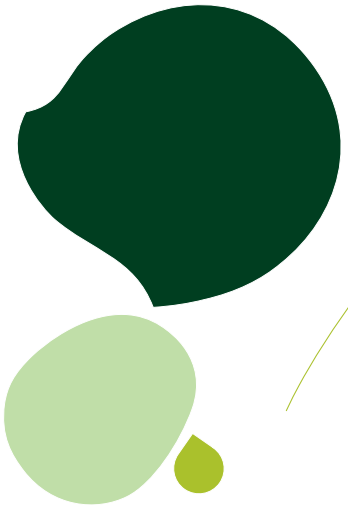
Sage ERP | White Paper

Profitable Innovation

Medical Device Business Model for Growth



Prepared exclusively for Sage by Cambashi, Inc.
www.cambashi.com

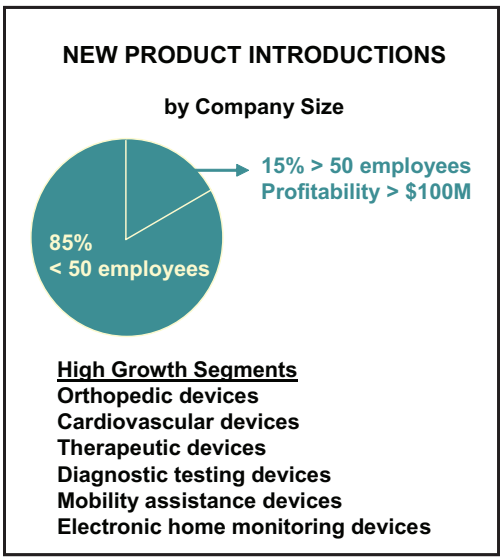
sage

Table of Contents

Sage ERP

The R&D Business Model

The medical device industry thrives on the innovations generated by its large base of privately held start-ups and small companies with less than 50 employees. Eighty-five percent of new medical product introductions come from these businesses, according to the Medical Device Manufacturers Association (MDMA),[1] yet profitability seldom occurs until after a company's first $100-150 million in revenues (see Figure 1).



After passing this size, many companies struggle to attain and maintain profitable growth due to product and operational complexities as well as regulatory, legal, and financial risks. This is further hampered in companies operating with an R&D-driven business model, which, as they grow from a start-up, tend to add on functions in a disjointed manner and without integrated information systems. In the U.S. profitability will be further constrained by the 2.3% sales tax on medical devices, which is scheduled to go into effect in 2013 as part of the recent U.S. Health Care Reform legislation.

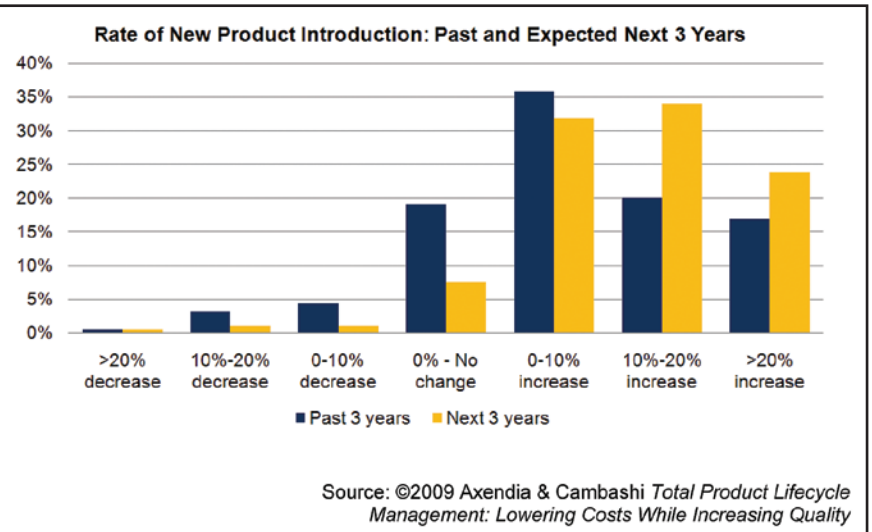
Most of the profitable medical products firms have grown by acquiring smaller innovative companies, outsourcing much of their operations, and expanding into emerging international markets. While the larger companies dominate in revenues, they represent less than 1% of the industry, which is listed as 8,000 businesses by the U.S. Department of Commerce. Even among this top tier not all have consistent profits. For example, Boston Scientific turned a profit in 2010 after four years of losses.

Despite the long-standing partnership with seasoned venture capital investors, many device companies fail to break free of their R&D-focused culture as they grow into full production, multiproduct-line growth businesses. This can seriously impact their long-term performance. To achieve profitable growth, they must review and, in some cases, restructure their business and deploy the new processes and integrated systems across the entire company—not just R&D—to accommodate growth complexities and manage risks.

The Double-Edged Sword of Product Innovation

Product innovation is seen as the lifeblood of a medical device company by executives, investors, and the marketplace. This singular R&D focus has led to an impressive history of technology breakthroughs that has changed the quality of patient care around the globe.

According to the MDMA, during the 1990s the R&D investment across the industry more than doubled as companies raced to be first in new material technologies and to provide solutions for heart disease, cancer, diabetes, and stroke. The pace of innovation—whether for new products or enhanced product capabilities—has not slowed down, and product introduction rates are expected to increase dramatically in the next few years, even during the current economic uncertainty (see Figure 2).



Source: ©2009 Axendia & Cambashi *Total Product Lifecycle Management: Lowering Costs While Increasing Quality*

Figure 2: Medical device companies' have been introducing new products at an increasing rate, a trend that is likely to accelerate into the future.

The challenge is to keep up with the increasing pace of innovation and greater complexity of products while ensuring quality, safety, and regulatory compliance across an outsourced and global operations network. Few medical device companies do all their own manufacturing and instead outsource all or most production and distribution to contractors. Currently the U.S. produces and consumes more devices than any other region. Yet this is now changing as more U.S.-based firms establish manufacturing facilities in China, India, and Latin America to address the emerging economies and their investments in healthcare. This global expansion adds further complexity and risk to bringing products to market.

New product introductions (NPI) and product line expansions can place considerable stress on a medical device company. Operations management becomes increasingly challenging with every new product and expansion of product lines. Each new product introduction requires the attention and coordination from departments across the organization, and very often they don't fit the assumptions made for existing products. Our research shows that while the average device company has five product lines, a growing number of companies are juggling up to 70 product lines in their portfolios. Within these, most products have about five configurable options to address specific requirements. In addition, it is not uncommon for medical devices to be complex electromechanical products made from more than 50 parts and a bill of materials that is three levels deep.

A 2009 joint research study by Axendia, Cambashi, and FDANews on Total Product Lifecycle (TPLC) management in medical device companies found that most medical device companies were experiencing more new product introductions, but with slower times-to-market and few able to improve in product recalls, product costs, engineering changes, quality problems, and compliance penalties. To prevent product portfolio growth adversely affecting their ability to operate efficiently, mitigate risks, and achieve profitable returns, medical device companies need to make improvements in new product introduction time, development costs, quality, and time-to-market.

Growth companies are those that consistently achieve both revenues and profits, and they stand out from others in the industry for their integrated and collaborative operating environments. Not only are they benefiting from coordinated and informed decision making across their organizations, but they have moved away from spreadsheet and paper-based manual systems that are costly, slow, inefficient, and prone to inaccuracies and missed information.

The most profitable device makers have identified business processes that add the greatest value to their customers and investors. These are very often product management, product quality, customer service, and manufacturing flexibility—all of which are affected by various departments across their organizations and outsourced networks.

To manage these critical aspects of the business, market leaders have deployed application systems that integrate their operations, measure performance, and facilitate cross-functional collaboration. According to the TPLC study, the most commonly used information systems are ERP, document management, asset management, and quality management. Over half of companies in the study either have these in production use or in pilot or test. Smaller medical device companies are much less likely to have implemented software then larger ones, as Figure 3 shows. None of these systems stand alone. They are integrated into one another, using ERP as the information backbone.

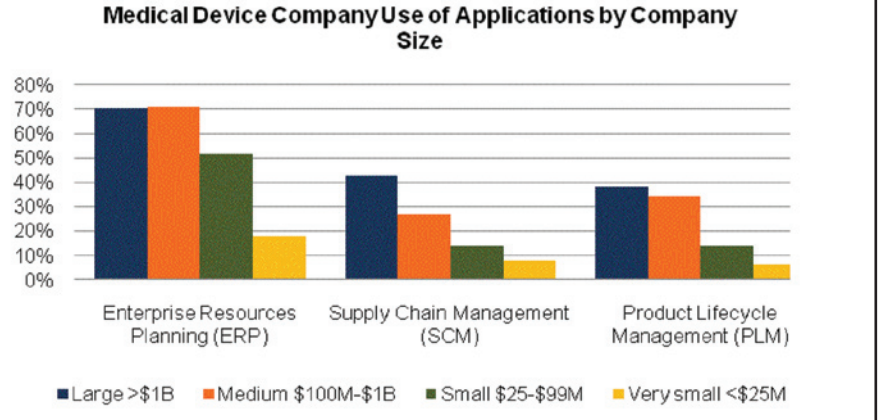
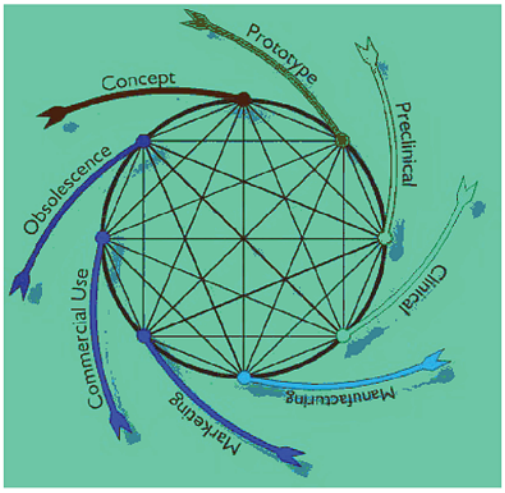


Figure 3: ERP is the most widely implemented software application in medical devices and most other industries. Most companies smaller than $1B in revenues do not use ERP, SCSM, or any of the major software applications today.

There are two areas of the business where growth leaders have focused their efforts to ensure continued profitability as they accelerate new product introductions on a global scale: total product lifecycle management and risk management. Both of these initiatives rely on process and data integration and teamwork collaboration.

Total Product Lifecycle Management

Back in 1977, the U.S. Food and Drug Administration (FDA) used a sequential or "Waterfall" diagram to illustrate control of new product designs. While the FDA did not intend it as a recommendation, it was acted on as if it were guidance. Now the FDA is trying to counteract that issue and strongly urging device makers to shift to a cross-functional, concurrent, and systematic Total Product Life Cycle (TPLC) process, which integrates quality and compliance into design controls and across the product life cycle (Figure 4).



Source: FDA CDRH

Figure 4: The FDA's vision for total product life cycle (TPLC) ensures every stage of the lifecycle feeds into and connects with all others.

The Waterfall and other sequential design processes are deemed:

- Insufficient, as products have become much more complex.
- Too slow in getting products approved and in the market.
- Ineffective for improving quality and regulatory compliance.

This sequential approach of completing one entire development phase before getting design review feedback has been used for many years now. At the same time, departments across the organization have established their own type of paper-based or computer systems for designing, testing, reporting adverse events, clinical and design documentation, and quality. This sequential and isolated environment fosters a reactive approach to problems with design or adverse events and makes it challenging to identify or resolve the root cause of a problem or attain proactive new product introduction feedback.

Total Product Life Cycle, on the other hand, better represents how products are developed and introduced into the market, including the interactions required between departments and partners at all stages of design, through clinical trials, into production, and beyond the sale for service. TPLC is an iterative, concurrent, and highly interactive environment that relies on sharing product and process information as events occur, with everyone involved at each stage of the product's development and beyond. As a result, any nonconformance to quality specifications or regulations is rapidly detected, and data is readily available to perform root cause analysis. As intended, TPLC facilitates both building quality in and a culture of prevention, rather than testing quality out and continual nonconformance and corrective and preventive actions (CAPAs).

Risk Management

Much like building quality assurance into R&D, market leaders recognize that risk analysis needs to be conducted at every stage of the product lifecycle and across its business and network. Financial, legal, and compliance risks in medical device companies most often stem from poorly executed product development and design transfer processes, poor visibility between

departments, sites, and partners, as well as incomplete risk and root cause analysis, ineffective correction actions, inconsistent data, and manually processed compliance paperwork.

FDA and similar regulators dictate that device makers must have formal processes of good governance to identify and quantify potential risks, the scale of their impact, and their likelihood. However, profitable growth companies have also integrated their operations with a common information platform to establish a single system of record and to facilitate teamwork and data exchange. That way, everyone has a full picture of potential risks at any point along the product lifecycle or in operations. This enables a company to apply risk analysis at the earliest stages of new product conceptualization to minimize financial and patient safety risks or in any business activity. Equally important, more of these device leaders are connecting their risk analysis to the CAPA process and to performance measures in order to determine the effectiveness of process improvements and root cause analysis.

Growing Beyond R&D

Medical device businesses are finding themselves at a crossroads as they face greater risks associated with more complex products, engineering changes, and multinational expansion. Companies cannot afford to maintain a culture focused on R&D. Those that find it difficult to recognize the cost of operating with manual systems and groups of people isolated from others across the business are at a strategic disadvantage.

It is getting more obvious both to the FDA and to those working in device companies that the current business model is unsustainable. It limits innovation to product R&D, which ironically slows down new product introduction cycles and generates not only CAPAs, but audit citations, adverse events, and recalls. The answer, which has worked well for profitable growth companies, is the adoption of more formal cross-functional business processes combined with companywide information systems that more fully support TPLC.

Medical device companies have the opportunity to grow and thrive with shifting worldwide demographics. However, to do so, innovation must focus on how to ensure not only breakthrough products, but sound business processes that can reliable generate profit.

1 Medical Technology and Venture Capital: A Fruitful yet Fragile Ecosystem, June 2009

About Sage North America

Sage North America is part of The Sage Group plc, a leading global supplier of business management software and services. At Sage, we live and breathe business every day. We are passionate about helping our customers achieve their ambitions. Our range of business software and services is continually evolving as we innovate to answer our customers' needs. Our solutions support accounting, operations, customer relationship management, human resources, time tracking, merchant services, and the specialized needs of the construction, distribution, healthcare, manufacturing, nonprofit, and real estate industries. Sage North America employs 4,000 people and supports nearly 3.1 million small and medium-size business customers. The Sage Group plc, formed in 1981, was floated on the London Stock Exchange in 1989 and now employs 13,100 people and supports 6.2 million customers worldwide. For more information, please visit the website at www.SageNorthAmerica.com or call 866-308-2378.

About Cambashi

Cambashi, based in Cambridge UK and Cummaquid, MA, USA, provides independent research and analysis of the business reasons to use of IT in industry worldwide. Its specialist fields include Engineering, Enterprise, Plant, and Supply Chain applications and the infrastructure to enable industrial firms to use IT effectively. Cambashi publishes market size estimates in the Engineering Applications Market Observatory and multiclient studies in Cambashi's Industry Directions. Its clients vary in size from small to large and include most of the leading software vendors and many pioneering IT users. Cambashi is a member of CATN, an international association of consultants. www.cambashi.com.

The information contained in this material represents the views of Sage on the issues discussed herein current as of the date of publication. As market conditions are always subject to change, the information contained herein shall not be interpreted as any commitment from Sage. This material is for informational purposes only and Sage makes no warranties, expressed or implied.

Sage
13888 Wireless Way
Suite 120
Richmond BC V6V 0A3
tel. 1-604-207-9480 I fax. 1-604-207-3620
www.SageERPSolutions.com

10-26008 10/10