

Medical Product OUTSOURCING

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The Latin American Connection

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Editor

Mexico and Costa Rica Emerge as Important Hubs for Outsourcing Medical Device Manufacturing

Offshore and outsourcing are terms increasingly intertwined in the medical device industry. As OEMs look for ways to shear costs, the list of low-wage producer nations seems endless. Asia's burgeoning status as a viable option for medical manufacturing is undeniable, but the trans-Pacific voyage products must endure narrows the type of outsourcing that can be shifted to China and its neighbors. So where else can device manufacturers turn for low-cost production without sacrificing lead time?

For a number of companies, the solution is to head south. A few Latin American markets are attracting growing foreign investment in the medical device sector despite rising interest in Asia. That's because countries such as Mexico and Costa Rica offer stable economies, low operating costs and close proximity to the U.S. and other nearby markets. Although Latin American wages are higher than those in China, the difference sometimes is offset by lower shipping costs, tax incentives and faster delivery times. For these and other reasons, some Latin American nations expect medical manufacturing growth to accelerate for the foreseeable future as U.S. OEMs gain confidence in their southern neighbors and move production abroad.

In fact, Latin American markets are emerging as a stop in the evolving manufacturing lifecycle of medical devices. As one contract manufacturer pointed out, new launches might initially be manufactured in the U.S. As products mature, their production could be shifted to Mexico or Costa Rica. As volume stabilizes and the product further matures to a point in which intellectual property protection is less of a concern, manufacturing might be moved again to Asia for additional cost reductions. Some see such a cycle becoming an important strategy for medical device manufacturers working toward constant cost improvements.

"Mexico will be not only important but critical" in the supply chain, said Randy Keene, president of Fort Worth, TX-based Avail Medical Products, a leading global provider of outsourced finished goods to the medical device industry. With facilities in Mexico and soon in China, the company is setting up a network of plants to serve a variety of clients and products. Keene said there is no question that Mexico and possibly other Latin markets will be pivotal in the development of a cost-



Costa Rican medical manufacturing facilities such as this one operated by Precision Concepts are helping U.S. companies fulfill their need for low-cost manufacturing in a nearby region. Photo courtesy of Precision Concepts Costa Rica.

effective manufacturing lifecycle. In fact, he added, outsourcing to Asia will be aided by growth in outsourcing to Mexico because the two markets will serve complementary roles.

Unquestionably, Mexico is the largest importer and exporter of U.S. medical goods in Latin America. According to the U.S. International Trade Commission (ITC), Mexico in 2004 was the largest Latin American exporter and third largest overall exporter of medical devices to the U.S. with a value of \$2.3 billion. Costa Rica was second among Latin nations with \$476 million in exports to the U.S. This small Central American nation of four million people has attracted strong investments from the medical sector in recent years and outgrew the Dominican Republic last year in medical devices exported to the U.S.

Although nations such as Brazil, Argentina, Colombia and Peru boast significantly larger populations, the outsourcing of medical device manufacturing to these regions has been stymied by economic and political instability.

While sourcing from Latin American nations is on the rise, Mexico and Central and South America are still not significant consumers of U.S. medical devices. According to the ITC, Mexico is the sixth largest purchaser of U.S. medical products with \$873 million imported in 2003, but that number is deceptive because much of the exports are used in the manufacture of finished devices that are eventually sent back to the U.S. The same holds true for several other Latin nations. An exception is Brazil, which imported \$234 million in U.S. medical devices last year, most of which were for its domestic consumption. So while U.S. medical OEMs have stepped up sourcing from Latin markets, few products made are sold back into those regions.

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Quality not an Issue

Why are U.S. companies willing to risk their products and reputations on manufacturing in Latin markets? Cost, obviously, is the driving force, but without meeting the required quality threshold, outsourcing abroad never would have taken hold, regardless of how low labor rates are. Over the past decade, markets such as Mexico have steadily improved quality systems while expanding manufacturing capabilities to service an increasingly complex product mix. In a sense, Mexico is very much an extension of the U.S., especially since the North American Free Trade Agreement (NAFTA) went into effect.

Steve Colantuoni, director of market research and communications for Tucson, AZ-based The Offshore Group, a provider of integrated manufacturing shelters in Mexico, said the quality of Mexican medical manufacturing today is generally recognized as competitive with those of U.S. plants. He noted that some high-precision industries such as aerospace outsource machining and other manufacturing in Mexico.

“You should see some of the products being made in our industrial parks,” Colantuoni said, pointing out that items such as defibrillators, diagnostic equipment other electronic products as well as traditional disposable medical devices are sourced from Mexico today. He added that more complex medical devices are being built in Mexico today than ever before.

“You’re going to see more movement in the next two years than in the past,” he predicted.

Indeed, Mexico continues to attract medical investment. Avail’s Keene said that his company has plans to open two more plants this year after establishing three in

Mexico last year. In fact, Avail has grown its workforce in Mexico from 26 people—the company first entered the market in 1995 with the acquisition of Pacific Device—to 2,600 today.

Keene said the investments are in response to OEM customers wanting to move manufacturing to Mexico in greater numbers than ever before. He said medical device companies are more at ease today with Mexican manufacturing because of the volume and types of products made there in recent years. With no major problems reported stemming from Mexican facilities, the perception about the quality achieved there is changing.

“I think the resistance that we used to see from our customers to go to Mexico has almost completely disappeared,” Keene said, attributing to the shift in attitude to “the resume of what’s been done in Mexico.”

Companies with facilities in Mexico say the traditional factors that have attracted U.S. investment to Mexico continue to draw medical manufacturers to the market. With low-cost labor plentiful, Mexico remains a hub for assembly-intensive products. At the same time, more high-tech, value-added devices are being produced because of a greater availability of skilled workers who provide services such as CNC machining.

While low-cost labor is one reason for Mexico’s outsourcing growth, another is the numerous incentive programs available to U.S. and Mexican companies. Under programs such as the Maquila Decree, Pitex and Altex, manufacturers in Mexico can bring in components, parts and even capital equipment from the U.S. free of import duties. While each program has some limitations, these agreements generally can save manufacturers sizable tariff costs.

Some medical product companies such as Johnson & Johnson and Pall Corp. operate “twin plant” facilities along the U.S.-Mexican border, according to Kevin Fraser, plant manager for Tech Group Mexico, based in Guadalajara. The facilities operate nearly side by side along the border, with the Mexican facility typically providing labor-intensive services.

Companies participating in the Maquila program—also known as Maquiladoras—operate along the border so they can more easily ship products to the U.S. The highest concentration of Maquiladoras is in the Tijuana region, said Fraser, with Reynosa and Ciudad Jarez also important manufacturing regions. Guadalajara, located in the western interior of the country, has emerged as the Silicon Valley of Mexico for its concentration of electronic firms.

Tech Group Mexico, a part of Scottsdale, AZ-based The Tech Group, a global injection molder, recently expanded its cleanroom facility in Guadalajara in response to stronger demands for hospital products. The company said a few of its customers in recent months have decided to move molding and assembly of products to Mexico, and Fraser said he believes these and other corporate decisions to relocate will drive the need for experienced outsourcing providers in some parts of the country.

“Over the past two years, we have seen additional requirements for cleanroom manufacturing in support of injection molding and contract assembly. There are very few contract manufacturers with cleanroom molding and assembly operations in the interior of Mexico,” Fraser pointed out. “I think you are going to start seeing more companies like the Tech Group opening up in Mexico.”

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Stable Supply Chain

Because of its proximity to the U.S., Mexico doesn't require OEMs to change their supply chain. Companies that operate lean manufacturing schemes can obtain components and finished medical devices from Mexico as if they were sourcing from within the U.S. Unlike China, which can require an eight-week shipping time, Tijuana is a short drive to Southern California, home to a large group of medical OEMs. Additionally, it is a strategic point for distributing to other Latin American markets.

However, operating a Mexican facility can be fraught with challenges. As any operations manager knows, keeping a facility adequately staffed—especially one that is inspected by the FDA and has high quality requirements—can be daunting. But because of low wages, employee turnover is a constant problem.

Avail's Keene said retaining a trained workforce is not easy. He noted that turnover can average 3-10% a month, the equivalent of losing one-third to 100% of the workforce annually. The problem stems from the fact that many Mexican workers are migratory and leave a job after a short period in search of higher wages or to return home. Turnover is especially high near the U.S.-Mexican border compared with interior sections.

"The exact same system that works for your Topeka, KS plant will not work in Mexico," Keene said.

Even so, outsourcing to Mexico remains an economically attractive option to medical device manufacturers. Companies have less to fear about IP theft than in China, Keene added. Shipping times are equivalent to that of the U.S., and tax incentives further draw foreign investment to the market. Although worker turnover remains a concern, many manufacturers are able to attract and train enough quality workers.

Finding skilled workers for medical device manufacturing hasn't been an issue in another major Latin market. With one of the highest literacy rates in Central and South America, Costa Rica—with a population of four million—has emerged as the second largest Latin exporter of medical devices to the U.S. Since 2000, exports have risen from \$185 million to \$476 million in 2004, an increase of more than 257%, in part due to the availability of skilled machinist and assembly workers. Although export growth to the U.S. slowed to just 2.2% last year, many medical companies have or are setting up shop in this tropical nation.

How has this Central American nation—with a geographical area smaller than West Virginia—become such an important producer of U.S. medical devices? According to Costa Rican officials, the country has tailored its workforce to provide the kind of skilled employees the medical device industry needs. CINDE, the Costa Rican investment and trade development board, said the country has been aggressively growing its medical device industry since it was established in 1986. Costa Rican officials continue to promote its sizable device industry to foreign investments.

Fabian Gonzalez, investment manager for the medical sector at San Jose, Costa Rica-based CINDE, said there are 15 foreign medical device manufacturers operating in the country, manufacturing a variety of products including monitoring devices, arthroscopic equipment, forceps, dental stones, IV sets, silicone implants, metal parts, injection molding and others. More recently, to bolster the supply chain for many of the medical device companies, Costa Rican officials are encouraging packaging, molding and sterilization service providers to set up shop to service customers in its market. All of these efforts are helping the country become a center for medical manufacturing.

“Costa Rica has developed into a hub for companies in medical device manufacturing as a result of the talent of its human capital, as well as its ability to understand quality control aspects and manufacturing technologies and its competence to adapt to the needs of the industry,” Gonzalez said.

Like Mexico, Costa Rica enjoys favorable tariff treatment from the U.S. As one of the nations covered under the Caribbean Basin Initiative, many companies operating in Costa Rica enjoy duty-free trade with the U.S.

Gonzalez pointed out that Costa Rica’s skilled workforce is another key attractions for foreign companies. The general population has a literacy rate of 95%, one of the highest in Latin America. The country boasts having more than 75 technical schools, including the National Training Institute, which offers courses in electronics, precision mechanics, materials technology and plastics. In addition, several universities offer engineering majors. With many educational institutions, Costa Rica has a rich talent pool from which foreign companies can pick.

And medical device companies are tapping into that pool. According to CINDE, over the past eight years foreign firms in Costa Rica have tripled their initial investment. And as OEMs continue to pour in investment, they’ve given suppliers good reason to follow them into Costa Rica.

That’s the reasoning behind Boulder, CO-based Point Technologies’ recent decision to establish a precision metal processing facility in Costa Rica. Vice president John O’Brien said his company expects the facility—which will employ about 10 machinists—to be operational by May. Company officials began looking into the market last year. With several customers already operating in Costa Rica, he said it made sense for Point Technologies to invest in what appears to be a booming market.

“We saw that a couple of major customers were located in Costa Rica. We thought it would be a good opportunity to supply them and new medical device companies coming in there and Latin America,” he said. “I think there will be explosive growth.”

O’Brien pointed out that Costa Rica is strategically located in Latin America and accessible by boat from both the Atlantic and Pacific. By air, Costa Rica is only hours away from South America as well as the U.S. He added that the country could possibly blossom into a significant source of products for the European market.

While Costa Rica is catching the eye of more medical device companies, some manufacturers have expressed concerns about its still-maturing supply chain and future wages as demand for labor grows. For instance, there are no outsourced ethylene oxide sterilization facilities so medical manufacturers must send products out of the country. Additionally, the network of outsourced service providers—from injection molding to metal finishing—pales in comparison with established lower-cost markets such as Puerto Rico or even Mexico. With only four million inhabitants, will labor rates rise with manufacturing growth?

Not so, counters Enrique Arguelles, general manager for Precision Concepts Costa Rica, a part of the Precision Concepts Group based in Winston-Salem, NC. He pointed out that over the past five years, wages have only risen 2-3%, keeping pace with inflation. Because the government constantly devalues the local currency (colon) against the dollar, it offsets inflation spikes for foreign companies. He said there had been similar fears about wage hikes when large companies such as Intel and Abbott established a presence there, but costs today remain stable.

In addition, he added, many suppliers are investing in capital equipment and workers to meet the needs of existing and future demand. For instance, Precision Concepts during the next three years will invest in a class 10,000 cleanroom for

stamping and molding services. The company, which also offers design and prototyping services, plans to add 10,000 square feet of manufacturing space to its existing facility in the Faret industrial park located in Alajuela, Costa Rica. These and investments by other manufacturers, he contended, will help attract more manufacturers to the region.

“We (Costa Rica) do low-cost manufacturing, but we are trying to be seen as a country that has more technical skills to provide,” he added.

Indeed, as Costa Rica and Mexico ramp up medical device manufacturing capabilities, there may well be a shift in the type of products outsourced there. As concerns about quality products subside, U.S. OEMs may find compelling reasons to head south of the border.

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