

Plan to Prosper

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Despite Rising Price Pressures and Upcoming Elections, Medical Device Companies and Their Outsourcing Partners Should Continue to Grow in 2008—But Some New Strategies May Be in Order

The aging process can be fraught with hazards. Consider the current state of your body. Chances are you're a bit heavier than you were 20 years ago. (Who are these experts who say we should weigh what we did when we graduated from high school?!) As you age, you'll likely find that even if your diet and exercise programs haven't changed much in the past few years, they're not as effective as they used to be. Extra pounds will creep on unless you pay close attention and adjust your nutritional intake and physical activity regularly.

A similar phenomenon can occur in business. Companies start lean and mean and willing to innovate continuously—finding creative solutions to challenges and correcting course quickly. As organizations grow, bureaucracy, complacency and “we do things this way” attitude can develop. Without periodic analysis and adjustment, the strategies that served a company perfectly 10 years ago may leave the business in less-than-optimal condition to compete against new challenges in today's marketplace.

Challenges are weighing heavy. Greater costs for energy, regulatory compliance, materials and insurance are squeezing margins. At the same time, medical device firms are facing increased pricing pressures from the marketplace, which is forcing them to keep prices flat.

“The cost of energy continues to be a problem for us since we are a large energy user in the injection molding part of our business. Business, liability and health insurance costs are also a concern,” noted George Blank, president of the MedTech Group, Inc. in South Plainfield, NJ. “The market is not allowing contract manufacturers to pass those costs on, so we are becoming even more efficient to keep costs competitive.”

Richard J. De Camp, vice president and general manager for Eagle Outsource, a division of Eagle Labs in Rancho Cucamonga, CA, echoed Blank's sentiments. “Because of rising fuel, energy and insurance costs, we're being forced to find ways to build things more cost effectively to absorb those costs and pass savings onto customers.”

Like many other public companies striving to implement the requirements of the Sarbanes–Oxley Act (SOX) and its Section 404, which regulates the establishment and auditing of internal financial controls for public companies, Memry Corp. has spent much time and money to come into compliance.

“Sarbanes–Oxley has hit us harder than developing new security plans or anything else. Because we’re a public company, it affects everything from IT to financials to quality systems. The cost of compliance and keeping up with the regulations are substantial undertakings,” said Dean J. Tulumaris, president and chief operating officer for Memry Corp. in Bethel, CT. AMR Research found that SOX compliance will cost companies an average of \$6 billion in 2007, with similar spending projected for 2008.

Formulating a Plan of Attack

As challenging as escalating costs are, successful companies are re-examining their strategies in numerous areas to keep ahead of the competition. To offer customers peak performance, contract manufacturers are:

Adding capacity and capabilities. “We continue to add new capacity in space and equipment in our quality, engineering and manufacturing areas,” Blank said. “We’re constantly adding and upgrading as our customers’ requirements change.”

Memry currently is focused on upgrading and improving its secondary operations, such as electropolishing, honing and things of that nature as well as plasma welding and plastic operations. “Every year, we look to add one or two new capabilities in each of our four facilities to differentiate ourselves from the competition,” Tulumaris said. The company looks carefully at its customers’ needs and industry trends as it considers its options. Within the past three years, the company has doubled its product engineering group, which now exceeds 15 professionals, in response to the increased industry demand for design and development services from outsourcing partners.

Contract manufacturers also would be wise to invest in some additional areas, noted David Scott, a study author and analyst for Kalorama Information, a division of MarketResearch.com in New York City. “Firms should invest in improved quality controls in manufacturing processes to reduce the risk of product failure and in effective IT systems that offer tracking and traceability. Speeding

up the time of product launches into established and emerging markets with good supply chain management operations and systems is critical as well,” Scott said.

Investing in new equipment. Not only is today’s new equipment more efficient—producing products more quickly and with increased reliability—much of it is more energy-wise than previous generations—up to 35% more efficient in some cases. Therefore, while in the past contract manufacturers may have made equipment purchasing decisions based solely on a machine’s capabilities, features and speed, equipment’s energy requirements now also enter the equation, Blank said. “The combination of implementing more efficient business and manufacturing processes coupled with adding new equipment and energy conservation approaches allows us to provide quality products at competitive prices,” he added.

Automating more processes also is allowing companies to offer cost advantages formerly seen only by sending manufacturing overseas. “We’ve invested in form, fill and seal multivac equipment that allows us to do higher-volume projects. The equipment saves costs because it allows us to buy materials in bulk, achieving volume pricing discounts, and it saves us labor costs since there is less employee involvement,” De Camp explained.

Minimizing materials costs. One key trend in packaging today, especially in light of increasingly stringent environmental standards, is simplifying design packaging to eliminate as much waste as possible. “There’s a trend away from using elaborate packaging, such as hard trays, toward more streamlined styles of medical-grade packaging. Pouches are shaped to just the right size, with no waste, which influences the types of equipment we purchase,” De Camp said. That said, there are OEMs with single-use medical devices that prefer using hard trays, so in 2008 Eagle Outsource will begin building hard plastic tray packaging on its new automated form, fill and seal equipment.

The actual cost of materials—particularly metals—also has been a concern in 2007. “While the overall level of inflation in the US is reasonable, increases in the cost of metals and their feeder stocks have been growing due to world demand, particularly from China and India,” Blank said. He noted that lead times to acquire metals such as titanium have had stretches of six to 14 weeks before falling back to six to eight weeks. “Material pricing and availability have caused potential problems in supply chains,” he said. “Manufacturers have to do extra work to ensure they have the materials available. I expect this trend will continue into 2008.”

Keeping employees safe and happy. To keep workers' compensation insurance rates as low as possible, manufacturers have kept worker safety and training at the top of their priority list. "Insurance costs and workers' comp claims can kill you. The key to success for any manufacturing business is to invest in your employees' health and safety through proper safety and training programs," De Camp said. Monthly training programs are de rigueur at many companies.

Eagle Outsource also has ensured that employee turnover—a costly problem in myriad industries (see sidebar on page 58)—is not a concern at its company. In fact, quite a few of the private company's 50 employees have been with the business for at least 15 years, a relative rarity in today's marketplace. "Our focus is on retaining our employees. Our philosophy is that we take care of our key people by offering competitive compensation and benefits and investing in them and our company through continued training," De Camp said.

The strategy makes perfect business sense, since the costs of hiring a replacement can range from 30% to 300% of the salary of the departing employee due to the expenses associated with recruiting, interviewing and training a new worker, in addition to lost productivity and expertise. Therefore, companies that protect the investment they've made in finding stellar employees will reap both tangible and intangible benefits over competitors with higher turnover rates.

Lots of Good News

During the past few years, the medical device industry has continued to experience strong gains. Kalorama Information reported that the 2006 global medical device market reached \$225 billion in revenues, with \$19.7 billion spent on outsourcing. The firm estimates the 2008 levels will climb to \$250 billion and \$23.1 billion, respectively.

"The medical device industry today is similar to the electronics industry 20 years ago, when around 20% of the cost of manufacturing was outsourced," noted Steven Heffner, publisher of Kalorama Information, in a recent news release. "That number has now elevated to an estimated 90%. In the medical device industry across the mainstream nine market segments, the level of outsourcing of manufacturing costs is currently around 30%, so there is considerable room for growth and manufacturing efficiencies to be gained during the next five to 10 years."

Outsourcing in the medical device industry has yet to reach “a critical mass,” pointed out Bruce Carlson, associate publisher for Kalorama Information. He noted that a couple of continuing trends will fuel double-digit annual growth in medical device outsourcing.

First, more OEMs are facing pressures to improve cost effectiveness in their operations and generate a better return for shareholders. Second, world markets are demanding more new products and innovations, as well as larger volumes of products. OEMs will find they need to produce more product not only to meet market demands, but also to overcome pricing pressures they face from group purchasing organizations. Plant capacity, as well as staff resources, will be overloaded, necessitating more reliance on outsourcing partners. “These factors are driving the outsourcing market, and they’re not going away,” Carlson said.

Even one market segment that traditionally has shied away from outsourcing—orthopedics—is becoming more active. “We’re definitely seeing more design and development outsourcing in orthopedics, although more on the instruments, cases and trays side than on the implant side,” said Michael S. Matson, senior analyst of medical device equity research at Wachovia Capital Markets, LLC in New York City. Matson added that orthopedic companies “have worked down their product inventories, which were a bit bloated,” and after several years of few new product launches, more innovations are expected to hit the marketplace in the coming years. Both of these factors will drive more demand for outsourcing partners’ services.

Core reconstructive (hip and knee) markets should have expanded by about 9%–10% in 2007, spine by 15%–16% and trauma by the low teens, Matson said, noting he expects similar growth for these sectors next year. “In spine, I expect that new technologies like motion-preserving products, artificial discs and the cervical disk just launched by Medtronic will accelerate growth,” he added.

On the medical device side, electronics had another good year. For the first six months of 2007, electronics-based medical contract manufacturers grew in the 15%–20% range compared with the same period the prior year. That’s on top of 25% growth in 2006 and 25% growth in 2005, noted Andrew Kinross, associate director for Navigant Consulting in Burlington, MA. Metals and plastics each experienced stable growth in the single digits.

“I expect to see more of the same going forward for the next five years—growth of 15% a year in electronics and 10% annual growth for metals and plastics companies,” Kinross predicted.

The healthy growth rates also are changing the landscape of the medical marketplace. “A lot of bigger orthopedic companies have a lot of cash, and they’re looking for ways to put the money to use,” Matson said. “We’re seeing stock buybacks, particularly at Zimmer and Smith and Nephew. We’re also seeing acquisitions of smaller companies with new technologies in the several hundred million to one billion dollar range.”

Venture capital interest in the sector also remains strong. According to the MoneyTree Report by PricewaterhouseCoopers and the National Venture Capital Association based on data from Thomson Financial, during the second quarter of 2007 (the latest for which data are available), the life sciences sector—medical devices and biotechnology combined—saw \$2.2 billion invested in 223 deals. While the dollar amount was down slightly from the record-breaking \$2.6 billion invested in Q1, it was the life sciences’ most active quarter in history, with deal volume reaching an all-time high.

While the subprime mortgage mess and resulting credit crunch could trickle into M&A activity in some sectors, the medical device industry should be relatively immune, experts said. “While banks are re-evaluating some very large deals, most medical device deals are smaller, and many are funded by the companies themselves. Larger OEMs and VCs have adequate liquidity, and there is a substantial amount of equity funds still looking for opportunities,” Blank said.

Some Reason for Caution

As promising as the fundamentals look, some cause for concern for growth in 2008 remains. Pacemakers and defibrillators had weaker sales this year due to several product recalls. Furthermore, while the industry’s largest sector, cardiology, continues to excel, news stories in 2007 questioning drug-eluting stents’ safety raised concerns and significantly reduced sales. “Even though the studies were later shown to be in error, the damage was done. The market is in flux now,” Blank said.

Also in flux is the consulting relationship that will be allowed between physicians and medical device companies. “The Department of Justice investigation into physician consulting

relationships [with orthopedic companies] that was just settled with fines totaling \$311 million, and efforts at the state and federal levels to control these relationships through new laws may dramatically affect how many relationships there are in the future and how much doctors can be paid for their advice,” Matson said. “These relationships are essential to the industry—companies need doctors’ expertise. Already, the DOJ settlement is changing the relationships, and that could affect the dynamics of the entire industry due to fewer royalties and loyalties.”

Matson added that OEMs—and their outsourcing partners—also will have to watch to see if hospitals will redouble their efforts to control the prices they pay for implants, particularly in the spine area, since more small companies are entering this space with new products. “This could lead to margin and price pressures,” Matson explained.

In fact, reimbursement continues to be a challenge for medical device firms, primarily because of excessive regulatory and reimbursement system requirements for developers of new technology, reported Randel E. Richner, president of Neocure Group, LLC in Newton, MA. “As the world of medical technology has migrated from being delivered in acute-care environments to a more personalized management model, regulators have created different regulations, with sometimes misaligned incentives, for technologies,” she said. “Unfortunately, regulators—from FDA staff to the gatekeepers at private and public insurers—have displayed a lack of understanding and appreciation of the enormous complexity associated with medical devices and technologies. Instead, they have modeled their requirements for medical devices on those of the pharmaceutical sector.” That is, too many “square” medical device technologies are being forced into “round peg” pharmaceutical-predicated requirements.

Richner fears that unless device manufacturers and their suppliers support the medical device industry associations, such as the Advanced Medical Technology Association and the Medical Device Manufacturers Association, and make their concerns heard to regulators, innovation may be curtailed. “Supplier involvement is critical, too, since on the manufacturing side, many issues are associated with design changes,” Richner explained. “Reimbursement rates change based on whether technology is implantable or has a lead or certain delivery mechanism. We’ll work with engineers to make sure that changes made to the design or manufacturing process don’t inadvertently affect the critical factors of how much a product will be reimbursed at and in what settings it can be delivered.”

To succeed in this environment, OEMs must commit a tremendous amount of dollars and human capital to developing product strategies that concurrently address regulatory, reimbursement, manufacturing, marketing and clinical plans. “No longer will a silo mentality suffice,” Richner said. OEMs and contract manufacturers may need to hire additional in-house expertise or, at the least, have a well-versed consultant on standby for help not only with initial planning, but with any issues that arise during the product’s lifecycle.

In the coming year, Richner expects the greatest reimbursement challenges to occur in diagnostics. “New methods of radiology and diagnostics imaging are under intense scrutiny, so it’s questionable what the final payments/coverage will be. Sometimes it’s not worth it to be the first company to market with a new technology,” she explained.

Finally, the US presidential election in 2008 could affect medical device sales. “As the economy slows down, tax revenues will go down and the deficit and trade imbalance will become bigger concerns. We’re hearing more rhetoric from the political candidates about healthcare, since it’s such a large part of the economy, and candidates are again discussing universal care,” Blank said. “I don’t think we’ll see a repeat of the early 1990s with a national medical plan, but the election could well affect industry growth and investment, creating some unstable and uncomfortable moments in the coming year, especially if the economy slows further.”

It would be the best of both worlds: finding a way to retain your star employees while simultaneously shaving millions of dollars in costs. How do you do it? Create an employee retention plan.

“Turnover expenses are one of the most overlooked costs of doing business because most companies don’t have a systematic process for calculating the true costs. They aren’t aware of how much they’re spending, nor do they know what to measure. There are more than 20 associated costs from the time you conduct an employee exit interview until you complete orientation and training of the new hire,” explained Ross Blake, president of Retention Associates, with offices in Jamestown, NY and Syracuse, NY.

Blake pointed out that what you don’t know can cost you—big. For example, studies show that hiring replacement employees can cost anywhere from 30% of an entry-level worker’s wages to 300% of the

yearly earnings of more specialized positions, such as an IT professional or experienced business development manager.

To see how such expenses can impact the company at-large, Blake recommended performing a quick calculation: Think of a job in your company that has experienced some turnover, perhaps managers. If a manager's average annual pay is \$40,000, then multiply this figure by 0.125% (or 12.5% of the annual pay, a reasonable estimate for this level of employee), and you'll find that it costs \$50,000 to replace just one manager. If 10 managers leave each year, your company will incur \$500,000 in turnover costs. If your company operates with a 10% profit margin, you'll need to generate new gross revenues of \$5 million just to recoup those costs.

The US Department of Labor noted that, in 2006, the average tenure of a US worker was four years, and the number has been trending downward. Generation X and Generation Y workers may be largely responsible for this shift, since they've observed their parents and grandparents devote lifelong careers to a single company, only to lose their job and benefits just years from retirement. Younger workers have vowed they won't face the same situation, so they focus on acquiring new skills and regularly look for better opportunities. Life/work balance also is a driver for them; they will forgo certain perks and bonuses if their employer will allow for more flexible work arrangements and more time for personal interests.

Within the medical device industry, worker turnover is in the double digits, experts report. Why do people leave? "Having an abusive, difficult or unhelpful boss is the single most important reason why people stay or leave a job," Blake said. Other top reasons include a lack of stimulating or challenging work, a lack of a plotted career path or opportunities for advancement, poor work/life balance and inadequate compensation.

To lower turnover rates and keep superstars happy, Blake recommended these five strategies:

1. Know four important "whys." "Know why employees leave your company, why they stay, why they're satisfied or not, and why you need to make improvements," Blake said. "You find out this information by talking with employees honestly and openly."
2. Train managers in people skills. "Managers must learn how to develop ongoing, supportive relationships with the employees who report to them. They need to provide sufficient feedback and help their employees deal with questions, mistakes and problems," Blake

said. He added that ideally, companies will link employee retention to managers' performance evaluations and bonuses. Some companies tie as much as 25% to 33% of bonuses to whether a manager has met set retention goals.

3. Do a better job of matching candidates with jobs before making a hiring decision. By clearly identifying and communicating the expectations for the job with candidates, and asking for candidates' feedback on their expectations of the job, hiring managers should be able to ensure a new employee will be a good fit for both the job and the company.

4. Build relationships that meet both the employer's and employee's needs. "Successful employment depends on open communication," Blake said. "Identify the needs and expectations [of both parties] and develop a process to update them after three months, six months and the first year of initial hire, and then regularly thereafter."

5. Implement strategies to counter the two most costly forms of employee turnover. "Losing new hires is extremely costly because you've just invested a lot of time and money in their training and orientation, and you've yet to recoup any of that investment," Blake explained. "Losing top talent means you also could lose the expertise needed to complete existing projects or win new business. Conduct 'stay interviews' with your best performers" to make sure you're offering them the opportunities, challenges and benefits they need.

In the end, companies also need to determine the answers to three questions: What is your turnover rate? What is turnover costing you in dollars? What are the other consequences to your business? For instance, Blake warned, companies that lose good workers also may lose customers and other good employees who leave because they've had to take on too many extra responsibilities or have had to work too many weekends because of a lack of staff depth.

Treat employees right, and both they—and your top and bottom lines—will thank you.

Editor's Note: For a copy of Ross Blake's latest study, "Five Strategies Outstanding Employers Use to Retain Employees," visit www.RetainsEmployees.com/FiveStrategiesReport.