Medical Product OUTSOURCING

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Offshoring in an Off Economy

Following a period of remarkable growth for medical device manufacturers in Latin America, the industry is re-evaluating its overseas investments as the global economy continues to plunge.

Tim Sohn, Associate Editor

According to a report by Espicom Business Intelligence in Princeton, N.J, the industry's market value stood at $7.4 billion in Latin America in January, $1.1 billion more than 2007, but growth is expected to slow this year and next as companies remain cautious. "The Outlook for Medical Devices in Latin America" shows the market is expected to grow only 4.6 percent annually between now and 2013, when it will reach $9.2 billion.

John O'Brien, president of O'Brien Consulting LLC in Lyons, Colo., which helps companies locate offshore opportunities, said companies that already have expansion projects under way are continuing with them because they realize they will eventually save money by establishing manufacturing operations in Latin America. "I talked to some customers in the past two months. I think some are putting off decisions over the next six months or so because of uncertainty. But some projects are under way, and they are going ahead with them. Cost is even more important now from a year ago. So, some companies are going ahead. Overall, however, you'll see some slowing."

Costa Rica President Oscar Arias Sanchez, left center, and ATEK Medical Costa Rica General Manager Jorge Vargas, right, look on as a technician demonstrates an adhesive bonding technique. Photo courtesy of ATEK Medical.

According to the report, Brazil is the largest medical device market in Latin America, followed by Mexico, Argentina and Colombia. Cuba, however, has the highest level of medical spending per capita in the region.

The medical regulatory environment in most of Latin America—except for Brazil and Mexico—is not as stable or mature as those in developed markets, the report states. As a result, the regulatory environment in much of the region is being consolidated. Brazil and Mexico have more complex and mature regulatory systems, with Mexico following U.S. Food and Drug administration laws.

Trade in medical devices and equipment is key to the region's development. All markets except Brazil, which has a strong domestic medical device industry, are dependent upon imports, the report concluded.

Brazil, Argentina and Chile import more high-specification medical technology products, while Peru, Mexico and Venezuela import more consumable merchandise. Mexico is the export powerhouse in the region, comprising nearly 90 percent of Latin America's export capabilities. Almost all of Mexico's medical exports are shipped across the border to the United States. Brazil's exports are low compared to the size of its medical market, but exports of dental devices and implantables have been increasing in recent years, the report found.

Benefits: Tax Exemptions, Proximity to United States

Medical device manufacturers are attracted by Latin America's proximity to the United States and its availability of highly skilled employees who are willing to work for low wages (at least compared with the United States). The North American Free Trade Agreement and the Central America Free Trade Agreement both provide advantages to manufacturing in Latin America. Duty-free trade zones allow companies to operate largely tax-free. For example, tax exemptions in Costa Rica include:

• Import duties

• Capital tax (10 years)

• One-hundred percent income tax exemption for eight years, then 50 percent for the next four years

• Sales tax

• Export tax

• Selective consumption tax

• Property tax

• Real estate transfer tax

• Withholding tax on payments made outside of Costa Rica.

Income tax exemptions of up to 12 years are available in certain circumstances. Another benefit to conducting business in Latin America is simplified customs clearance procedures, according to Pilar Madrigal, director of international affairs for the Costa Rican Investment Board, or CINDE, a San Jose, Costa Rica-based nonprofit organization that helps advance the country's social and economic development.

Mexico also offers advantages to device manufacturers. Those include low wages and geographic proximity, according to Steve Colantuoni, director of market research and communications for The Offshore Group, a company in Miamisburg, Ohio, that provides manufacturers with the necessary infrastructure to set up shop in Mexico. "The obvious wage advantages found in Mexico draws OEMs and contract manufacturers, as does its close geographic proximity with the United States. Very important is that Mexico has developed an increasingly skilled work force over the last 40 years and has intellectual property laws in place that function. This is not the case in all developing economy environments."

Trade zones offer many perks for companies, too.

In Costa Rica, "This varies depending on the type of manufacturer and where they do their manufacturing. If a company is located within a free trade zone, there are numerous benefits from a duty/tax standpoint. The labor rates are competitive to other low-cost regions around the world. In addition, the quality of workmanship is very good, and the caliber of work force is quite good. Also, it is worth mentioning that Costa Rica is a wonderful country to visit with a lot to see and do, making it quite enjoyable working within the region," said Chris Oleksy, presidentof Atek Medical, which produces disposable, implantable and electromechanical devices.

Medical device manufacturers do face some challenges operating in Latin America. One challenge is a language barrier.

"Although English is taught in all schools, there are some language barriers that occur from time to time. This is more prevalent on the shop floor than it is at the indirect workforce level, where college degrees are more common. In addition, the local supply base is still evolving requiring many companies to ship in goods from other locations outside of Costa Rica, which can be costly. The demands on infrastructure also are high, creating an area that is a bit congested from time to time," said Oleksy.

The economy has become a particularly difficult challenge to manufacturers setting up Latin American operations.

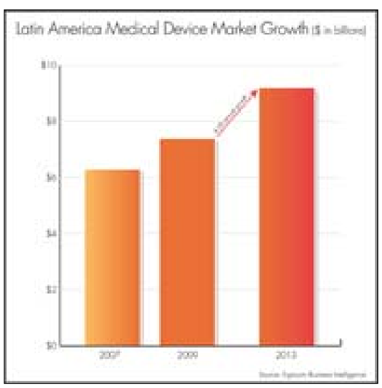
With job losses mounting and consumer confidence nosediving, people are opting out of surgeries or waiting longer to afford them.

"Some reductions in mandatory surgeries are due to people losing their jobs and their insurance and cannot afford their surgery until they find employment or benefits," said Oleksy.

Costa Rica Keeps Expanding

One medical device manufacturer that is forging ahead with its expansion in Costa Rica is St. Jude Medical, based in St. Paul, Minn. Madrigal said the firm will invest more than $40 million in its new Costa Rica plant, and the facility could generate 500 new jobs by 2010.

St. Jude Medical will initially use the facility to increase production of the company's heart valve products. "The construction of St. Jude Medical's plant started in December 2008 at Coyol Free Zone & Business Park in Alajuela. The future scope is for the production process in the new plant to start in 2010 and for the first products made in Costa Rica to be exported in the second half of that same year," said Madrigal.



Boston Scientific also is expanding its Costa Rican operations. In 2007, it announced a $35 million expansion program that includes the doubling of its workforce there to 2,400. The company opened its first production plant in Costa Rica in 2004 with an investment of $11 million. The plant, located in the Global Park free zone industrial park in Heredia, currently employs 1,200. The company manufactures surgical forceps and all its snares in the Costa Rica plant. Annually, Boston Scientific is responsible for about $50 million of exports from Costa Rica, and the expansion of Boston Scientific Costa Rica will take place in the Coyol Free Zone & Business Park, where St. Jude's new facility also will be located.

Enrique Arguelles, general manager of Precision Concepts Costa Rica, S.A., which specializes in contract manufacturing of single-use medical and electro-medical assemblies and is based in Alejuela, Costa Rica, said, "Fortunately for us, we have seen more business opportunities than what we have seen in the last few years. We have been approached by several small and midsize companies based in the United States looking for opportunities to reduce their costs and are searching for excellent engineering and manufacturing services that can trigger them to newer opportunities."

The economic downturn may have helped speed up the process of companies expanding to Latin America, said Arguelles.

Precision Concepts is focusing on growth and part of that growth will involve molding services that will be offered from Costa Rica within the next three months.

Another manufacturer that is expanding in Costa Rica is Grand Rapids, Mich.-based Atek Medical. The company plans to hire 150 additional workers and add a 5,000-square-foot mobile expansion to its 35,000 square-foot facility.

"Our facility just opened, so there is no comparable data to earlier years. We expect a nice business to evolve for us in Costa Rica in future years," said Oleksy.

Two other companies also have expanded in Costa Rica.

BeamOne, a San Diego, Calif.-based electron beam contract sterilization service provider, opened its new plant in Costa Rica in February. This new facility, located in the Coyol Free Zone in Alajuela, offers specialized jobs to about 25 people, and symbolizes a $5 million investment.

Precision Wire Components, a Tualatin, Ore.-based firm that specializes in custom wire components including grinding, wire processing, assembly, coil winding and rapid prototyping, recently opened its 15,000-square-foot medical wire component manufacturing facility in San

Jose.

The new facility began production in December and offers many of the same services as their U.S. headquarters, which include wire straightening; flattening, former; centerless grinding; coil winding; and special grinding.

Expansion Slowing in Mexico

The economic downturn has forced many companies to delay expension projects in Mexico, which is the second largest med-ical equipment market in Latin America and is dominated by imports mainly from the United States. The market is valuedat $2.4 billion.

"Given the present economic climate, many companies are delaying expansion projects until they feel that the economic environment has stabilized. Large publicly traded companies like Boston Scientific, Abbott Labs, Medtronic, C.R. Bard and others have had and will continue to have a large presence in Mexico. Their moves were motivated by the need to reduce cost and to optimize shareholder value. The move of midsize privately owned companies in the medical device manufacturing industry have not followed a similar migratory path as that followed by the automotive, and, increasingly, the aerospace industry. This is because midsize medical device manufacturers maintain healthy margins today while manufacturing in the U.S. As these manufacturers begin to feel the pinch of higher taxes on business, lower reimbursements from Medicare and higher labor costs, they will increasingly migrate to lower cost venues to maintain their profitability," said Colantuoni.

U.S. manufacturers that set up operations in Mexico benefit from geographic proximity and preferential terms under the North American Free Trade Agreement.

"Some of these imports are used to produce goods which are eventually sent back to the U.S.," said Colantuoni.

Medical device consulting firm Emergo Group Inc. also has opened an office in Mexico. The Austin, Texas-based firm is expanding to meet demand for regulatory approval and in-country representation services south of the border. The company's division, Emergo Mexico, offers services to help get approval for medical devices there.

They can determine classification of medical devices; gather, prepare and submit registration documents to COFEPRIS, a division within the Mexican Ministry of Health responsible for medical device oversight; answer questions from COFEPRIS during the submission process; and file necessary paperwork to obtain an import permit.

Emerging Countries

Despite the economic downturn, Nicaragua is drawing attention of medical device companies that are looking for offshore operations that will let them boost productivity and cut costs, according to Gabriel

Sanchez of Pro Nicaragua, a nonprofit, public-private institution whose mission is to generate economic growth and job creation in Nicaragua by attracting foreign investment.


A medical device assembly line at Command Medical's facility in Managua, Nicaragua. Photo courtesy of Pro Nicaragua.

The country offers generous tax incentives, a competitive cost structure and a highly skilled and productive labor force, which is ideal for labor-intensive production at manufacturing facilities.

"The current economic crisis has definitely forced companies to be more thorough when considering a country to expand their operations. Latin America is a natural selection due to factors such as the proximity to service markets like the United States, which allows companies to send shipments faster and at a lower cost than from other regions, such as Asia," said Sanchez.

According to Sanchez, Nicaragua wasnamed the second top location in Central America for starting a business in the 2009 "Doing Business Report," which is published by the World Bank.

The Foreign Investment Promotion Law and its bylaws in Nicaragua establish a series of guarantees for foreign investors. They include:

- Equitable treatment to foreign investors
- Free currency convertibility
- Freedom to repatriate all capital and profits, dividends or earnings generated in the national terrority, after paying pertinent taxes
- No discrimination against foreign investors, whether it be on total ownership of the company or as shareholders
- Prompt and fast depreciation of capital goods
- Access to local funding available at local banks, according to terms and conditions of approval
- Security and property protection.

Command Medical, a contract manufacturer based in Ormond Beach, Fla., which has a plant in Nicaragua, is building a second 29,000-square-foot manufacturing facility in that country where it will invest another $3 million. "Command has not seen any affect on our Nicaragua plant due to the economic downturn. We are currently under construction on our second Nicaragua manufacturing facility, which will boast extrusion capabilities along with two clean rooms. Our goal is to be operational in June of 2009," said Stephanie McGee, regional sales and marketing manager of Command Medical.

The firm opened the first medical device manufacturing plant in Managua, Nicaragua, in 2005 with an initial investment of $1 million.

The new facility consists of a state-of-the-art clean room that is currently under construction. The company expects to hire 200 additional people.

O'Brien said the possibility of hiring low-cost labor in Nicaragua and re-exporting medical products to Costa Rica is an attractive one. "You can ship from a duty-free zone in Costa Rica to a duty-free zone in Nicaragua and vice versa. There's a lot of investment going into Nicaragua, Guatemala and Honduras. Up to now, it's been those companies requiring low-cost labor and proximity to the U.S.," said O'Brien.

Sanchez attributes Command Medical's success to "the country's ideal conditions for investments in this sector, such as logistics infrastructure, competitive operational costs and abundant qualified human resources. The plant currently is operating with almost all of the original staff employed more than a year ago, which speaks to the incredibly stable labor market available in the country. The work force is committed to manufacturing high-quality products and as a result has been able to meet the requirements for the ISO 13485:2003 site certification."

The 2009 Labor Market Risk, published by the Economist Intelligence Unit, places Nicaragua as the second country in the Central American region with the lowest market risk.

The report measures various indicators, such as union strength, labor disputes, wage restrictions and hiring and firing restrictions.

Guatemala is another up-and-coming country when it comes to medical devices.

RobertoMancilla, senior investment adviser for Invest in Guatemala, a company that specializes in providing solutions for investments in Guatemala, said the economic downturn is not hurting the medical device market there.

"Guatemala has the biggest market in the Central America region, training facilities and incentives for export activities," Mancilla said. "The consumption is growing, and better costs in Latin America are good incentives for outsourcing."

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