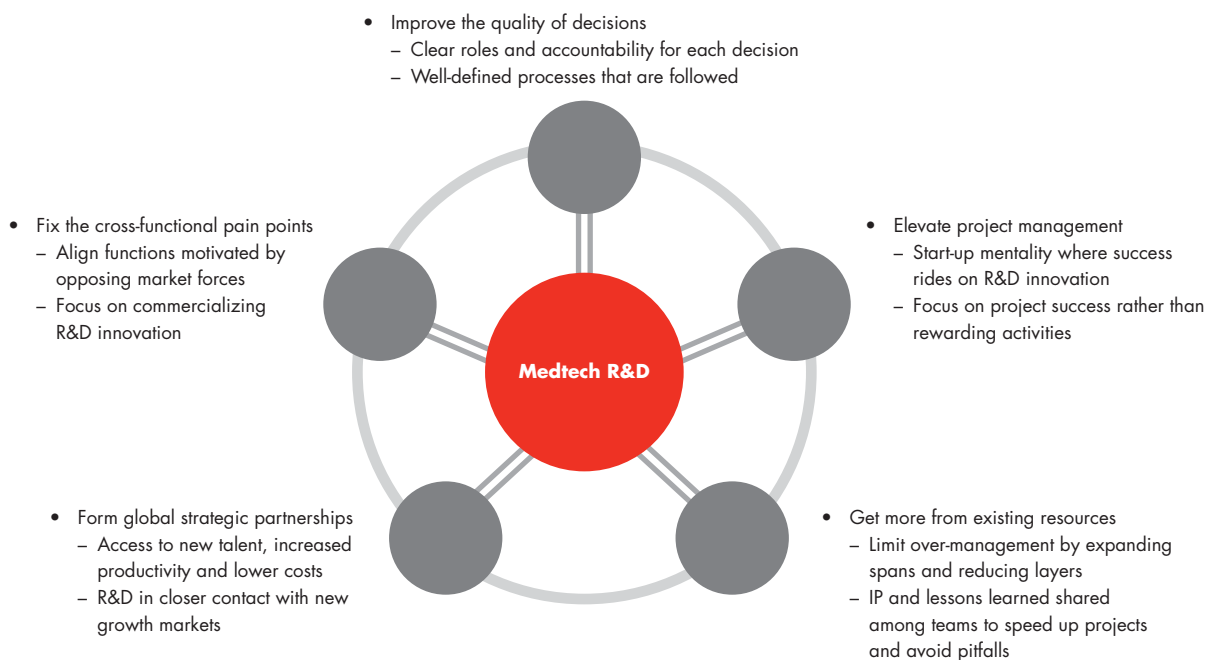
### Rethink how to develop the product

In our experience, five levers are key to reengineering R&D for major gains in efficiency and effectiveness (see Figure 3):

- Improve the quality of decisions:** Every medtech company has a PDP (product development plan) with major milestones and activities in place. But the PDP doesn't drive success; good decision making does. What companies need are clear decision rights—who owns the inputs, who synthesizes the recommendations and who makes the decision—with processes that are well defined and adhered to. In the absence of these elements, decisions take too long or are made poorly. This leads to late project cancellations or “go” decisions for products that don't actually merit investment because they won't truly meet customer needs.

- Elevate project management:** Large companies need to recapture the spirit of start-ups where everything rides on R&D success—and project managers are the heroes who get products over the finish line. As many R&D organizations have grown, they have tilted too much toward functional structures that focus on optimizing activities instead of project success. To rebalance, a medtech company can start by installing a senior head of project management and a team of highly skilled project managers who have leadership responsibility and budget authority. Next, the company can embed all the elements that make project management work, including committed cross-functional team members, metrics and incentives tied to project success, and a rigorous cadence of project reviews with the C-suite to drive accountability.
- Get more from existing resources:** In most leading medtech companies, R&D organizations are well stocked with resources—people, assets and knowledge. Typically, in these companies, adding more resources isn't what's needed. Rather, the more common problem is over-management and over-capacity that can clog the pipeline with activity

Figure 3: Five levers to revamp medtech R&D and address changing market needs



and delay progress. In our experience, companies can do more with less. They can expand spans and reduce layers of management; set tougher performance hurdles; utilize centers of excellence to promote IP sharing and new ideas for technology combinations; and capture and reuse knowledge so that teams start faster and avoid previous pitfalls.

- **Form global strategic partnerships:** Outsourcing vendors are maturing rapidly in the medtech space. Traditionally, clinical research organizations such as Quintiles, Parexel and PPD focused on biotech and pharmaceutical customers; now they are shifting attention to medtech as a new growth frontier. And hardware and software engineering vendors such as Infosys, HCL and Wipro that built competence serving the aerospace and automotive industries are investing in healthcare. This is an opportunity for medtech companies to form strategic partnerships, including expanding their reach into India and China. This move will broaden their access to new talent, increase productivity and lower costs, plus bring R&D in closer contact with new commercial growth opportunities, particularly value products in emerging markets.
- **Fix the cross-functional pain points:** R&D is always intertwined with marketing and regulatory, quality and manufacturing functions. Now companies

need to find ways to strengthen these cross-functional linkages because opposing forces are straining the bonds. Marketing tries to capture the new “voice of customer” that comes from hospital procurement. The regulatory department responds to FDA pressure and new hurdles for approval. Quality control is busy trying to prevent warning letters and product recalls that immediately damage businesses. Manufacturing redesigns its plant network to take advantage of lower costs and higher tax benefits in emerging markets. Various forces tug at each function, straining their ability and willingness to work seamlessly together on product development. Alignment is thus critical, or else all the hard gains made in R&D are washed away by the enormous time and cost burden of cross-functional breakdowns.

Pulling these five levers means transformational change in R&D, and such change takes time. Most medtech companies can expect to realize the benefits from reengineering R&D only after several years. But companies need to make these fundamental changes to stretch their R&D dollars and meet the shifting needs of customers. For medtech leaders, it’s a call to action. By showing vision and confidence, making tough choices and inspiring the organization, they can fix the “what” and the “how” of R&D.

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