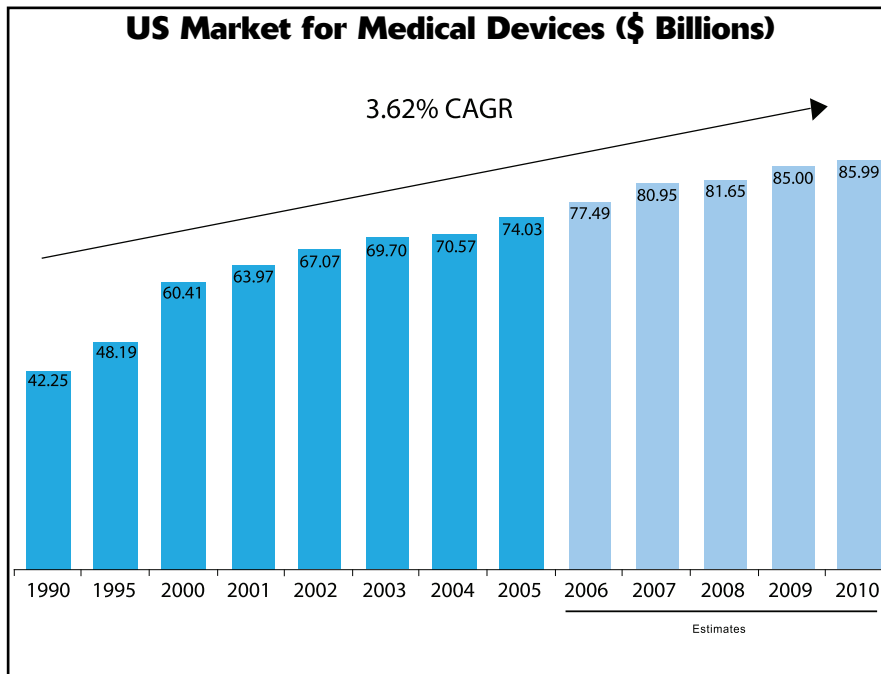


Market Opportunities in Outsourcing

A Financial Expert Provides an In-Depth Examination of the Financial History and Related Trends in Outsourcing

The concept of outsourced manufacturing is hardly new to the US economy. For decades, the automotive, defense, apparel and elec-

turing provides a compelling value proposition for OEMs. That is not to say the model is without inherent risk. As with any outsourcing partnership, a successful initiative requires a lot of oversight and organization. Regulation, performance standards and supply chain integration are just some of the issues that make contract manufacturing a challenging environment to conquer. That said, outsourcing is a generally accepted alternative and is being used in a greater range of areas to provide solutions for major device OEMs.



Source: IBISWorld

tronics industries have relied heavily on outsourcing to contain production costs and streamline supply chains. In the medical device industry, contract manufacturing adds another dimension to an increasingly competitive market, allowing device OEMs to focus on their core competencies of R&D, technology, sales and marketing. The trend toward outsourcing is proving to be a vital strategic tool because a competitive advantage is based as much on timing of product launch as it is on product cost.

Factoring in quicker production ramp-up, lower capital expenditures, access to highly skilled labor markets and raw materials, expert design teams and global distribution networks, there is little doubt that contract manufac-

Device Industry Trends

The rising popularity of outsourced manufacturing is best examined in the context of broad industry trends that are shaping the future business models of medical device manufacturers. Double-digit growth rates in certain market segments, an increasing rate of product development, industry consolidation among OEMs as well as pricing and regulatory pressures all are contributing factors.

Market Growth Is Outpacing Capacity Expansion

Growth of the broader device industry is being fueled by population demographics, product innovation and significant market potential outside the United States. High estimated growth in device end markets, such as cardiovascular, endoscopy and orthopedics, is challenging many OEMs' ability to plan and meet long-term internal manufacturing capacity requirements. Furthermore, any expansion of internal capacity over the long run will require significant capital investment, which otherwise could be invested in new product development.

Ben Dunn
Covington Associates, LLC

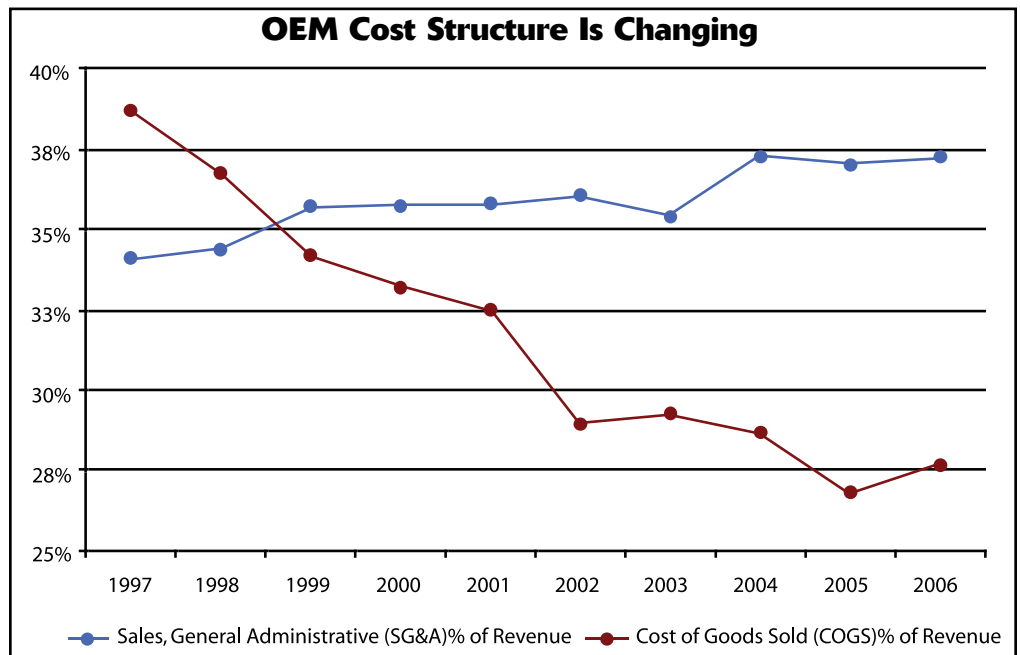
Operating Margins Are Under Pressure

Today, OEMs are trying to achieve revenue growth through a combination of new products, corporate acquisitions and product price increases. At the same time, governments, third-party payers and healthcare providers are consistently pushing for price concessions in an effort to reduce the effect of rising healthcare costs across the industrialized world. Technical innovation is a key driver of revenue growth. As technological advances occur, older technologies are relegated to use in commodity items and new technologies drive growth through premium pricing strategies.

The industry generally has improved gross margins over time due to productivity gains and shifts in product mix, yet gains in gross margin face eventual erosion as competition drives operating expenses higher in an environment of increasing pricing and reimbursement pressures. Competition in the device industry fundamentally is based on the expiration and infringement of patents, the primary driver of the research and development of new products. The dual effect of pricing pressure and rising costs suggests that firms within the industry increasingly must exploit sources of cost leadership such as economies of scale, proprietary technology and lower product acquisition costs to remain competitive.

Shortening Product Lifecycles

Technological parity among competing products makes time to market critical for the majority of device product lines. OEMs are stepping up new product development and are seeking ways to get their products to market more quickly, in order to gain market share ahead of entry by equally effective devices.



Source: Company filings

Note: Device OEMs include Baxter International, Biomet, Boston Scientific, CR Bard, Medtronic, Stryker, Varian Medical Systems and Zimmer Holdings

Consolidation Creates Supply Chain Challenges for OEMs

Industry consolidation continues among OEMs for a number of reasons, including:

- Using scale to drive operating leverage
- Gaining access to new technologies
- The convergence of biopharmaceuticals and devices
- Cost of developing distribution channels
- The generally large universe of small and medium-sized companies unable to complete the development of promising products

An issue for any consolidator, typically larger and in a stronger financial position, is the integration of disparate manufacturing and supply chain networks. This integration issue has the potential to create an organizational focal point that draws attention, resources and time away from an acquiring company's core competencies—the development and marketing of innovative products.

Contract Manufacturing Segment

In terms of participants, the medical device contract manufacturing segment is highly fragmented with thousands of independent operators competing for a piece of the OEM outsourcing opportunity. More than 3,000 firms currently are engaged in the business of machining, stamping, assembling, sterilizing or packaging medical devices. These firms range in size and complexity from relatively small owner-operated machine shops to larger niche manufacturers of specialty components and highly sophisticated, professionally managed organizations offering a broad range of services under one roof.

Approximately 50% of the estimated \$4.4 billion (as of 2005) outsourcing market is controlled by no more than 12 firms, with market leader Accellent Inc., controlling about 12% of the market. Accellent has grown from a small contract manufacturer to a fully integrated “one stop shop” with the help of a financial partner. Accellent's nearest competitor,

US Contract Manufacturing Market Size (2002–2010E) (\$ in Billions)			
	2002	2005	2010E
Medical Device Revenues	\$67.1	\$74.0	\$86.0
OEM Gross Margin	68.6%	70.0%	74.0%
OEM COGS	21.1	22.2	22.4
COGS Penetration	10.4%	19.7%	40.0%
Contract Manufacturing Market Size	\$2.2	\$4.4	\$8.9

Source: Medical device market size and gross profit from IBISWorld estimates. Contract manufacturing market size based on consensus among Frost and Sullivan, Millennium Research, MedTech Insight and Accellent estimates.

Symmetry Medical serves customers principally in the orthopedics market and has a 6% market share. Other competitors include Greatbatch, a manufacturer of batteries, capacitors and precision engineered components for implantable medical devices (among other things), with a 5% market share, Heraeus and Avail, both with 4% market share. The Tech Group, Lake Region and Fort Wayne Metals have 3% market share each and Orchid International and Doncasters Medical Technologies each have 2% of the market. The MedTech Group, Synovis, Creganna, Trivirix and Memry each have 1% of the market share. The top firms represent 49% of the market while the remainder of the market (51%) is highly fragmented, composed of firms that enjoy less than 1% market share each.

Market Size and Growth

The exact market for outsourced medical device manufacturing remains unclear, yet consensus estimates put it at approximately \$4.4 billion in 2005, up from \$2.2 billion in 2002. Primary drivers of the segment's growth include not only the growth of

the overall device market, but the degree to which device OEMs elect to outsource their manufacturing operations. As outsourcing gains acceptance among OEMs, its growth rate will exceed that of the medical device industry.

Research suggests that gross profit for all medical devices sold in the United States was a little more than \$52 billion in 2005, or roughly 70% of sales.¹ This translates into approximately \$22.2 billion COGS (cost of goods sold) for device OEMs. Assuming a \$4.4 billion market size for contract manufacturing, we can deduce that the production of approximately 20% of all devices sold in the United States in 2005 were outsourced to third parties.

Looking ahead to 2010, the market for outsourced manufacturing is estimated to grow at 15% annually to \$8.9 billion from \$4.4 billion in 2005. Assuming modest gross margin gains (due, in some part, to the continued trend to outsource), we reasonably can expect OEM gross margins to approach 74% on average. (Note: Improvement of OEM gross margins, ceteris paribus, reduces the size of the outsourcing opportunity). With estimated device revenues of approxi-

mately \$86 billion in the United States by 2010, a 40% COGS penetration rate translates into a potential market size of \$8.9 billion, more than double the current market size.²

Economics of Outsourced Manufacturing

As expected, the margin profile of device OEMs differs greatly from that of their outsourcing partners. Intellectual property, pricing strategy and customer concentration play major roles in determining how budgets are allocated and margins achieved.

There are two main profiles of medical device contract manufacturers. The first is not unlike any other outsourced manufacturing operation, in which high volume and low margins are characteristic traits. For OEMs, COGS constitute a relatively small portion of revenue due to the ability to maintain premium pricing. Contract manufacturers that lack intellectual property compete, to a large extent, on the basis of pricing as the primary differentiator. Without substantial value-added services, firms are unable to distinguish themselves in a sea of competition and generally are unable to break out of the high-volume/low-margin tradition. A second profile of medical device contract man-

Outsourcing Trends

ufacturers is niche players that produce low-volume, highly specialized products. These companies may offer specialized expertise or services, hold proprietary intellectual property or have solid relationships with customers that differentiate them as niche providers.

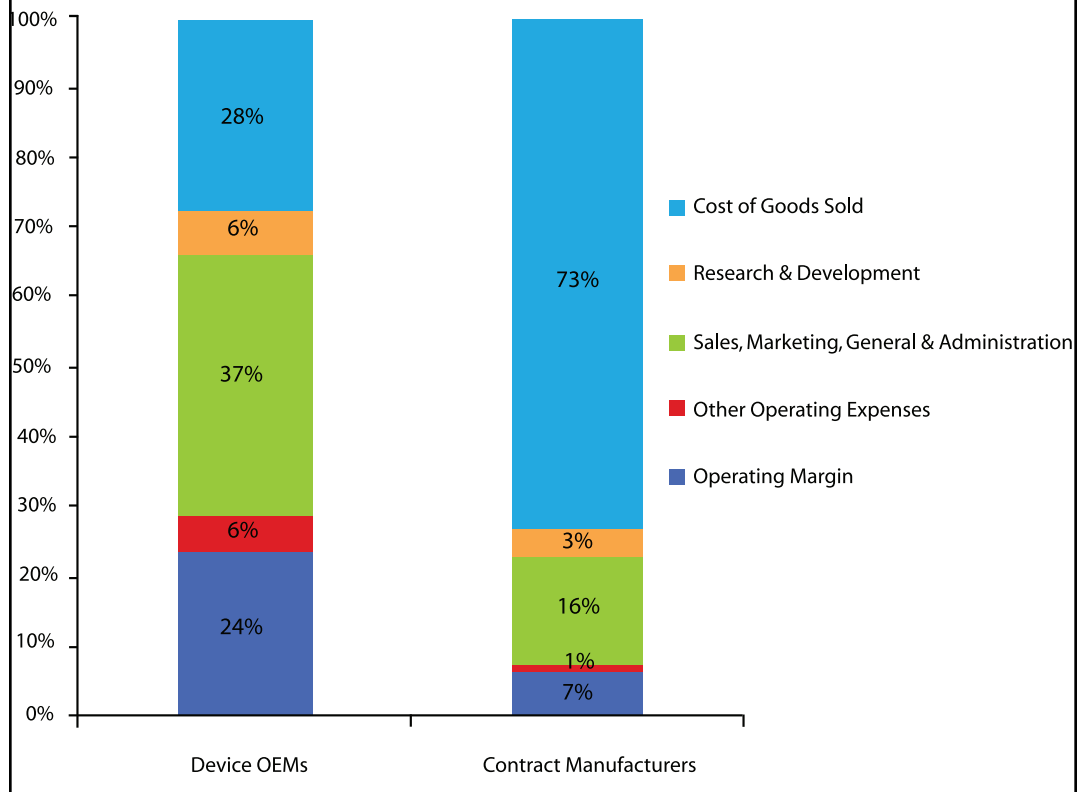
Advent of the Full-Service Contract Manufacturer

Having identified the opportunity to manipulate their own cost structures, leading contract manufacturers are attempting to broaden their service offerings to include R&D, engineering and supply chain management—value-added services that not only exhibit higher margin potential, but also enable an increase in the number of entry points into the OEM

cost structure. No longer will full-service manufacturers be competing solely for the opportunity to lower OEM product acquisition costs. Top-tier manufacturers increasingly are competing for the opportunity to co-develop products, patent manufacturing processes and establish distribution networks to handle finished goods.

With an increasingly strategic view of contract manufacturing, OEMs are more likely than ever to establish long-term contracts with their outsourcing partners. The benefits of working with a limited group of suppliers extend beyond mere supply chain efficiencies. Rigid quality standards in a highly regulated environment call for a significant degree

Comparison of Expenses: OEM vs. Contract Manufacturing (CY2006)



Source: Company filings

Note: Figures are medians. Device OEMs include Medtronic, Stryker, Zimmer, St. Jude Medical, Biomet, Edwards Lifesciences and Smith & Nephew. Contract Manufacturers include Accellent, Symmetry Medical, Synovis Life Technologies and Plexus.

of trust and oversight in establishing supply agreements. Consequently, OEMs go to great lengths in choosing contract manufacturing partners, often including specific vendors in the 510(k) process. The costs of moving production from one manufacturing facility to that of a competitor generally are quite high.

What's Next for Contract Manufacturing

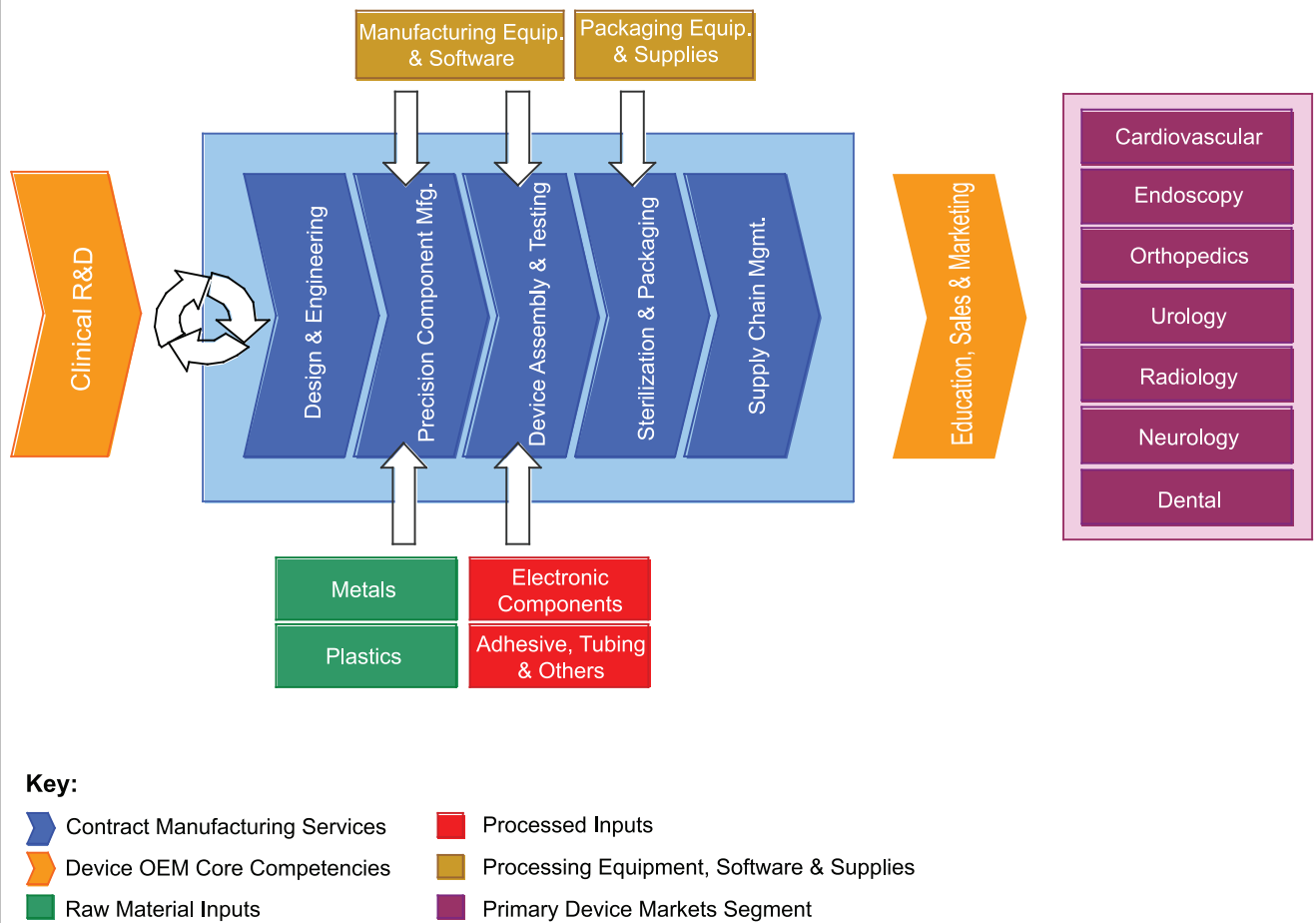
Given the growing acceptance of (and need for) outsourced services by medical device companies, the market will continue to grow rapidly. As companies entrust more processes and services to outsourcing providers, their dependence on outsourcing will rise. This is a positive

trend for all involved, as it will allow medical device companies to focus on their core competencies—research, product development, sales and marketing.

As outsourcing becomes the norm, medical device companies are seeking better ways to manage their outsourcing partners. This trend favors one-stop shops (suppliers of multiple services) that are able to demonstrate an ability to coordinate multiple services. As a result, firms that are niche providers will need to coordinate and work closely with other suppliers to achieve a similar level of coordination and ease of management by the customer.

This expanding, highly fragmented market provides opportunities for

Full-Service Contract Manufacturers are Assuming a Greater Role in the Supply Chain



existing firms and will attract new entrants as well. For firms currently providing services, the question is how to best take advantage of the overall growth. On one hand, OEMs are expanding their use of outsourcing, while on the other hand, they are looking to better manage their partners and, ideally, have fewer of them. An existing supplier needs to carefully protect its position with its customers while strongly considering what other services it can provide to its current customers. New entrants into the field must achieve credibility through a reputable customer. This can be achieved either through a successful initial sale or the purchase of an existing business with customer relationships.

Given the fragmentation of the market, attractive industry dynamics and the need for more coordinated suppliers, some consolidation is inevitable. Existing firms will seek to increase their footprint through customer acquisition and supply a greater range of services. A successful consolidation strategy can achieve both. New entrants will seek to stake out their positions and likely will look to acquire existing businesses to do so. However, given the continued growth of the industry and the difficulty that new entrants or consolidators will face as they combine businesses, there will still be opportunity for strong niche players that provide a compelling service or solution and work well with other suppliers. This

should result in a market with a few large one-stop-shop suppliers with significant market share and a number of small niche players that have an ability to provide unique services and work well with other suppliers. ❖

References

1. *Projected growth rates of medical device companies provided by Capital IQ*
2. B Dunn and J Finn, *A Strategic Review of Outsourced Manufacturing for Medical Devices* (Boston: Covington Associates, 2007).

Ben Dunn is managing director of Covington Associates, LLC (visit www.covllc.com), a specialty investment banking firm based in Boston. He can be reached at Ben@covllc.com.