

Medical Product OUTSOURCING

Articles » 2008 » April 2008 » Feature

Steady as She Goes

Latin America's medical device sector is keeping pace with increasing demand from the United States, Europe and Asia

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One thing is a sure bet—as baby boomers in highly developed regions such as North America, Europe and Asia get older, the demand for medical devices will continue to rise. Even though the United States remains one of the world's leading manufacturing hubs of medical devices, more American companies are expanding to near-shore locations to cut manufacturing and shipping costs—and Latin America continues to increase its presence as a viable destination of choice.

According to Frost & Sullivan's November 2007 Assessment of Medical Device Market in Latin America report, investment in Latin America's private sector has shown "a steady and constant growth in the past years, which is forecast to keep its pace during the following five years."

For now, the overall medical device market in Latin America still is quite small, according to John E. O'Brien, president of Lyons, CO-based O'Brien Consulting LLC, a firm that helps companies locate offshore opportunities. "The vast majority, if not all, of the finished medical devices and their components and sub-components made in Central America are exported to the US, Europe or Asia," he said.

Piribo, a biomedical research firm, estimated that the value of the medical market in Latin America was \$6.3 billion in 2007. Significant growth in the Mexico, Brazil, Argentina and Venezuela markets is expected to drive that figure to \$7.7 billion by 2012. A report by Piribo, titled Outlook for Medical Devices in Latin America, emphasized that the medical device industry is critical to the economic development of Latin America, especially the export of high-specification medical technology products.

Both local consumption and export manufacturing are contributing to the industry's growth in Latin America.

Right now, "Brazil and Mexico are the largest consumer markets, with more than 180 and 100 million inhabitants, respectively," said Natalia Scomparin, industry manager for healthcare at Frost and Sullivan Latin America. "They both have a high number of healthcare units with some type of diagnostic imaging equipment—about 8,000 in Brazil and 7,000 in Mexico. Also, nearly every country in the region has designed a plan with public funds in order to increase the number of insured citizens, like the Seguro Popular in Mexico."

Hybrid markets, where medical device companies can manufacture products to export, as well as sell to the local population, are especially robust. "Mexico is a good example of a hybrid market," said Mark R. Cohen, director of sales for healthcare at The Tech Group, a Scottsdale, AZ-based contract manufacturer that has a facility in Guadalajara. "From what we have seen in Mexico, the local economy is progressing, healthcare is becoming available to a larger percentage of the population on a daily basis and more companies operating in the country can meet the needs of the local economy, as well as their export demand."

The Latin American Advantage

Latin America is a location of choice for medical device manufacturers because it is close to the United States and Europe, has highly skilled workers who work for lower wages and provides trading advantages with trade deals such as the North American Free Trade Agreement (NAFTA) and the Central America Free Trade Agreement. (NAFTA, however, has been drawing increased attention—and sharp criticism on the Democratic side—during the current presidential campaign.)

"Another major attraction for US companies is that Latin America is in the Central Time Zone and only a few hours flying time from the US," said O'Brien, whose in-depth knowledge of the market comes, in part, from his previous tenure with Point Technologies S.A. (a Veridiam company), a contract manufacturer with operations in Costa Rica. "Contrast this with doing business in China, where you might get a call in the middle of the night and have to pay \$10,000 to \$15,000 for a flight."

Stephanie McGee, regional sales manager for Command Medical Products, a contract manufacturer based in Ormond Beach, FL, with an additional facility in Nicaragua, agreed. "Transit time to Latin America from the US is shorter than going to Asia," she said. "That translates into less raw materials and inventory, which can be a significant savings. In addition, many companies agree that the culture challenges seem to be less difficult when working in Latin America, compared to Asia."

There's also the all-important issue of political stability (ie, less risk). Mexico, Costa Rica and the Dominican Republic have long histories of proven political, economic and social stability. "Nicaragua, Guatemala, Honduras and El Salvador—in that order—are now on stable trends, and I think they have a good future," said O'Brien. "All now have a 'reverse brain drain' where people who have left the country are now coming back because there is more opportunity."

With myriad benefits touted for each region, certain Latin American countries already have positioned themselves to serve medical device companies.

Leading the Way: Costa Rica

According to CINDE, the non-profit Costa Rican Investment Promotion Agency, over the last six years Costa Rica's medical device industry has expanded from eight companies to 23, employs about 6,300 people and consistently ranks as one of Latin America's leading exporters. In

2006, Costa Rica exported \$633 million in medical devices and attracted \$150 million of foreign direct investment.

By far, the biggest attraction in Costa Rica is the high-quality labor force. "The workers are literate [with a literacy rate of 95%], highly educated, productive, fluent in English and have very low turnover—less than 5% a year as a country," said David Mabie, vice president of business development for ATEK Medical, LLC, a Grand Rapids, MI-based company that operates a San Jose, Costa Rica facility along with other locations within the United States. "Compare that to Mexico, where turnover rates can be as high as 25% per year."

Mabie also indicated that more medical device suppliers are establishing operations in Costa Rica. Companies such as thermoform tray manufacturers, component suppliers and sterilization service providers have either already established operations in Costa Rica or have plans to do so in the short term.

Boston Scientific, Hospira, Arthocare, Cytyc Surgical, Med Tech, Precision Concepts and Veridiam are some of the major players located in the greater San Jose area, including the communities of Heredia, Alajuela and the city of San Jose. "All companies are set up in free zone operations such as Global Park and Ultra Park (Heredia), SARET Parque Industrial (Alajuela) and Parque Industrial Cartago (Cartago)," O'Brien said. "Costa Rica has a new Free Zone and Business Park called Coyal that is being developed, and there are already several companies that have committed to move in."

Companies that have expanded their manufacturing capacity include Cytyc, Allergan and Boston Scientific, which recently announced it would undertake a \$35 million expansion and increase its workforce 100% by 2011. The new facility will be located in Propark, Coyal de Alajuela and create 1,200 new jobs for operators, technicians, engineers and administrative personnel. Because of its previous success in Costa Rica, Boston Scientific expects to eventually transfer its higher-end products and technologies to the new plant. Furthermore, several companies, including Horizons International, recently moved operations from Puerto Rico to Costa Rica as a result of changes in tax laws in the former location. "The Costa Rican government is also preparing a new incentive structure that will go to Congress due to WTO [World Trade Organization] 2015 deadline," added Mabie, noting this is intended to further improve incentives for businesses.

Costa Rica's President Oscar Arias Sánchez and his government are continuing to shape a progressive business climate. They recently announced a national English-language plan, named "Costa Rica Multi-lingüe," to accelerate English proficiency throughout the country, with additional language programs planned in the future. Through the current program, the government plans to teach English to more than 35,000 Costa Ricans in 2008-2009. The goal is for every high school student to be fluent in English by 2017, in accordance with the standard of the Common European Framework.

Mexico: A Top Importer

Along with Costa Rica, Mexico also has developed an extensive infrastructure for manufacturing over the last 30 years. "Our three industrial parks are equipped with modern infrastructure," said Steve Colantuoni, director of market research and communications for The Offshore Group, a "shelter" maquiladora organization in Mexico (with US headquarters in Tucson, AZ) that enables medical device manufacturers to set up their own plants in Mexico.

Major maquiladora centers are located in Tijuana, Nogales, Ciudad Juarez (across from El Paso), Matamoros (across from Brownsville, TX) and various other locations including Guadalajara, Saltillo and Mexico City.

At present, Mexico imports 70% of the medical devices that it uses from the United States. Colantuoni indicated that because medical device companies typically have higher margins for their products than other industries, such as automotive, electronics and aerospace, they are not under the same immediate pressure to reduce costs. "To date, the migration of medical devices manufacturers to Mexico in large numbers has not been as rapid as that of other industries," he said. "However, as the US begins to take measures to control its healthcare costs, over time this will change."

With an increase in technical know-how (the number of doctorate degrees in Mexico is increasing at a rate of 17% a year, many in engineering and life sciences) and advanced manufacturing methods, some medical device firms soon may let their Mexican facilities build new products for launch instead of only producing mature products.

Baja California—especially the city of Tijuana—is beginning to emerge as a desirable medical device manufacturing center. Tijuana's outstanding system of universities and colleges provides a steady supply of highly qualified workers for the device community, and companies are taking advantage; more than 60 medical device firms currently operate in the Tijuana area. Welch Allyn recently expanded operations there with 220,000 square feet, and in January, Medegen announced it would build a 42,000-square-foot facility in Tijuana's Parque Industrial Chilpancingo to serve the increased demand for contract manufacturing in the medical device market.

"This expansion will provide medical device companies with high-quality and cost-effective outsourcing solutions," said Jeff Goble, president of Medegen, whose main manufacturing and distribution facility is in Ontario, Canada, with an executive office in Scottsdale, AZ. "This marks a new milestone for Medegen as we focus on growing our medical manufacturing services business unit."

To continue fueling growth in the area, Southern California and Mexico's Baja California are working together on "The Life Sciences Gateway Initiative," which is being carried out by San Diego Dialogue and funded by Merck & Co., one of the world's largest pharmaceutical companies. The partnership will focus on improving communication, sharing best practices and creating strategic, long-term research initiatives between biomedical companies in the northern region of Mexico and Southern California.

Other Emerging Locations

As companies move into key clusters within Mexico and Costa Rica and compete for resources such as talented workers, the cost of doing business continues to increase. As a result, some manufacturers are taking a harder look at other emerging Latin American countries with hope of finding lower wages and more stable workforces.

"Several of these, including Nicaragua, Honduras and Guatemala, are getting into the business of trying to attract foreign direct investment into their countries by targeting firms in the medical device industry," said O'Brien. "Nicaragua and Honduras already have a fairly large base of

companies in the textile industry.”

Guatemala especially has been active in trying to attract investment, especially from the medical device community. “Guatemala can offer all the infrastructure, quality labor force, training facilities, free trade agreements and other incentives that manufacturers need to produce medical devices supplies in our country,” commented Roberto Mancilla, senior investment advisor for Invest in Guatemala.

DeRoyal, based in Powell, TN, is one manufacturer that recently established an operation in Guatemala, where it will produce medical disposables such as intravenous products and anesthesia items. “Our already-established manufacturing cluster can support the medical device industry by providing the high-quality materials they need, such as plastics and textiles,” said Mancilla.

Another region gaining attention is Nicaragua. Command Medical Products, the first company to manufacture medical devices there, has been pleased with the region’s offerings. “We started with one small plant in Managua and are now looking to triple the size of our Nicaragua presence,” said McGee.

Nicaragua’s appeal became clear, she explained, after the company evaluated the country’s offerings in comparison with other Latin American regions. “Prior to establishing our facility in Nicaragua, our president, David Slick, conducted desktop reviews of several different countries. Due diligence revealed Mexican labor is more expensive than it used to be, and the turnover is tremendously expensive. It takes a lot to train someone to be compliant with our quality systems and regulatory requirements, and the continuous turnover in Mexico was a big concern. The Dominican Republic was also rejected because it lacked a stable supply of electricity,” she said.

Taking all of these factors into account, Slick eventually settled on Nicaragua, which appears to be taking new investments seriously with upgrades of its own. The country has been busy upgrading its transportation infrastructure and establishing several free trade zones for manufacturing—including Astro Nicaragua—providing discounted rates for services and electricity.

“Setting up in Nicaragua was a huge step for a small company like Command Medical,” McGee said. “Now we have a virtuously limitless supply of labor. All our employees have the equivalent of a high school education. There is no turnover and the labor force is very trainable. We have had huge success in transitioning our production down to the Nicaragua facility and are looking forward to expanding our presence there very soon.”

Looking Forward

As Latin America continues to gain ground with attracting the medical device industry to set up operations there, governments and investment promotion agencies are continuously working to improve the business climate to attract even more businesses by establishing treaties with key countries, creating better incentives, cutting the costs of energy and providing other business support.

“All Central American governments offer fiscal incentives, usually in the form of no import duties on raw materials and capital goods and tax holidays for extended periods of time,” said O’Brien. “To qualify for these incentives, a company would have to commit to hiring a certain number of people and a determined investment level.” (Honduras, El Salvador and Guatemala, he noted, also have economic development groups, but they still are in their infancy as far as the medical device industry is concerned.)

On a continental scale, efforts to increase Latin America’s global position to better compete with other emerging markets, such as China and India, are moving slowly because regional development organizations are in disagreement about the best way to create a united front, especially regarding bilateral free trade agreements.

Nonetheless, Scomparin said, “according to our studies and research on these markets, Frost & Sullivan forecasts for the total region a compound annual growth rate in the range of 6% to 8% for the 2008 to 2012 period.” Other estimates for 2008 by the International Monetary Fund, The World Bank, and the United Nations Economic Commission for Latin America and the Caribbean vary from 4.3% to 4.9%.

“By the end of 2008, the region will have grown by around 30% since 2004,” said Peter Rösler, deputy general manager for the German business group Ibero-Amerika Verein. “Already now the combined economies of Latin America have the dimension of Germany or China. Since most exports of medical devices from Central America are bound for the US or Europe, it is probable the medical device market will follow the rise or fall in their economies.”

As manufacturing techniques advance and the labor force matures (both in technical and managerial expertise), it is likely medical device companies will start adding some research and development initiatives to their Latin American operations. “At this time, our plant is set up for sustaining manufacturing only,” said Mabie of ATEK. “However, with the strong technical university system in Costa Rica, we envision a time in the not-too-distant future when we will expand our service offerings to include development engineering.”

McGee concluded: “There have been lots of issues lately with products manufactured in Asia (ie, lead in paint, blood thinner, dog food recalls) that question the quality of manufacturing [in that region]. As companies look at total costs including inventory, freight, manufacturing costs, quality control and sustaining business, Latin America makes a strong case for attracting future manufacturing operations.”

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