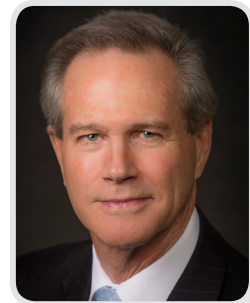


15 KEYS to Medtech R&D Success

Research and development is the lifeline for all medical device companies, large and small. While some rely more heavily on the “R” and others on the “D,” together these functions fuel the industry’s product innovation pipeline. Here Medtronic’s former CEO outlines what he sees as the critical elements of a successful R&D program, borne out of his 30 years of industry experience.



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The following is the text of a presentation that Art Collins, the former CEO of Medtronic plc, gave to a group at Northwestern University’s Kellogg Graduate School of Management in Chicago. R&D presents different challenges to large and small medtech companies, but all product companies and the industry as a whole share a reliance on ensuring the success of such programs. Collins has distilled from his three decades of experience in the medical device industry a set of key factors intended to help all product companies increase the success of their respective R&D programs.

When my friend Pete McNerney asked me to be the speaker at a recent Kellogg Graduate School of Management event in Chicago, I gladly accepted. The luncheon was attended by about 60 students representing the schools of business, law, engineering, and medicine, together with faculty and representatives of a number of local businesses and friends of Northwestern University. “What Are the Keys for Successful Research & Development (R&D) and Innovation in the Medical Technology Industry” was the topic Pete gave me.

In preparation, I grabbed a handful of index cards and decided to jot down some of the lessons learned during the more than three decades I spent at Abbott Laboratories and

Medtronic, as well as a four-year stint at Booz, Allen & Hamilton early in my career. I also added a few observations from my current role as a director on the corporate boards of Alcoa, Boeing, Cargill, and US Bancorp. As I remembered one “do” and “don’t” after another, I started to run out of index cards. I finally decided to cap the list at 15.

Several students and professors suggested I write down my comments. What follows is a reasonable representation of what I said at Kellogg, with a few additional thoughts that came to mind after the fact.

Three disclaimers are in order. First of all, the list that follows is not exhaustive. There are many addi-

tional keys to success that I or other individuals familiar with the field could include. However, I believe that most of those items are either related to or are a subset of the original 15. Secondly, much of what I learned came from experts who had plenty of firsthand knowledge and wisdom, or rather, they gained it the hard way by making a mistake and learning from it. Finally, innovation and discovery are certainly not static—particularly in the areas of biotechnology and information technology (IT)—and neither should be the list I developed. As technology evolves, so does the attendant knowledge that ultimately translates into best practice. That said, let’s get on with some lessons I’ve learned.

1

While organizational structure and process count, creative and motivated people ultimately make the difference

Any successful group (R&D or otherwise) needs some degree of structure and a minimal set of “rules” that govern the activities to be undertaken. However, if the organizational structure and the policies and procedures that are put in place start to take priority over making sure that the very best people are recruited, motivated, focused on a goal, and incented to succeed, innovation will soon be stifled. Specifically, beware of complex organizational charts and reporting relationships, a plethora of forms and reports to be completed, and other activities that distract the people needed to accomplish critical work. In fact, the most successful R&D programs and new product launches I’ve witnessed have been structured around what needed to be accomplished, rather than around any pre-existing organizational structure. While I was at Abbott Laboratories, it was not

uncommon for the Diagnostics Division to staff “tiger teams” with some of the best employees from various parts of the existing organization in order to increase focus on the launch of new products. We managed tiger team operations from “war rooms” with status boards on each of the walls, providing continual updates to employees in the field, back in the R&D labs, and at headquarters. At the conclusion of these new product launches, the tiger teams would be disbanded and the team members would return to their original duties and respective organizations. This process was utilized when in 1988 Abbott introduced the *IMx*, an immunodiagnostic testing system that performs a number of diagnostic assays for infectious diseases and physiological functions. The *IMx* launch is still regarded as the most successful in the history of the medical diagnostics industry.

2

The popular concept of “Too Big Too Fail” that has been used to describe some mega banks can be modified to read “Too Big Will Fail” for most R&D organizations

“Big” is definitely not “best” when it comes to R&D organizations. Even in organizations that collectively employ thousands of scientists and engineers, small teams working independently or in collaboration have proven to be the most effective. Although experts may argue as to whether teams numbering anywhere from single digits to 20-30 are most optimal, they tend to agree that the size is generally not in the hundreds. While I was at Medtronic, we were constantly breaking apart the largest R&D organizations. For example, Cardiac Rhythm Management, a business dominated by pacemakers treating bradycardia and heart block, spun off a number of

new organizations to address ventricular tachycardia, atrial fibrillation, heart failure, and other electrical abnormalities of the heart, all of which wouldn’t have evolved as quickly if they had remained as a less important part of the “mother ship.” Also, while face-to-face communication is always preferable, virtual teams that are connected by advanced communication technology can be very effective. Finally, and segueing to Lesson Learned #3, it is my strong belief that the risk of incurring counterproductive bureaucracy tends to increase proportionally with the size of an organization, particularly if the function is centralized at the corporate level.

3

Beware of excess layers of bureaucracy and unnecessary meetings—if an activity or structure adds value, streamline it; if not, get rid of it

I am convinced that expanding bureaucracy can become a cancer in any organization, and it should be struck down whenever it appears. Time devoted to burdensome administrative activities and any meetings that don’t enhance R&D efforts are both counterproductive and frustrating to R&D team members and anyone else involved in the process of innovation. Before each meeting commenced at Medtronic, it was common practice to reconfirm why the meeting was being held in the first place, specifically what decisions and other actions were to be taken, and why all the allotted time was necessary. As an aside, any meeting I chaired (or attended) started on time and ended on time or early, whether or not all the invited attendees were present. A leader should never be afraid to cancel or truncate a meeting that is ill defined, too long, or unproductive. Another useful rule of thumb is to review periodically all key administrative activities and the organizational structure to determine if they are adding value. If the answer is “yes,” then great and go ahead and streamline it; if the answer is “no,” then don’t waste your time and just jettison it.

4

Listen to your customer, and ALWAYS clearly define what problem you are solving BEFORE commencing any R&D project

While basic research for the sake of science is appropriate in some academic research settings, R&D efforts in support of new commercial products require customer input and a clear definition of what problem is being solved. Product design goals are best set if viewed through the eyes of the customer; they should be quantitative, measurable, and put in place before the R&D efforts begin. In order to move forward with the development of a new medical device, service, or procedure, Medtronic required management to demonstrate that there would be a measurable improvement in medical outcomes, a reduction in the cost of care (immediately or over the life of the product), and a customer preference over what is in the market already. The magnitude of the financial payoff, assuming a successful new project launch, was always

a consideration at Medtronic, so quantifying the unmet market potential, the degree of technical risk, and probability of market acceptance were always part of the decision-making process. One cautionary note comes from author Clay Christensen, a Harvard professor I had speak at Medtronic on several occasions. In a book he authored, *The Innovator's Dilemma*, Clay argues that sometimes successful companies fail because they reject a breakthrough technology that doesn't necessarily meet customers' currently expressed needs, but that can fulfill a future need that customers (and consumers) haven't yet identified. Classic examples include the unreliable first automobile being scorned by satisfied horse and buggy owners, or more recently the iPod (utilizing mini hard drives) and several other Apple products.

6

Since every new product has a defined life cycle and endpoint, time to market is critical for overall success

A recognized but often-forgotten fact is that every new product has a predetermined lifecycle (i.e., introduction, growth, plateau, and decline) and endpoint. Either your organization will obsolete the product or competition will do it for you. Knowing this, time to market is critical because lost time and revenues can never be regained. Everything that has been discussed so far, and that will come afterward, is directed at not only hitting the mark when the new product is introduced, but also at getting the new product to market as soon as practical. The normal tradeoff made between exceeding every design goal and missing deadlines is healthy, and balancing these tradeoffs always requires discipline and often leads to difficult decisions. This concept was repeatedly applied when products were developed and launched while I was at Abbott Diagnostics and Medtronic, and it came into play recently when Boeing announced the 737 Max. In order to

shorten the time to market and maintain its competitive position versus Airbus in the large and growing single-aisle commercial aircraft market, Boeing management decided to shelve the idea of developing a completely new airplane to replace the highly successful 737. Making this decision took into account the risk of development, the financial impact over the new product's expected life, and the desires of all the major global airline customers. By the way, this decision was widely applauded by Boeing's customer base and the investment community, and the development timeline for the new and improved 737 Max continues to proceed on time and on budget. One factor that can help extend or shorten a product's life cycle is the degree to which an invention is protected by intellectual property (IP) in major world markets. We took this very seriously at Medtronic, and it was common to conduct patent searches and to aggressively file global patents to protect our IP.

5

Only invent what is required: greater invention (both amount and magnitude) = greater complexity and risk

Innovative people like to invent, but not all successful new products need invention at every turn. In this regard, never forget that simplicity is always preferable to complexity. Another helpful rule of thumb to remember is that complexity, time to market, and risk to a successful product introduction all increase with the amount and magnitude of invention undertaken. While there definitely are cases where a new technology will be required to meet some critical design goal, the first question should always be whether an existing technology could be reused or repurposed to meet the objective. To reinforce this idea, Boeing created the Replication Award several years ago. This award allows employees to receive the same recognition for doing a great job of reusing an existing technology as they could by inventing a new one. While every R&D team needs core expertise, they don't need all of the requisite skills to be in house. In fact, sometimes the best and most cost-effective expertise resides outside the organization and will need to be purchased. This thought will be further expanded in Lesson Learned #10.

7 Include early input from those who will eventually bring the product to market (e.g., clinical & regulatory, manufacturing & distribution, marketing & sales, etc.)

Unlucky and unwise are the R&D organizations that think they alone know everything, and worse yet that end up “tossing” their invention “over the wall” to those who will need to launch and support the new product in the marketplace. Remember that a new product’s success is not just measured by time to introduction, but by its success in satisfying customer needs over the product’s lifecycle. For example, at Medtronic we recognized very well that each new medical device we developed had global market potential and required regulatory and reimbursement approval. As a result, a new product had to pass muster with the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) in the US, together with their counterparts overseas, before it could be launched. Similarly, if a new product wasn’t effectively marketed and sold, it would never reach its full potential. Finally, if significant demand was created and the company couldn’t reliably and cost-effectively manufacture and distribute the product at scale, customer goodwill would soon turn to ill will. Yes, wise is the R&D team that understands the power of cross-functional collaboration.

8 Clearly define objectives, assign authority and responsibility for key activities and decision-making, and always focus on the critical path items

Any high-functioning team needs to know the answer to a few basic questions. For example: What are our objectives? Who is responsible for what? Who has decision-making authority, and when and how will key decisions be made? If no one is in charge, nothing will get done; if everyone thinks they are in charge, chaos or inertia is likely to ensue. While most R&D projects have multiple important activities to track and accomplish, those items on the critical path to success need

special attention and should be prioritized. Needless to say, the critical path items are likely to change as time passes and the finish line comes closer. I can’t think of a new product I tracked while at Abbott or Medtronic, or as a member of the board of directors at Alcoa, Boeing, Cargill or US Bancorp, where the following question wasn’t asked of the person presenting the status of a development program: “What’s on the critical path, and what’s keeping you up at night?”

9 Be aggressively realistic with schedules—create a sense of urgency, but remember that “all green lights” scenarios hardly ever happen

The words “aggressively realistic” may seem like an oxymoron, but the concept is important when setting objectives and timetables for completion. If unrealistic stretch is incorporated into targets, people may give up and become disheartened. If targets are too easy, the team will never reach its full potential. The sweet spot is finding the per-

fect middle ground that motivates and challenges team members, while at the same time minimizes the chances of failure and resulting disappointment. Even though contingency buffers and plans are useful tools when setting external expectations, they should never be used as crutches for “sandbagging” internal targets.

10 Don’t be afraid to go outside for expertise if it is needed, continually guarding against the “not invented here” syndrome

One unfortunate trait of inexperienced R&D leaders and teams is to think that they must do everything themselves—the “macho man” or “not invented here” syndrome. It is neither a sign of weakness nor incompetence to go outside the team or organization to obtain needed expertise; it is a sign of strength and competency. Not only can external experts sometimes be a better option to solve difficult problems, they also can shorten timelines and be more cost effective over the long-term. In a recent example, Boeing elicited significant outside academic and industry experi-

ence in dealing with a lithium-ion battery issue, reducing both the time and cost to implement the ultimate solution. However, one final warning—team leaders should never abdicate their leadership responsibility to management consultants or other outside surrogate leaders. I can tell you from experience having sat on both sides of the table that even though management consultants can bring independence and do sometimes serve a useful purpose, they rarely have as much insight and never have as much skin in the game as do competent in-house leaders.

11

Killing a project that will never be successful does not equate to failure; R&D teams should be rewarded rather than punished if they recommend this course of action

Not all R&D projects are destined to succeed. Recognizing that there are always limited resources (financial, human, and otherwise), senior leaders would always rather redirect resources to more promising endeavors than stick with a losing proposition. Wise leaders also encourage team members to bring unvarnished news forward, even if it is bad news, because downside surprises that could or should have been dealt with earlier are always costly and never welcome. Finally, R&D teams should be praised and rewarded rather

than ridiculed or punished if they recommend their own project be terminated because, despite their best efforts, success is not likely and resources could be better deployed. Near the end of my time as chairman & CEO of Medtronic, I remember the positive reaction in the R&D community when my executive staff publicly praised the senior vice president for medicine and technology when he recommended that we kill his favorite pet R&D project because the technical risk was too great on too many dimensions.

12

Attempting too many projects at once generally ensures that none of the projects will be successfully concluded

Experienced R&D leaders have learned the value of focus, and they recognize that having too many projects underway generally ensures that none of the projects will be successfully finished on time and within budget. It is particularly important to consider the changes in human resource requirements and the financial “burn rate” over the expected duration of a project; for example, a stable of early-stage projects may not be overwhelming at the beginning, but as the

projects progress and require more resources, they may collectively become untenable. This discipline was repeatedly used at Medtronic during the annual operating plan and strategic plan reviews. As a result, existing and potential R&D projects were evaluated and prioritized, after which some were accelerated, delayed, canceled, or postponed. Here again, it is much better to plan well and prioritize early, rather than to face tough start-and-stop decisions later on.

13

Encourage people to attack ideas, but never each other—this is very easy to say, but hard to put into practice

The best solutions often result after different points of view have been put forward, vigorously debated, and winnowed down to the most viable alternative. “Group think” can be dangerous, and it is more likely to occur if leaders don’t lead by example and foster open communication which encourages differing opinions to be expressed and appreciated. No one likes to be personally attacked, particularly less aggressive individuals, so some team members may be reluctant to speak their mind if they think they will be ridiculed for taking a contrary view to the general consensus. I remember sitting in on a product design goal review when a new manager who had been recently hired from a well-respected Fortune 100 company couldn’t resist repeatedly belittling anyone who disagreed with his position. Even though this person was certainly entitled to his view, his behavior was completely counterproductive and inconsistent with the Medtronic culture, and I later learned that he lasted less than six months. While spirited debate is a strength and should be encouraged in any healthy organization, once debate has taken place and a final decision has been made, it is important that all team members get on board and support the chosen course of action. What I have just recommended is very easy to say, but hard to put into practice unless a leader “walks the talk” each and every time.

14

ALWAYS comply with existing laws and regulatory requirements, and **NEVER** sacrifice safety

To my knowledge, the perfect product has never been invented or introduced. Given additional time and more resources, most R&D teams could improve upon the current version of what they have designed or developed. As discussed previously, tradeoffs between product performance and time to market inevitably must be made. However, when those tradeoffs are made either before a product is launched or when issues are identified post-launch, there are certain inviolable principles that must be upheld. First, a product and the associated activities surrounding its manufacture, regulatory approval, sale, and use must comply with all existing laws and regulations in applicable geographies around the world. Second, product safety (and the safety of


those who manufacture, distribute, and utilize the product) should never be compromised. Recognizing that there are few if any 100% risk-free surgical procedures or attendant medical devices, one “acid test” used while I was at Medtronic involved the question: “Would I recommend that my parent, spouse, or child be given or continue to use this product?” Over my career, I have witnessed more than one competitor make what they thought was an expedient decision to bend the rules on product quality or legality, only to see that decision later result in a significant loss of market share, a fine or other legal penalty, and in one case the demise of the company. The bottom line here is that ethical behavior always wins in the long-term.

15

Don't forget to celebrate individual and team victories (both large and small) as they occur—and while you should take what you do very seriously, don't take yourself too seriously!

Morale is an important determinant to the success of any organization, and successful R&D rarely happens without hard work and a series of frustrating problems or setbacks that must be overcome. These large and small “road bumps” can be extremely frustrating (on a one-off basis and collectively), and it is important to help keep morale high by celebrating the corresponding individual and team victories as they occur. These celebrations don't need to be elaborate, and they can be as easy as handing out “on-the-spot” awards or holding spontaneous pizza parties—it's the thought and the sincere recognition that counts, not the amount

of money you spend. Considering that the successful outcome of many R&D projects directly affects the quality of people's lives, and sometimes makes the difference between life and death, the work of R&D team members is serious. Correspondingly, R&D team members and their colleagues should take their responsibilities and what they do on a day-to-day basis very seriously, but not themselves too seriously. In short, it is important for team members to maintain a sense of balance, check their egos at the door, support each other, keep a good sense of humor (particularly in the darkest hours), and have some fun along the way!

Art Collins is the retired chairman & CEO of Medtronic plc. While at Medtronic, Collins also served as chairman of AdvaMed, the medical technology industry association. He is currently a member on the boards of directors at Alcoa, The Boeing Company, Cargill, and U.S. Bancorp, where he also serves as lead director. In addition, Collins is a senior advisor to Oak Hill Capital Partners, a private equity firm, as well as managing partner of Acorn Advisors, LLC, a consulting firm to nonprofit institutions. 



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