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An Epicor White Paper

Spotlight on Medical Device Manufacturing: 6 Ways to Justify Prices and Rein in Costs with Enterprise Software

Executive Summary

Medical device manufacturers have long marketed their products with limited concern for costs. But today, an aging population and skyrocketing medical costs are prompting private insurers and government payers worldwide to limit reimbursements for medical devices.

Medical device manufacturers are responding in two ways, by:

- Justifying product price points by carefully documenting their value in improving patient outcomes
- Reducing costs throughout their operations by rethinking how they sell and market their products, outsourcing operations, and implementing lean manufacturing principles

This white paper details how enterprise software enables medical device manufacturers to more successfully implement these price justification and cost cutting initiatives.

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Why Medical Device Manufacturing is Becoming Cost Conscious

A decade ago, many medical device manufacturers paid limited attention to costs when they developed products. After all, when making a drug delivery advice, for example, drug costs could exceed device costs by as much as 1000 to 1, leading many providers to pay more attention to optimizing delivery than device cost.

Today, payer pushback against rising costs, healthcare reform, and increasing competition all limit what manufacturers can charge for medical devices, even as R&D costs continue to skyrocket. In their efforts to maintain their bottom line, medical device manufacturers must justify prices while reducing costs throughout their operations. Indeed, a recent survey by the American Society for Quality found that "cost reduction while maintaining quality" is one of the top concerns for medical device manufactures in 2010.[1]

Payer pushback most

As the population ages and healthcare costs soar, insurers and government programs are limiting reimbursements for medical devices and debating the value of paying higher prices for new devices. As Altico Advisors[2] reports, "Because of rapidly increasing healthcare costs, private insurers and government programs like Medicare have moved to limit payments for many medical treatments that require medical supplies or devices." As part of these cost control efforts, the report continues, "third party payers such as Medicare, Medicaid, MCOs and commercial insurers are becoming more involved in determining the types of diagnostics and treatments eligible for cost reimbursement to doctors, hospitals and other providers. In many cases, third-party payers play a flat fee, which encourages the provider to use the lowest cost treatment."

As a result, when Deloitte Consulting[3] surveyed medical device manufacturers on what they saw as their biggest risk through 2015, thirty-six percent of the respondents identified pricing and sales as their key concerns.

Healthcare reform

The Patient Protection and Affordable Care Act that President Obama signed into law on March 23, 2010 may increase these price pressures. The new law includes a 2.3 percent excise tax on all sales of medical devices, scheduled to take effect in 2013, as one way of paying the cost of insuring 32 million more Americans. The impact is uncertain. Some medical device manufacturers may benefit from increased sales. Larger companies may be able to pass along the costs of the tax. However, smaller manufacturers fear that they may not be able to raise prices sufficiently to cover the tax and may become less profitable.

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1 "Medical Device Industry Identifies Healthcare Reform Among Top Challenges," American Society for Quality, February 9, 2010.

2 "The future of the life sciences industries: Transformation amid rising risk" Altico Advisor's.

3 "The future of the life sciences industries: Transformation amid rising risk" Deloitte, 2009.

Increasing competition

As medical device manufacturers continue to face pricing pressures, successful companies will be those that develop innovative products, distinguish them from their competitor's offerings, and maintain a competitive advantage through a strategic IP portfolio, reports a recent article in Medical Design[4]. An increase in innovation generally leads to an increase in competition which puts further pressure on prices.

High R&D costs

At the same time, the cost of innovation is high. This is a particular challenge for devices that address rare diseases. According to Stephen Ubl, president and CEO of the Advanced Medical Technology Association, "Medical technology companies face potentially enormous (research and development) costs in developing new devices with little hope of recouping their investment due to the small market for some products."[5]

Responding to Pricing Pressures and Increased Costs

As medical device manufactures adjust to new pricing pressures and higher costs, they are working to justify the value—and hence the prices—of new devices as well as working to reduce costs throughout their operations by adopting new sales models, outsourcing operations, and adopting lean manufacturing principles.

Documenting device effectiveness

To stem rising costs, reimbursement authorities of national health systems in Europe are taking measures to evaluate and reimburse new products at higher price levels only where they show increased efficacy over existing products on the market. In the U.S., legislation is being considered to undertake federal research into the comparative effectiveness of new vs. existing products. As a result, medical device manufacturers must justify their prices by testing and fully documenting the effectiveness of their products compared with existing products.

Rethinking sales and marketing

With sales and marketing investments among the industry's largest expenditures, medical device manufacturers are asking whether it makes sense to support massive field sales organizations when governments in Europe and managed care in the U.S. are increasingly responsible for reimbursement decisions. The Deloitte[6] survey found that, "Executives foresee adopting sales strategies that have been successful in other industries, including value-added services that use technology to drive relationships and partnering with customers and end users/consumers."

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4 "Healthcare reform calls for proactive IP portfolios" Medical Design, October 1, 2009, by Eric Raciti and Timothy McAnulty.

5 Franken, industry urge more incentives for medical device makers to develop products for rare diseases," By Julian Pecquet, July 21,2010, Healthwatch, The Hill's Healthcare blog.

6 "The future of the life sciences industries: Transformation amid rising risk" Deloitte, 2009.

Outsourcing operations

Medical device manufacturers are increasingly interested in outsourcing to reduce costs, allocate internal resources more strategically, and take advantage of different competencies of other firms to speed new product development.

A Knowledge@Wharton report[7] found that most medical device companies see great potential in outsourcing with nearly all companies surveyed in this space planning to outsource over the next few years. Medical device manufacturers have outsourced manufacturing for more than a decade and those that do have been able to reduce product development costs by 10-30 percent. Many are also outsourcing R&D, often to Asian countries were costs are significantly lower.

Implementing lean manufacturing

Finally, lean manufacturing initiatives are growing in popularity as medical device manufacturers strive to reduce costs by eliminating waste throughout the product lifecycle. An article on key trends for 2010 in Medical Design Technology[8] quotes Kay Phillips, president of ATEK Medical Manufacturing as saying, "We see many more companies focused on lean manufacturing and lean/six sigma practices. This trend will continue as the industry is challenged with maintaining and improving margins and improving the quality of its products."

Lean manufacturing is an adaptation of the highly successful and often copied Toyota Production System (TPS), which many view as a model of efficiency and productivity. Lean principles require manufacturers to strive to identify the "value" of processes to the customer and eliminate "waste" or processes that the customer would not perceive as something for which they would be willing to pay. This waste elimination is a continuous pursuit. While people most commonly associate manufacturing processes with lean initiatives, Lean can and should extend beyond the plant to indirect activities such as logistics, administration, engineering, and warehousing, as well as non-manufacturing activities such as accounting or marketing.

[7] http://www.nerac.com/nerac_insights.php?category=articles&id=46

[8] "Key Trends and Issues" Medical Design Technology "Key Trends and Issues" Medical Design Technology.

The Role of Enterprise Software in Price Justification and Cost Cutting

Enterprise software is central to the operation of any medical device manufacturer. These solutions serve as the central source and repository of operational data. They document and automate workflows. They even allow manufacturers to efficiently collaborate with customers, partners, and suppliers. As such, enterprise solutions can play a key role in helping medical device manufacturers justify prices and implement measures to reduce costs.

Justifying product prices

In their efforts to prove a product's quality to regulators—and justify its price—medical device manufacturers make substantial manpower and cash investments in product testing. They document their results through every step of the product lifecycle, accumulating massive amounts of data. For example, a typical phase three study for a drug delivery device can generate enough data to fill a container lorry.

A vendor that fully integrates product lifecycle management (PLM) capabilities with its enterprise software can help manufacturers manage the documentation of proof required through the trials process to identify and communicate the value of these devices.

Rather than having to rely on multiple databases and documents in multiple locations, manufacturers can rely on PLM as a central knowledge repository for process and product history. The PLM repository can control and manage all documentation associated with a product throughout its lifecycle, including CAD drawings. It provides an electronic vault where documents can be stored securely and where access and versioning are tightly controlled.

Accuracy and completeness of documentation is ensured because PLM automatically manages and groups source documents with supporting sub documents. PLM promotes integration and exchange of this documentation information among all enterprise users who interact with the product. It enables audit tracking and can provide advanced document search and retrieval functionality.

Using PLM capabilities will make it easy to gather appropriate documentation, simplifying the process for demonstrating product quality and efficacy to insurance companies, Medicare/Medicaid officials or payment authorities for national healthcare organizations in Europe.

Implement new sales and marketing paradigms

Rather than sending direct sales forces to physicians offices, many medical device manufacturers are providing considerable information about their products and how to use them, as well as allowing customers to order their products over the Web. Medical device manufacturers that wish to put in place these new sales and marketing paradigms can simplify their efforts using Customer Relationship Management (CRM) functionality embedded within Enterprise software.

CRM capabilities simplify the order management process by aggregating information from across the business and making it readily available to customers, sales reps and customer service agents. Integrated pricing, configuration, order validation, availability checking and credit checking smooth the order-handling process.

As part of these CRM capabilities, workflow management speeds order processing, eliminating delays and handoffs to all affected departments. As soon as an order is captured, inventory, accounting, planning, production and shipping are immediately notified and can start fulfilling the customer's requests. All participant's activities are synchronized to work effectively toward more quickly fulfilling the customer requests. During the life of the order, current and accurate status information is available online so the customer can track their order with a few mouse clicks, eliminating administrative burdens for the manufacturer.

Simplify outsourcing

As medical device manufacturers seek to outsource functions such as R&D or manufacturing to reduce costs, they need to collaborate efficiently and effectively with suppliers and monitor supplier performance. Enterprise software systems offer capabilities that promote tighter collaboration and efficient operations throughout the supply chain while allowing medical device manufacturers to analyze key metrics regarding supplier performance.

Automation improves coordination with suppliers. Electronic queues on supplier portals, direct connections with Web services allow manufacturers to automate the communication of RFQs, purchase orders, changes, releases and payments. Vendors can respond with electronic acknowledgements, electronic invoicing, and coordination on availability. These capabilities make communication faster and more detailed while eliminating human error from manual entry, messy or illegible faxes or lost paperwork. Additionally, optimal integration with supplier systems helps manufactures avoid miscommunication, delays and confusion.

Business Intelligence capabilities within Enterprise solutions that include graphical queries and drill down capabilities provide manufacturers with metrics about supplier performance. Manufactures can view supplier metrics such as measurements of supplier quality and supplier nonconformance to reduce risk in outsourcing.

Support lean manufacturing

Enterprise systems support Lean manufacturing through their ability to reduce waste in numerous business and manufacturing processes.

For starters, it's impossible to improve what you can't see. Enterprise systems store all the data, definitions, and records of the activities of the organization. Reporting and analysis capabilities allow manufacturers to analyze this data to find opportunities for improvement, offer "what if" analysis to help focus efforts on the highest payback activities, and measure the progress of efforts to eliminate waste.

Enterprise systems also reduce or eliminate wasteful paper based processes, allowing manufacturers to manage their enterprise information and business workflows using efficient electronic processes. Enterprise systems typically store enterprise information from applications centrally, allowing different departments and companies within the organization to share and use information in real-time. This reduces data redundancy and inaccuracy to ensure that key strategic and tactical decisions are made from accurate and up-to-date information.

Automated workflows improve the efficiency of business processes by enabling entire processes to be real time and paperless—whether they're best practices or processes unique to the organization. The system keeps track of all the tasks that must be completed in each process and presents individual workers with a list of

activities they must accomplish in order for the task to be completed at the right time. It also gives users instant, online access to all the information they need to complete the task, whether that's drawings, material requirements, manufacturing instructions or quality documentation. Manufacturers can customize automated workflows as necessary to further improve efficiencies by building business rules into any function in the system.

Automate Smaller Production Runs

When Medical Design Technology Magazine[9] asked what one process that gained acceptance over the one process that recently gained acceptance will lead to more efficient manufacturing, Ron Earle, recently retired group senior vice president of B. Braun Medical Inc's OEM/Industry Division, replied, "Automation for smaller production volumes that need finite quality checks and repetitious tolerance assembly. Companies have been looking at lower cost production sites around the world over the past decade or so for commodity products. Today, with technology being target specific, alternate therapies are being assembled in the U.S. by contract manufacturers with small-volume automated assembly processes."

Lean plants often use Flow production and Kanbans to flow work smoothly through the plant based on demand with minimal delays, handling, inventory, downtime, scrap, and rework. Flow manufacturing is characterized by production lines and/or cells in which work is pulled piece by piece through the process, not in batches. The flow of work is controlled through physical signals called Kanbans that can be tags, labels, containers, or electronic signals. Kanban based flow manufacturing is conducted without work orders and the waste associated with work orders. Flow manufacturing is also much faster than traditional processes, more flexible and responsive to changes, ties up less inventory and delivers higher quality at less cost.

When Lean manufacturing is supported by enterprise software, production of smaller product quantities can be automated. With enterprise software, as inventory levels or order demand require additional product, Kanbans are automatically triggered for replenishment, whether through the movement or manufacture of product or by notifying the supplier to ship off an existing blanket order. This removes wasted processes in planning and production.

9 "Key Trends and Issues" Medical Design Technology.

Support for continuous efficiency improvements

Lean manufacturing is not a one-time implementation; it is an ongoing process of improving efficiency. Enterprise software support continuous improvement.

Enterprise systems contain the definition and documentation of processes and procedures, which are embedded within the system's routings and workflows. This existing "documentation" allows organizations to clearly see what happens today. As improvements are made and changes are entered into the system's files, these new definitions enforce and perpetuate the improvements. Comparative measurements document the effect of changes on lead times, costs and efficiency. After the initial objectives are achieved, the system captures the input needed for the next round of improvements.

Business intelligence tools embedded in the enterprise software provide a way to measure efficiencies across the entire enterprise. They enable:

- After the fact analysis
- Dashboards and real time alerts warn management of impending problems early, before waste is generated and these warnings can also point to areas needing improvement
- Powerful interactive tools allow managers to dig deep into data and mine for waste and elimination opportunities
- Graphical views of information provide insight into how different parts of the business interact with each other. With this insight, organizations can avoid changes in one area that will negatively impact other parts of the business

Conclusion

Enterprise software serves as a central source for operational data, documents and automates workflows, and provides capabilities for collaborating more effectively with customers, suppliers and other partners.

PLM capabilities take advantage of these characteristics to make it easy to store and retrieve massive amounts of documentation that justifies the value—and price—of each medical device. Portals and CRM capabilities give customers self-service access to information and allow them to place orders online, thus enabling new ways of marketing and selling. Because enterprise solutions automate communication and collaboration between manufacturers and suppliers and provide supplier metrics, they simplify outsourcing and reduce risk. These solutions provide information, analytics and workflow automation that lean manufacturing initiatives require to minimize waste in manufacturing. They also automate Kanbans that facilitate demand-based manufacturing and the furnish the analytics necessary to continuously improve operations. As such, enterprise software serves as an ideal platform for helping medical device manufacturers justify prices and reduce costs throughout their organization.

About Epicor

Epicor Software Corporation is a global leader delivering business software solutions to the manufacturing, distribution, retail, and service industries. With more than 40 years of experience, Epicor has more than 20,000 customers in over 150 countries. Epicor solutions enable companies to drive increased efficiency and improve profitability. With a history of innovation, industry expertise and passion for excellence, Epicor inspires customers to build lasting competitive advantage. Epicor provides the single point of accountability that local, regional, and global businesses demand. For more information, visit www.epicor.com.

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