Strategic Product Life Cycle Management Partnerships as the New Means of Competitive Advantage for Medical Technology Companies

A Frost & Sullivan White Paper
During the 20th Century, innovation determined a medical device company's success. However, in the future, innovation for medical technology companies will no longer mean simply making a better product, but executing an overall better business model. This business model needs to cover every stage of a product's life cycle from design, manufacturing processes and regulatory submission at the beginning through distribution and after market service at the end. While success in the market demands that all stages of this life cycle be well executed and done cost efficiently, fewer companies are devoting internal resources to developing competencies in all of them. This is true across many industries, with the medical devices industry included.

Product life cycle management in medical devices is key to the success of a product and company. As one product approaches maturity, new innovative products must be introduced that offer improved clinical efficacy, ease-of-use, or cost-effectiveness. Device improvements can be patented and, thereby extend the company's intellectual property and its unique selling proposition in the competitive marketplace. Because of the high value of intellectual property, medical device companies have considered new product innovation to be their core competency. Traditionally, the continual innovation of the same device and the need to protect intellectual property have contributed to medical device companies being slow to outsource their R&D and manufacturing processes. However, companies in the industry are increasingly exploring new business models that are more reliant on strategic supply chain partnerships in order to lower costs, gain access to skills and resources, and enter new markets faster.

Contrary to this, pharmaceutical companies have openly embraced outsourcing since the 1980s. Expiry of patents on main revenue-generating drugs, competition from the generic versions of branded drugs, and increasing research and development costs have forced pharmaceutical manufacturers to look for strategies to cut costs and speed-up processes. One of the strategies commonly adopted is outsourcing of processes to lower cost regions. The functions usually outsourced are manufacturing, development (pre-clinical and clinical trials) and sales. Clinical research organizations (CROs) have expanded their services from clinical trial management to comprehensive management of all complex drug trial processes.1 Hence, in the last three decades, pharmaceuticals outsourcing has moved up the value chain from drug manufacturing and

1 Global Pharmaceutical Outsourcing—Trends, and Growth Opportunities, #4668-90 © 2009 Frost & Sullivan www.frost.com
CRO outsourcing to a more strategic role in identifying new compounds and drug development. Frost & Sullivan believes that the medical devices industry is likely to follow a similar evolutionary pathway in the coming decade. In the future, medical devices companies will be pressured by customers and shareholders to provide continual innovation while operating under increasing financial demands for efficiency and profitability. At the same time, regulatory scrutiny is expected to increase and supply chain logistics will become more complex as these companies continue to expand globally. Tackling all of these seemingly antagonistic goals at once is a daunting challenge for any one company by itself, which is why Frost & Sullivan believes that in the years ahead more medical device companies will be relying on strategic partners with the skills and resources necessary to meet these demands. These partners will need to be able to provide not only skills and resources to help medical device companies with specific business challenges, but also comprehensive suites of solutions for every phase of the product life cycle. For medical device manufacturers, partners with these types of competencies in regulatory affairs will become increasingly valuable as demands from government agencies continue to grow.

THE BENEFITS OF COLLABORATING WITH A STRATEGIC PRODUCT LIFE CYCLE PARTNER

A strategic product life cycle partner can help companies maintain their focus on the capabilities that provide its competitive advantage, while outsourcing the functions that are less critical to the value of the company. For the medical device industry, in particular, managing the product life cycle is an important function but innovation is what drives the value of the stock on Wall Street. By outsourcing manufacturing, and sustaining engineering functions, for example, the company can then focus on innovation and new product development. Partnerships can be used as virtual extensions of R&D to help maintain strategic focus, operating flexibility and cost effectiveness across the portfolio. Although truly strategic partnerships take time and effort to establish and operate, companies that use them effectively can benefit from their partners’ abilities to:

- Reduce unit costs and create a more variable cost structure
- Provide operating agility and flexible capacity to support unexpected changes in demand due to scientific, regulatory or market shifts
- Provide selective access to high talent pools, diverse knowledge bases, emerging technologies and innovative treatment solutions
- Create global research, manufacturing and distribution networks to break into new markets faster
- Allow the company’s most talented scientists, clinicians and others to focus on innovation

These types of partnerships free a company to focus on its core competencies, which, in the case of medical device companies, is usually clinical and technical innovation, sales and marketing. Bob Rothfritz, Vice President of Operations at NovaMin Technology, Inc., and a

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2 Ibid.
seasoned operations executive with years of experience managing contract relationships while working for Ethicon Endo-Surgery, Kimberly-Clark, SpectRx, and Bausch & Lomb, stated, “There are three pieces you’ve got to have to create a winning business strategy: innovation (disruptive technology); the right marketing strategy (i.e. the right product at the right time at the right price); and third, you have to be able to get the product built. Of those three, getting the product manufactured is probably the least important of the bunch.”

Within the broader life sciences industry, Eli Lilly is a prime example of the benefits of outsourcing a variety of its operations. In 2008, Eli Lilly set forth a strategy to transition away from its traditional vertically integrated pharmaceutical model and moved towards a fully integrated pharmaceutical network. The company forged new, innovative partnerships with Indian life science companies, private investment funds, and CROs (contract research organizations) to spread the risks of R&D. It shifted a significant portion of development to Covance and Quintiles Transnational, a drug development services company, transferred clinical data management to i3, a global clinical research organization, and established a virtual drug development organization with Chorus, an early phase drug development body. Through its network, Lilly now has developed access to a broader pipeline, increased the leverage of its R&D investments, reduced cycle times and late-stage attrition, and created a flexible, variable cost structure.4

CELESTICA: PROVIDING BEST IN CLASS STRATEGIC SERVICES FOR MEDICAL DEVICE MANUFACTURERS

In a global search for a strategic product life cycle management partner who has delivered high value to its clients, Frost and Sullivan identified Celestica, a global supply chain provider who offers end-to-end product life cycle solutions throughout a global operations network. Building upon the company’s extensive experience in servicing highly regulated industries with complex technology solutions, Celestica has made strategic investments to further tailor its offerings to healthcare customers. These investments include expanding capabilities and industry expertise. Celestica’s healthcare division provides design, complex electromechanical assembly, automated manufacturing, final system test/QC, fulfillment, and after-market services to medical equipment companies.

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“Today’s healthcare companies need partners who are prepared to invest in their success and who can deliver customized solutions to help them accelerate results,” said Craig Muhlhauser, President and Chief Executive Officer, Celestica. “Our approach is to collaborate with our healthcare customers to deliver new and innovative supply chain solutions designed specifically for the healthcare industry of the future.”

Edward Hickey, Director of Supply Chain Management at SonoSite, a manufacturer of hand-carried and mountable ultrasound systems, acknowledges that like many medical device companies, SonoSite views its major strengths as research, innovation and marketing as opposed to manufacturing. While SonoSite continues to invest in both existing and new products, the company’s growth priority is to devote its most critical technical resources to its new product lines.

In 2003, SonoSite chose Celestica as its partner for all its circuit board manufacturing. According to SonoSite, Celestica won the contract because it provided the best mix of price, performance, and global manufacturing capabilities. Since that time, the relationship between the two companies has grown as Celestica has begun performing “box build” in addition to the circuit board manufacturing.

“We continue to enhance [the partnership with Celestica] and see them moving more and more in the direction of building more complete medical devices [for SonoSite],” said Hickey. “Celestica certainly has very good manufacturing and technical strengths. They build good quality [products], and they do it very cost effectively. I think they have good distribution skills and a good worldwide footprint.”

“We have more of our technical resources working on new products than we do on sustaining activities with existing products,” added Hickey. “We would like to be more reliant on partners like Celestica over time. We have core competencies in some of our manufacturing processes, and we will probably keep them in house, but there is nothing ‘magical’ about building basic electromechanical stuff. There are people in the world who do that better than we do and we need to work with those people. We are actively trying to figure out the balance between what process technology and IP we need to retain to support our core competency and what outside manufacturing partners can do better.”

Celestica has a strong history of strategic partnering with companies in highly regulated markets such as aerospace, defense, communications and healthcare. In 2006, Celestica received the North American Frost & Sullivan Award for Customer Service Leadership because of its work with clients in the aerospace and defense category. Frost & Sullivan cited the company’s strong customer focus, its understanding of customer needs, its customized services and solutions, supply chain expertise, and leadership in regulatory legislation as the basis for the award. These same traits which Celestica used to the benefit of its aerospace and defense clients are equally applicable to all of the company’s clients in every industry it serves, including healthcare. The transferable skills, experience and resources across industries that Celestica brings to every client relationship sets the company apart.
The company’s partnership with Juniper Networks is a good example.

Juniper Networks, a $3 billion provider of networking products, software and services, selected Celestica as a strategic partner in 2001 because of the proximity of their engineering resources in Toronto, their global footprint and their ability to offer economies of scale and lower cost structures.

“We have very complex, electromechanical assembly and we needed to have a certain level of expertise and Six Sigma engineering capability in the manufacturing process in order to be successful,” said Kevin Canty, Senior Vice President of Worldwide Operations at Juniper Networks. “We wanted a partner who could drive initiatives and steer us in directions that would be advantageous in the long term as we grew.”

And growth is exactly what occurred at Juniper Networks with the company rapidly expanding its global presence. Juniper has manufactured in Malaysia and China and grown their customer base significantly in Asia. They have most recently moved their Toronto manufacturing to Mexico to benefit from lower manufacturing costs. “We have benefited immensely from Celestica’s broad capabilities and geographic locations,” said Canty.

Juniper expects to do more and more work with Celestica to drive their value up the chain. “The days of companies looking to build factories and be vertically integrated are over,” Canty said. “You want to create centers of expertise.”

The most impressive part of working with Celestica, according to Canty, has been the direct line of communication that Celestica CEO Craig Muhlhauser has maintained with Juniper. Celestica has even developed some educational tools for Juniper’s internal management, executives and field personnel to provide a better understanding and appreciation of the company’s global manufacturing, physical logistics and activities that drive day-to-day operations.

THE BENEFITS THAT PARTNERSHIPS PROVIDE

In the course of its research, Frost & Sullivan identified five major benefits that strategic product life cycle management partners bring to medical device companies:

1. Reduced capital requirements for start-up companies: Many medical device innovations are developed from venture capital funding with limited resources. As a start up, Juniper did not want to invest precious dollars in building manufacturing capability.

“I think there is definite knowledge and understanding that you compete on the supply chain and your fulfillment capabilities so all those linkages throughout your supply chain are vital to business, irrespective of whether you are in-house or using
contract manufacturing,” said Canty. “It was clear that managing parts inventories and assembly was not really going to change the game.”

One of the most valuable services that Celestica offers Juniper is on-demand inventory management, from raw materials to finished goods. This allows Celestica to work with Juniper to free up its cash so that it can reinvest in other parts of their business. “It requires a level of trust and partnership that you don’t see very often,” said Canty. “We both recognize that we have significant skin in the game.” Canty believes that this type of partnership is a competitive advantage. They get the best people working on their projects. In return, Canty does not feel that he has to fight his contract manufacturer for the “last 1 percent” of cost savings. More than just a relationship between a customer and vendor, Juniper and Celestica have a true partnership with an established level of trust and an effort made to develop mutually beneficial strategic business decisions.

2. Innovating business models in a rapidly changing industry and competitive landscape: Hickey reports that with more than half of SonoSite’s sales now outside the United States, the company is considering whether and how to put into place a more globally distributed manufacturing model where it can bring more final assembly and testing closer to local customers.

“For a company like ours, we cannot afford to build plants everywhere like some of our huge competitors. So if we are going to have a distributed manufacturing model, it is going to have to be with a company like Celestica. Their footprint all over the world gives us the opportunity to have a much more sophisticated and cost effective manufacturing and distribution model than any company our size could ever afford to do on its own,” Hickey said. “Companies that are our size have to take advantage of partnerships like this or they are not going to survive.”

While SonoSite was able to use Celestica to adapt its business operations to an increasingly global market, Kevin Canty from Juniper pointed out that for his company Celestica’s logistical expertise was especially valuable. “When you are shipping multiple products on the same order from different origins and need them to arrive at the same time to the same customer, Celestica handles this very well. They also consolidate the billing so the customer receives one invoice from Juniper. Their expertise in global logistics is a key advantage.” In addition, when product is manufactured closer to the end-consumer, production and delivery can be far more efficient. For many clients, Celestica has been able to leverage its local sourcing expertise and understanding of regional differences to lower total cost of ownership to its customers or adapt to changing needs in operations.

3. Cross-industry expertise: Just as much of the manufacturing infrastructure and systems Celestica uses for its medical devices customers are also used for non-healthcare companies, Celestica has been able to leverage its intellectual capital developed from other industries to the benefit of medical device companies. For
example, Canty comments that Celestica’s experience with manufacturing adhesives across many industries helped Juniper identify and put in use new adhesives that could contribute to better product longevity.

Frost & Sullivan believes that in the increasingly competitive medical devices market, manufacturers would be wise to look to relevant new sources for ideas that can make them more successful. In many instances, these insights will come from other industries. Research, design, and manufacturing expertise for the aerospace, defense, and information technologies (IT) industries may prove to be valuable for medical devices.

Bob Rothfritz of NovaMin commented, “The robust requirements for products in the defense and aerospace industries translate well into medical device. Products that treat critically ill patients need to be as reliable as products that send a man to the moon!”

Companies like Celestica with this broad experience are poised to become catalysts for this type of interchange.

4. Improved efficiency (lower R&D and manufacturing costs): The rising cost of labor in the developed world, pressure to contain the escalation of healthcare expenditures, and the increase in R&D as a percentage of revenue are all trends that have pressured pharmaceutical companies to globalize operations in order to maintain profit margins and grow a global revenue base. This globalization of industry over the past several years has created a new world economy. As manufacturers have increasingly outsourced to lower-cost countries such as China and India, these emerging markets have improved their skills to offer more technically advanced services at lower costs as well. “I think to most (small and medium-sized medical device companies), it is essential to take advantage of contract manufacturing partners’ low-cost facilities overseas in order to compete with large multi-nationals,” Hickey at SonoSite states.

5. Improved access to global markets: As outsourcing of manufacturing to India and China has increased, the per capita income in these countries has created a new wealth and prime market of consumers for future revenue growth. These emerging markets represent key future opportunities for medical device companies. One executive at a major global diagnostics and device manufacturer interviewed by Frost & Sullivan sees outsourcing growing more in the future since it provides easier and less risky access to low cost geographies. He also notes that the medical devices industry tends to have a much greater concern over margin performance compared to the pharmaceutical industry. As medical device companies compete with each other based on margin, there is a real opportunity for outsourcing companies with diversified, flexible manufacturing capabilities around the world to help device

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6 Ibid.
companies hit those margin targets. Still, he notes that among medical device companies there is always the temptation toward vertical integration to hold on to as much margin as possible, but this may not be sustainable in the future in light of global expansion.

The same executive believes that many Western medical device companies have become too change averse, with too much red tape in place to slow down new product development. Instead, the prevailing model is for major device companies to acquire smaller companies with innovative products and to then adjust the acquired companies’ internal systems. However, this acquisition strategy often underestimates the difficulty in resolving and integrating complex internal systems. Instead, what device companies might want to consider is lower cost, offshore design and development which “could be an enormously differentiating feature,” according to the executive cited earlier. He believes that while contract manufacturers are used today primarily for margin savings, there is great potential for using similar partners for end-to-end design and manufacturing as well.

“That’s where the real value is—the lower overhead design,” according to the executive. “That model could make sense, but it is a tough model. Just like doctors do not want to admit that computer programs can do 80% of what they do, engineers and designers in the Western world do not want to admit outsourced designers can do the same thing as well. No company wants to make R&D a lousy investment. Companies worry about that. If you get a really successful product, getting it right is worth a lot.”

**STEPS FOR SUCCESS IN STRATEGIC PARTNERSHIPS**

Deloitte LLP conducted a recent study of senior executives from 25 large pharmaceutical and biotech companies including heads of R&D, Clinical Development, Strategic Planning, Virtual R&D organizations, External Scientific Affairs and other functions. The goal of the study was to understand the potential for strategic partnerships in the future R&D operating model and to identify effective practices and pitfalls in defining and executing R&D partnerships. The executives interviewed in the study identified a common set of effective practices for building partnerships which were supported by interviews Frost & Sullivan conducted in the course of its own research:

- **Commit at the top levels of the organization:** Analyze the partner strategy and clearly convey the benefits of the strategic partnership. Get buy-in from all levels of the company, including top executives. Articulate a vision that links to broader business goals and is promoted throughout the organization.

- **Know your core needs and objectives:** Develop a set of explicit objectives your company wants to achieve through its strategic partnership. Carefully analyze your company’s capabilities, understand your core skill sets, and identify where each party

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7 Starck, et Al.
can add value to ensure both parties have a dominant need for the partnership. In response, each party must develop solutions that align their strengths with what the portfolio needs.

**Identify the right partners:** Executives surveyed in the course of Deloitte’s research agreed that identifying the right partners was fundamental to the success of strategic partnerships, but how does a company know when a partner is a fit? Edward Hickey of SonoSite states that for medical device companies like his, supply chain partners must have quality and process systems that are proven and rigorous in order to meet FDA requirements. He believes that in the future the most successful medical device contract manufacturers will not only continue to provide high quality and low cost manufacturing, but value added services and very specific and specialized skill sets that are important to customers in market segments those manufacturers are attempting to serve.

Bob Rothfritz described NovaMin’s rigorous evaluation processes. “We send a team of quality engineers to do an audit to ensure that the supplier has the right infrastructure and the right resources available,” he said. “We make sure that potential partners have the support staff to address any problems that may come up. Do they have maintenance staff? Do they have a quality engineer, manufacturing engineers, etc. It is the ability to address problems that separates the good from the bad.” And, don’t automatically select the lowest bid. “I am interested in a balance between a good competitive price and organization and infrastructure that can support the product as it goes forward and it grows,” said Rothfritz.

Hickey states that SonoSite actively looks for outside partners who are considered “best-in-class” in very specific areas of expertise which can bring value to SonoSite’s manufacturing processes. In his view, these companies have already made the investments and learned the hard lessons about what works and what does not, and that all of those resources and experience can benefit SonoSite itself.

**Build a mutually beneficial relationship:** Invest time and resources in the beginning to build a strong foundation for a long-term partnership. Customize the structure of the partnership to fit the maturity of the company and its individual products. A successful partnership is built on a common foundation of trust, aligned incentives, a commitment to investing in each other’s capabilities, joint management structures, and the contractual and operational flexibility to change direction. The two companies should engender a culture of continuous improvement, by measuring performance and sharing best practices throughout both organizations.

**Manage partnerships to achieve outcomes:** From the start, build a team of dedicated resources devoted to managing the strategic partnership, and any potential problems that arise as the program rolls out. Create mutual goals with the strategic partner as to the length of the contract and, if successful, the potential for additional contracts in the future. Rothfritz from NovaMin adds that one way to improve the
chances for a successful partnership is to get the strategic partner involved in the development process as soon as possible to ensure manufacturability of the product.

Global companies need a partner that can help them anticipate problems and proactively propose creative solutions to solve them. As a highly regulated market that requires a sharp focus on quality and compliance, the medical device industry, with its life critical applications, is no exception.

PROFILE OF A NEXT GENERATION MEDICAL DEVICE SUPPLY CHAIN PARTNER

Healthcare is not a new market to Celestica, but it is one in which the company has made significant investments in recent years because of growing demands in the market and Celestica’s ability to leverage the skills and resources it uses to serve clients in other highly regulated, high complexity/low volume production markets. While the company devotes most attention to higher complexity devices, it has begun applying its automated manufacturing operations to adjacent markets for higher volume products, such as single-use cartridges used for diagnostic equipment and certain personal care products. Growing the company’s presence in medical technology is key to Celestica’s growth strategy for the coming decade, according to Sandra Ketchen, Vice President, Healthcare, Celestica.

“In today’s patient-centric market, healthcare technology providers need to invest in innovation to stay competitive amid increasing pressure to manage product costs,” said Ketchen. “We help medical equipment companies focus on core activities, improve their time-to-market, lower manufacturing costs and mitigate risk by maintaining a relentless focus on quality and compliance.”

Ketchen reports that her recent conversations with medical technology companies indicate a growing interest in supply chain partners like Celestica. “Medical device companies I’ve spoken with have said they want to get their products to market faster—without sacrificing on regulatory risk. But setting up their own infrastructure for manufacturing and regulatory control can take up to 18 months and be very expensive. They are looking for partners that already have these systems in place that they can quickly tap into.” Ketchen also states companies have expressed interest in how
companies like hers can support their entire product life cycle and also bring in best practices and knowledge from other industries.

In addition to faster time to market, Ketchen sees medical technology companies re-evaluating their core competencies in order to focus more on innovation and less on operations. “The innovation cycle is speeding up, and medical device companies need partners to not only deliver product to market faster, but to also find newer, lower cost ways to innovate, especially in lower cost markets outside of traditional markets like North America,” Ketchen said. “But to do this correctly, device companies need partners with a very robust infrastructure. The components of that infrastructure do not need to be novel, but they need to be robust in that they are reliable, flexible, and scalable.”

Ketchen states that when considering a global manufacturing operations plan more of Celestica’s medical technology clients are interested not just in cost management, but also in maintaining a transparent, integrated and harmonized quality control infrastructure. In 2008, Celestica’s healthcare operations made an investment in its Suzhou, China facility for “high mix, low volume” medical device manufacturing there. The facility possesses a Class 1000 clean room for optics assembly, and is its first Center of Excellence for low cost operational improvement to support healthcare customers. In addition to developing its offshore capabilities, Celestica is planning to build a North America Center of Excellence—an R&D center coupled with high complexity assembly that is not suited for offshore manufacturing. Celestica recently announced that it will acquire Austria-based Allied Panels, a leading medical engineering and manufacturing service provider, offering concept-to-full production solutions, with a core focus on diagnostic imaging products. This acquisition significantly expands Celestica’s capabilities in the healthcare diagnostics and imaging market and gives the company a healthcare Center of Excellence in Europe. “This acquisition is highly strategic for Celestica,” said Ketchen. “Together, Celestica and Allied Panels are able to offer global healthcare customers comprehensive, end-to-end solutions that combine Celestica’s scale, broad range of capabilities and financial strength, with the focus, track record and specialized expertise of Allied Panels.” Celestica also has a variety of other sister sites supporting healthcare customers. Its Singapore/Malaysia facility is an alternative to the China facility and provides lower costs than North America in a place where there is a hub of medical activity.

By understanding the unique complexity of each customer’s business, Frost & Sullivan believes that Celestica represents a new breed of strategic partner for medical device companies because of its ability to develop customized solutions that drive product innovation, cost savings, supply chain efficiencies and improved time-to-market. Celestica offers its customers an efficient global network including specialized Centers of Excellence. This strategic network provides customers with the flexibility they need to respond quickly to changes in end-market demand. Celestica has the infrastructure, relationships and technologies to help its customers innovate, meet market demands and expand their business.

Frost & Sullivan
Medical device companies that are able to build powerful strategic partnerships with full-service external companies will be more competitive in their markets. A partner who can leverage its expertise to achieve these goals will undeniably help medical device companies become more successful. Ideal partners will provide a complete portfolio of services that are specific yet adaptable to the changing needs of their clients, such as design, prototype development, testing, manufacturing, sourcing, logistics and after-market services, while maintaining high quality manufacturing standards, managing regulatory requirements, and product life cycles.

**THE CELESTICA SOLUTION**

With 75 years as an OEM manufacturer, Celestica (Toronto, ON) is a leading global strategic service provider to the medical devices industry. With over $6 billion in revenues in 2009, the company has historically excelled in supporting manufacturers of high complexity devices competing in heavily regulated industries, including aerospace, communications and healthcare. Celestica provides flexible and innovative supply chain solutions for the healthcare industry. The company provides customers with a broad range of services including design, automated manufacturing, electronics manufacturing, fulfillment and after market support.

Celestica has a strong track record across a wide range of healthcare products. As a recognized leader in automated manufacturing, Lean and Six Sigma, Celestica is dedicated to delivering operational excellence to its healthcare customers. The company has significant experience in product, process and equipment validation, documentation and implementation, and supply chain management. Celestica also provides customers with product registration experience and support to over 30 countries and most economic regions around the globe. The company has made significant investments in developing systems for quality and compliance which sets it apart from competitors. The company is US FDA registered and an ISO 13485:2003 certified manufacturer of medical devices. Celestica also has robust cGMP and QS processes, and meets QSR compliance.
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ABOUT CELESTICA

Celestica is dedicated to delivering end-to-end product life cycle solutions to drive its customers’ success. Through its simplified global operations network and information technology platform, the company delivers informed, flexible solutions that enable its customers to succeed in the markets they serve. Committed to providing a truly differentiated customer experience, Celestica’s agile and adaptive employees share a proud history of demonstrated expertise and creativity that provides its customers with the ability to overcome any challenge. For more information, visit http://www.celestica.com.

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