

Looking Beyond the Product: How Top Medical Technology Companies are Engineering Solutions, Not Just Devices, for Competitive Advantage



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TABLE OF CONTENTS

Introduction 4

Medical Technology Solutions..... 4

Trends Driving the Engineering of Solutions..... 6

The Challenge of “Engineering Solutions” 8

A Company “Engineering Out of the Box” 9

Case Study: Scaling Up Innovation at Endo Pharmaceuticals 12

Conclusion 12

INTRODUCTION

Technology alone is no longer the only source of competitive advantage for medical device companies. More companies are developing advantages based on the services, data, relationships, and overall value they can bring to customers in addition to, or even instead of, the devices themselves. The industry is already witnessing a transformation away from product to solution-based business models in some segments. This important trend demands a different approach to R&D that takes a more holistic and long-term perspective, forcing developers to “engineer outside of the box.”

In this paper, we define and review examples of medical technology solutions and the trends driving the “engineering of solutions.” We then examine the challenges companies face in developing solutions-based business models. Finally, we explore how one company has created a novel approach for helping companies sell solutions, providing a case study of a business they have helped to “engineer outside of the box.”

MEDICAL TECHNOLOGY SOLUTIONS

In business innovation, a solution

...is a customized, integrated combination of products, services, and information that solves a customer problem. Solution innovation creates value for customers through the breadth of assortment and the depth of integration of the different elements.¹

Solution innovations differ from traditional conceptions of innovation; they are not an iterative change in product features. In fact, the development of solutions requires a change in focus from product features to product benefits. Companies must ask, “How can we position our product to solve a larger, systemic problem?”

Solutions have most commonly been developed in those segments of the industry that are more data intensive or may benefit from more data. The value in a solution is tied to data management streams so that customers are able to make better decisions. And companies sometimes tie their business model to the success of the solution for their customers.

Often, a solution is based upon the integration of a medical device and software for managing data derived from the device. However, solutions may also be developed from the integration of software with pharmaceuticals or a combination of pharmaceuticals and devices. There are numerous examples of medical technology solutions already on the market (see Figure 1) that demonstrate important characteristics of solutions:

¹ Sawhney, M. et al. “The 12 Different Ways for Companies to Innovate,” MIT Sloan Management Review, Spring 2006: 78.

- Integrates software with devices and/or pharmaceuticals.
- Solves a larger systemic problem.
- Includes the gathering and management of data.
- Focuses on product benefits instead of features.

Figure 1: Examples of Medical Technology Solutions

Insulin pump and glucose monitor with wireless data connection to computer or mobile device for data analysis

RFID technology and RFID-enabled storage systems and receptacles to manage inventory

GI imaging technology with wireless image transfer and software data analytics and management

Ingestible sensors embedded in medications to monitor date and time of ingestion and physiological parameters

Telemonitoring devices and services for remote monitoring of patients in their homes

Given Imaging’s PillCam, for example, is a vitamin-sized video capsule that, when swallowed by the patient, is able to transmit images of the gastrointestinal (GI) tract to a sensor worn by the patient. As the PillCam passes through the GI tract over approximately eight hours, the patient is able to carry on with normal activities. The PillCam has a clear advantage over traditional GI endoscopy or radiological imaging because of greater patient comfort and the ability to examine the GI tract during the patient’s normal routines. The PillCam’s value to clinicians, though, is enhanced through Given’s RAPID Software Suite, which aids in image interpretation, generates reports, manages studies, and connects to a facility’s existing network. By linking their medical device with a platform for interpreting and managing the data it produces, Given Imaging has simplified the adoption of the technology for their customer.

Proteus Biomedical provides an example of a solution developed for the pharmaceutical industry. It has developed a food-based, edible sensor that they embed in medication. Once ingested, the sensor—dubbed an “ingestible event marker” or IEM—is activated by stomach acids and emits a digital signal. A microelectronic recorder captures the signal, recording data on the date and time the pill was taken, the type and dose of medicine, where it was manufactured, and the patient’s physiological parameters. This cutting-edge technology can be used to solve an age-old problem in medicine: ensuring patients take their medications. This is particularly troublesome for conditions impairing a patient’s mental faculties, such as Alzheimer’s disease or schizophrenia. But the technology also has the potential of enabling competitive differentiation in the vast generic pharmaceuticals segment.

Solutions to problems may be created around even the simplest medical devices. Retained surgical items (RSI) such as sponges and instruments, for example, are a common medical error that can result in significant postoperative complications, patient infection, and even death. ClearCount Medical Solutions has developed a solution using embedded

radio-frequency ID (RFID) chips to count and track surgical sponges. Founded in 2004, the company has received FDA approval to market two versions of its sponge counting and detection system, and is considering expanding to other markets, such as metal surgical instruments.²

The SmartSponge system reads the ID number of the tagged sponges or towels during the different stages of an operation: when a sponge is removed from packaging, used in the patient, and then discarded in a scanner bucket. In the event of a missing sponge, the SmartWand system is used to scan the patient and locate the missing tagged sponge, preventing a medical error from occurring in the surgical ward. In 2010, ClearCount, in conjunction with Aon Risk Solutions and CNA HealthPro, introduced a precedent-setting Never Event Warranty (N.E.W.), which provides hospitals with up to \$2 million for uncovered surgical costs should a tagged sponge or towel be left behind when the SmartSponge System is used. Mike Garofalo, director of Aon, stated, “This product innovation illustrates the opportunity that exists for businesses willing to take the time to understand risk and use that knowledge to differentiate them from the competition.”³ This is a particularly powerful solution when one considers that the Centers for Medicare and Medicaid Services (CMS) stopped reimbursing for the consequences of RSI in 2008.⁴

RFID technology is being used by other companies, including WaveMark, Stark RFID, and Stanley InnerSpace, to develop solutions for hospital inventory and supply chain management. WaveMark, for example, has developed a system of RFID supply tagging and RFID-enabled cabinets and scanners to monitor the inventory of expensive consumables in the catheterization laboratory. RFID technology is combined with Web-based software to solve common inventory problems: more stock on hand than necessary, expired products remaining on shelves, and frustrated staff who must manage the inventory. Hospitals pay a subscription fee for the service, while WaveMark retains ownership and responsibility for the equipment.

TRENDS DRIVING THE ENGINEERING OF SOLUTIONS

There are numerous trends driving medical technology companies to consider solution-based models (see Figure 2). The ultimate result of each trend is a change in the way innovation is conceived and done. Innovation becomes more than technological wizardry, alone, where the development of a remarkable device to solve one part of a problem is the end goal. Innovation, instead, becomes the value created by the device and the way it is integrated into the continuum of care. Innovation must demonstrate improved outcomes, and this means innovating solutions.

² ORLocate™, a product of Haldor Advanced Technologies, received FDA approval for its RFID system that detects surgical instruments.

³ Medline. “ClearCount Medical Announces Never Event Warranty Coverage Provided by CAN HealthPro.” Medline Press Release, July 27, 2010. <http://www.medline.com/media-room/press-release.asp?ID=166>, January 28, 2011.

⁴ Pear, R. “Medicare Says it Won’t Cover Hospital Errors.” *New York Times*, August 18, 2007.

Figure 2: Trends Driving the Engineering of Solutions

Complex, systemic problems in healthcare industry require systemic solutions

Solutions provide manufacturers with competitive differentiation and new revenue streams

Reimbursement cuts causing more providers to look for solutions to help with efficiency and costs **IN ADDITION** to clinical outcomes

Demand for transparency and accountability from providers encourages adoption of solutions that can provide data streams supporting these goals

Shortage of healthcare providers encourages adoption of solutions to take over functions formerly performed by humans (i.e., inventory control, patient follow up, etc.)

“Defensive medicine” encouraging adoption of systems that generate data that can justify clinical decision-making beyond simply clinical judgment and experience

1. Complex, systemic problems in healthcare industry require systemic solutions

Many of the problems facing healthcare today are complex and systemic, often spanning clinical, economic, and workflow or supply chain issues. And healthcare reform will increasingly reward companies that are able to solve such problems. For example, surgical site infections are an enormous health and economic burden in the United States. Successful solutions will address infections at the systemic level. So, for example, an antibiotic capable of wiping out an infection does not address the larger problem of burdensome rates of infection. A company that is able to develop a solution that integrates a device or pharmaceutical with data and data management to reduce infection rates will greatly enhance the value of the device or drug alone.

2. Solutions provide manufacturers with competitive differentiation and new revenue streams

In the new healthcare economy, innovations must prove their value over existing technology. Medical device innovation has started to mimic the consumer electronic industry, where new iterations of a device may enhance features but do not increase their price. Medical technology companies will need to innovate continuously just to remain relevant and maintain revenue.⁵ Innovating solutions are an attractive means of growing revenue and differentiating a company from competitors.

3. Reimbursement cuts causing more providers to look for solutions to help with efficiency and costs **IN ADDITION to clinical outcomes**

Reimbursement cuts are putting greater pressure on medical device companies to bring greater value to the table. Providing solutions is one clear way to add value. For example, by making its software solution Web-based, WaveMark provides tremendous value to hospitals over competitors because the service becomes an operating expense rather than a capital expense.

⁵ Wasden, C, Mowen, D. “Medical Technology Innovation.” In Vivo: The Business & Medicine Report. September 2010

4. Demand for transparency and accountability from providers encourages adoption of solutions that can provide data streams supporting these goals

Payers and regulators are demanding transparency and accountability for outcomes. As a result, providers are increasingly demanding companies demonstrate that their products have proven outcomes. Assessing the value of medical devices has not been easy for medical device companies. One means of demonstrating value, though, is through the development of a solution around the core product.

5. Shortage of healthcare providers encourages adoption of solutions to take over functions formerly performed by humans

By 2020, the United States is projected to have a shortage of approximately 90,000 physicians and 340,000 nurses.⁶ Healthcare providers are relying on technology solutions to replace the shortage of healthcare workers. For example, telemonitoring solutions in home healthcare allow a single nurse to monitor more patients than previously possible.

6. “Defensive medicine” encouraging adoption of systems that generate data that can justify clinical decision-making beyond simply clinical judgment and experience

Annual medical malpractice-related costs in the United States are estimated to be \$55.6 billion or 2.4 percent of annual healthcare spending.⁷ Medical technology solutions are based on the provision of more data to enable better decision-making. And more data also helps providers demonstrate their decision-making processes in cases of liability.

THE CHALLENGE OF “ENGINEERING SOLUTIONS”

Medical device companies often find it difficult to develop solutions around their products because it takes skills, resources, and technology most device companies do not already have in-house. Developing these technology systems and business models requires an understanding of systemic problems, how customers might use a prospective solution in their workflow, and the economic implications of adopting the new solution. Additionally, companies need to have experience in monetizing solutions, which is a very different challenge from traditional revenue models in the medical device industry.

Device companies wishing to add solutions to their portfolio should consider partnering with an experienced company. A partner will be able to devote its skilled resources to developing numerous solution-based options quickly and cost-effectively, giving the device

⁶ Auerbach, D. et. al. “Better Late than Never: Workforce Supply Implications of Later Entry into Nursing.” *Health Affairs* 26(1), 2007:178-185. COGME. “Physician Workforce Policy Guidelines for the United States, 2000-2020.” Council on Graduate Medical Education, January 2005. <http://www.cogme.gov/report16.htm#sumrec> (January 4, 2011).

⁷ Mello, M. et. al. “National Costs of the Medical Liability System.” *Health Affairs* 29(9), 2010:1569-1577.

company “more shots at the goal.” With this approach, the device company will expend fewer of its own R&D resources on ramping up its in-house infrastructure. Instead, it can remain focused on its own core competencies (see Figure 3).

Figure 3: Advantages of Partnering with a “Solutions Engineering” Company

Access to multidisciplinary expertise needed for developing innovative solutions

Improved innovation

Able to explore more potential solutions—“more shots at the goal”

Lower R&D costs

Faster time to market

Improved productivity

Able to focus on core capabilities

One of the greatest added benefits of establishing a partnership to pursue solutions is improved innovation. Medical device companies are facing harsher financial and regulatory barriers to innovation and greater market competition. At the same time, innovation today requires multidisciplinary teams because of the complexity of both solutions and devices. By establishing partnerships in R&D, a company expands its intellectual capital, brings new perspectives to the process, lowers costs, and, when the partner is located in a previously untapped overseas market, opens access to that market.

In choosing a “solution engineering” partner, companies should search for particular experience and strengths. Medical device and solution development experience are givens. Multidisciplinary expertise outside of healthcare and existing in-house technologies to incorporate into their client’s designs, which bolsters the partner’s ability to formulate truly creative solutions, are also valuable assets. But to maximize the benefits of collaboration, potential partners should also have global experience. After all, the greatest growth in healthcare in the future will occur in markets outside of the United States, Europe, and Japan. Finally, partners should have experience in minimizing and managing risks.

Figure 4: Qualities to Seek in “Solutions Engineering” Partners

Medical device experience

Solution development experience

Existing in-house technology to support solution design

Global experience

Multidisciplinary expertise

Risk mitigation expertise

A COMPANY “ENGINEERING OUT OF THE BOX”

HCL Technologies Limited (HCL), a leading global engineering and IT services provider, is a perfect example of a company serving as a long-term innovation and “solutions engineering”

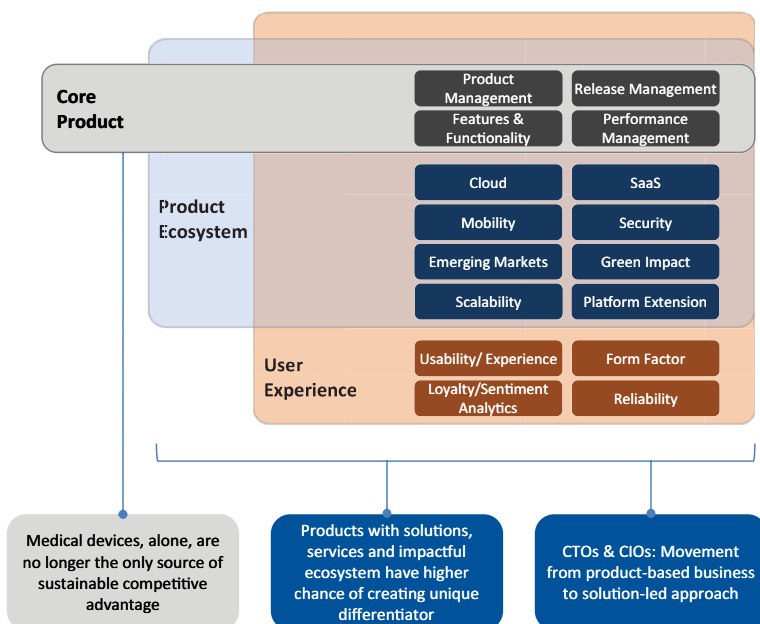
partner to medical device companies. Headquartered in Noida, India, with operations in 29 countries, HCL's medical device practice leverages its significant product engineering knowledge and experience to offer fast and cost-effective services across a variety of devices. The 34-year-old company has more than a decade of experience in the medical technology industry, working on more than 90 different medical device projects and partnering with seven of the top 10 global industry leaders.

HCL recognizes that more and more medical device companies are exploring solutions models. HCL states:

Products are no longer a sustainable competitive advantage for the OEMs, and we recommend a movement from a product-based business to a solution-based business. That is exactly the approach that we are creating, so that we can create a new avenue for that revenue channel.

The company has developed a novel approach to helping medical device companies innovate, called “Engineering Out of the Box” (EOOTB). The approach is based upon a philosophy that medical devices are embedded in an ecosystem and that the user experience informs what happens within that ecosystem (see Figure 5). HCL offers capabilities in each sphere: the core device, its surrounding ecosystem, and user experience. This comprehensive approach is particularly important for companies invested in developing solutions for their clients. The breadth of services that EOOTB covers also allows HCL to become a full R&D partner, and not merely an outsourcing vendor for medical device companies.

Figure 5: The EOOTB Approach



Source: HCL

At the center is a company's core product—the medical device. HCL provides traditional engineering services such as product life cycle management and system design to support the development of the core device and provide sustaining engineering.

Surrounding the medical device is the ecosystem—those technologies, interfaces and platforms that communicate or otherwise engage with the device itself. What is its interoperability? What is its delivery system? How will it communicate with other devices? An ecosystem includes:

- Cloud computing
- Mobility
- Needs in emerging markets
- Scalability
- Security
- Green impact
- Platform extensions
- Software as a Service (SaaS)

Finally, user experience is the way in which humans engage with the medical device and its ecosystem. It is the user experience that defines how the device and its ecosystem should be structured. Understanding the user experience is a key element of HCL's EOOTB approach because it helps ensure better adoption of the solution.

HCL's unique EOOTB approach is significant because it:

- Expands a product's ecosystem by focusing on solutions;
- Minimizes a company's time to market; and
- Increases the product's adoption by focusing on user need and experience.

In addition to services provided through its EOOTB process, HCL offers a set of proprietary technologies to clients called "Solution Accelerators," which can be used to help develop new medical devices and broader healthcare solutions, including:

- eLink for remote monitoring
- Non-invasive blood glucose monitoring
- Flow measurement
- eInk display
- IEEE 1073 implementation
- Wireless solutions
- Continua-based solutions
- Ultrasound medical imaging
- On demand
- Web 2.0

Each Solution Accelerator can be customized to fit the needs of HCL's customers, making scale up extremely fast and cost-effective. These technologies allow HCL to more proactively address its clients' needs.

With both the EOOTB approach and its Solution Accelerators, HCL is able to serve as a complete innovation partner to medical device clients. HCL's team becomes an integral part of its partners' R&D function, developing and testing ideas at a pace far faster than a company can do on its own. And, putting into practice its emphasis on the need for companies to offer "solutions," HCL itself often structures partnerships with clients so that its compensation is tied to the outcomes it produces, not the number of people and hours devoted to an engagement. The following case study provides an example of the benefits of this type of partnership.

CASE STUDY: SCALING UP INNOVATION AT ENDO PHARMACEUTICALS

Endo Pharmaceuticals Inc. (Endo) is a mid-sized specialty pharmaceutical company based in Chadds Ford, Pennsylvania. Established in 1997, the company develops and markets branded and generic pharmaceutical products for pain management. Endo's strategy to diversify beyond pharmaceuticals led to the acquisition of Indevus in 2009 to form a company that offers solutions to healthcare professionals to help them manage the needs of patients in areas such as pain, urology, oncology and endocrinology. In 2010, the company decided to further expand its portfolio in urology and acquired HealthTronics, Inc., a leading U.S. provider of urological devices and services, located in Austin, Texas.

Endo is building on its foundation in the pain, urology, oncology, and endocrinology markets, not just by acquiring new products and technologies through acquisitions, but also through organic growth. In describing the company's growth strategy, Sujat Sukthankar, vice president of device R&D at Endo Pharmaceuticals, said:

The idea was to really diversify sources of revenue for the company and truly move away from being a product-based company to a solution-based company. As you know, when you look at the continuum of care for any particular healthcare situation, you need a portfolio of both devices as well as drugs to help diagnose, treat, or manage a particular condition.

To achieve this, Endo needed to rapidly establish its R&D capabilities in devices. "The question was: how do you do that within a company that has very little [medical devices] infrastructure?" Sukthankar said. The company chose a semi-virtual R&D model, where it would establish a partnership with a company to provide R&D services for product development, an approach it was already using in its pharmaceutical division. "We really had already bought into the idea that in today's R&D environment, you really have to be flexible, scalable, cost-effective, and very agile," Sukthankar said.

A semi-virtual R&D approach provided Endo with the capabilities of a full-fledged R&D infrastructure without the pitfalls of high capital investments tied to a static pool of skills and resources.

Endo selected HCL as one of its virtual R&D partners for its medical devices initiative with the vision of developing a long-term relationship and driving the creation of a center of excellence that Endo could count on for long-term development. Endo's initial goal was to expand its portfolio in urology devices, a completely new endeavor for the company. Working in close collaboration with Endo, the HCL team followed the phased approach it uses with its EOOTB strategy.

HCL started the project with a market assessment, conducting primary research with physicians, patients, and caregivers to identify the unmet and un-expressed needs in the treatment of urinary problems. These insights were translated into business opportunities, and proposed areas of investments were identified. With the help of domain experts, mechanical engineers, and industrial designers, the team generated new product concepts in the form of sketches, illustrations and animations, and validated the designs through panel discussions with doctors, patients, and caregivers. An extensive patent search was simultaneously conducted to ensure that the new concepts would not infringe on existing IP.

Endo's partnership with HCL allowed the company to identify 12 high-quality opportunities for the urology segment in only six months. This is a scale and pace that Sukthankar says would be hard to achieve within this timeframe without an established partner with existing infrastructure and experience that could be leveraged "out of the box." A significant advantage of the partnership is that the partner, HCL, is paid solely on its concept and product delivery, and not by the number of people staffed or the amount of time spent on the project. It is a solution that, Sukthankar notes, is customer-friendly and, more importantly, results-driven.

Describing the partnership, Sukthankar says:

We are relying on our R&D partners to create value for the organization, and they play a key role in driving our technology and R&D strategy. We believe that close collaboration with our R&D partners will drive results, and we have shown that successfully in a relatively short amount of time. We also believe that a results-driven, semi-virtual model provides a scalable, agile, and cost-effective means of driving innovation forward.

CONCLUSION

Companies can no longer rely on technology alone to remain competitive in the medical devices marketplace. One very attractive means of differentiation is in offering solutions to customers. By combining medical devices, communications technology, and software into solutions that gather, analyze and manage data, companies are able to offer greater value to their customers. Innovating solutions can be difficult for companies with no such infrastructure or experience. Consequently, partnerships with experienced service providers and technology companies are an ideal approach to help companies wishing to develop solutions. And partnerships offer the collaboration that is important to creative innovation:

The management of innovation is changing. No longer is the creation and pursuit of new ideas the bastion of large central R&D departments within vertically integrated organizations. Instead, innovations are increasingly brought to the market by networks of firms, selected according to their comparative advantages, and operating in a coordinated manner. In this new model, organizations deconstruct the innovation value chain and source pieces from partners that possess lower costs, better skills and/or access to knowledge that can provide a source of differentiation. The aim is to establish mutually beneficial relationships through which new products and services are developed. In short, firms increasingly seek superior performance in innovation through collaboration.⁸

⁸ MacCormack, A. "Innovation through Global Collaboration: A New Source of Competitive Advantage," HBS Working Paper 07-079. Boston: Harvard Business School, 2007.

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9 industries, including medical devices

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