Medical Device Manufacturing in Tijuana, Mexico

Advantages of Nearshoring in Mexico, Key Highlights and 2013 Industry Overview

WHITE PAPER





WHY ARE MEDICAL DEVICE MANUFACTURERS EXPANDING TO MEXICO?

Mexico has rapidly become a top global destination for medical device manufacturing. Executives and trade organizations cite major cost savings and ease of doing business benefits including:

- Low-Cost, Highly-Skilled Workforce
- Proximity to Major Markets (US, Canada)
- NAFTA, No Tariff Zone
- Maquila Duty-Free Temporary Imports
- Strong Intellectual Property (IP) Protections
- Established Infrastructure

This white paper examines current news and industry reports important to the medical device manufacturing industry. Meant to assist executives in understanding the benefits of expanding operations to nearshore Mexico, this paper analyzes Mexico as a potential site for medical device manufacturing activities by examining important factors such as proximity to major markets, infrastructure, labor supply and cost, transportation and ease of doing business.

SECTION 1

Mexico an Attractive, High-Growth Market to Watch

Mexico is ranked third out of five high growth markets which include Brazil, China, India and Russia, according to the annual KPMG 2012 Guide to International Business Location Costs.³ More specifically, Mexico's exports of medical equipment and supplies were valued at \$8.56 billion in 2011, of which exports to the US accounted for \$6.45 billion.^{1,9}

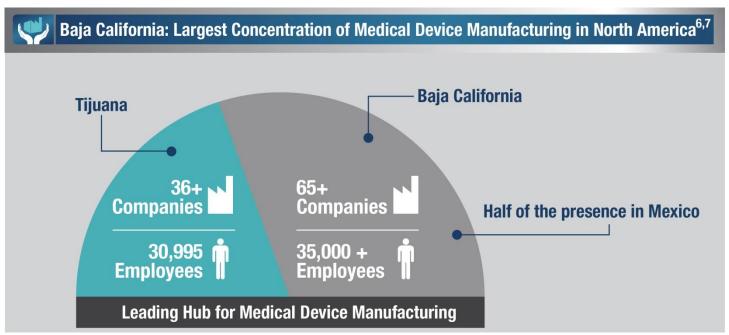
SPOTLIGHT

\$8.56 Billion

Mexico's Medical Equipment and Supplies Exports in 2011⁹

From temporary imports for final assembly to full production operations, Mexico's medical device sector is equipped to handle a broad range of medical device manufacturing activities. Industrial facilities carry international and industry recognized accreditations and comply with global standards for quality and safety. Companies find first class facilities that are FDA, CE and ISO 13485 certified, as well as special processing plants offering clean rooms ranging from Class 100 to 100,000.

Mexico is Latin America's leading exporter of gloves, gauze and bandages; the third-largest exporter of tubular metal and suture needles; the fifth largest exporter of medical,



surgical, dental and veterinary instruments and devices; and the sixth-largest exporter of mechanotherapy, massage and psychotechnical equipment. Additionally, Mexico is estimated to be the second largest medical equipment market in Latin America, valued at \$3.4 billion in 2012.

Tijuana, Baja California: Medical Device Industry Capital

Baja California is home to 67 of the 233 companies that comprise Mexico's medical device industry, with a total estimated value of approximately \$3.4 billion.² With 40 of these companies calling Tijuana home, the industry has named the northern Mexican city as a "medical device cluster," with 91% of the medical device investments coming from the United States.

Baja California has the largest cluster of medical device companies in Mexico as a whole, boasting 67 companies in the state. In addition to the concentration of medical device manufacturing activities; the first Pharmaceutical Industry Census in Mexico reported that despite the collapsing global economy the sector saw a 24.2% sales growth between 2007 and 2010.

San Diego Biotech Cluster

San Diego, located just minutes north of Tijuana, is considered the top US National Biotech Cluster and is known as a hub for its world-renowned life sciences industry. Proximity to San Diego is also a huge plus for some medical device manufacturers, choosing San Diego for R&D and Tijuana for production. The two cities geographic, economic and cultural ties make the region rich in industry and industry support services.

SECTION 2

NAFTA: How Manufacturers Get it Done for Less

Welcome to Effortless, No-Tariff Trade

During the last 15 years, Mexico's Foreign Trade Policy has focused on establishing strong commercial trade partnerships with other countries. Mexico has entered into 12 major free trade agreements giving preferential treatment to 49 markets on three continents.

Despite multiple strong agreements with the European Union and Latin America, it's the North American Free Trade Agreement (NAFTA) that remains the most attractive to North American companies selecting Mexico for their next facility. Signed by the United States, Canada and Mexico in 1994, NAFTA created one of the largest trade zones in the

world with more than 160 million consumers within its borders.⁴

"Mexico has a free market economy in the trillion dollar class," according to a KPMG report, with trade to the US and Canada nearly tripling since it's signing in 1994. NAFTA has proven to be a successful 20-year global case study on how lucrative trade agreements can be, especially between neighboring countries.

An Infrastructure of Support Services

After nearly 20 years since the signing of NAFTA, Mexico has fostered a pro-business environment ideal for manufacturing activities. From industry support services and legal consulting firms to administrative services outsourcing, such as call centers and trade and logistics specialists.

Most companies carry years to decade's long expertise in leaning operations by nearshoring to Mexico, shortening the supply chain and maximizing benefits from trade agreements such as NAFTA. For businesses looking to establish operations in Mexico, Co-Production Interntational (CPI) is one of these whose purpose is to take on the logistical and legal tasks of establishing your new operations so that your medical device company can focus on its production

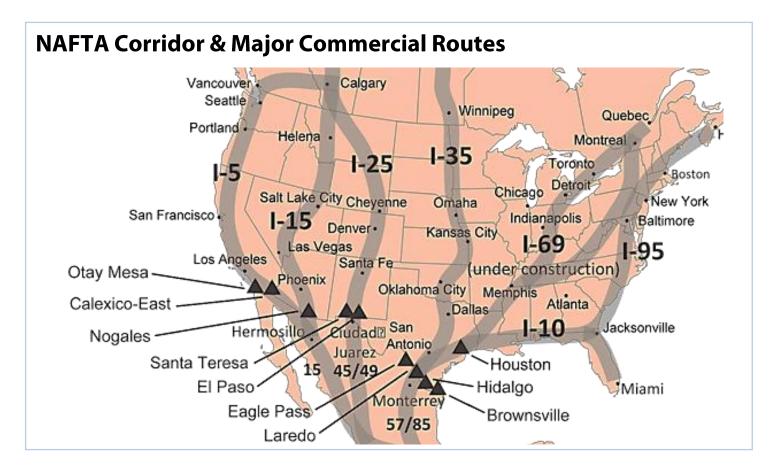
No Tariff Zone

NAFTA's main purpose is to gradually reduce or eliminate trade barriers between its three member nations, with 99% of imports currently duty-free in Mexico, and the remaining 1% benefiting from preferential duty. In very few cases where NAFTA does not apply, the Mexican government established programs such as IMMEX and PROSEC to fill these gaps.

IP Protections

Mexico is regarded as having strong IP protections and enforcement. Two main Mexican laws govern intellectual property. The Industrial Property Law, enforced by the Mexican Trademark Office (IMPI), and is mainly for inventions, trademarks, industrial designs, and appellations of origin. The second is the Copyright Law enforced by the Mexican Copyright Office (INDAUTOR), and is primarily for literary, musical, artistic, photographic and audiovisual works.⁴

Both of these laws were modeled after international standards set by the World Intellectual Property Organization (WIPO) and carry similar legal provisions for IP protection and enforcement as seen in the United States. The Mexican Patent and Trademark Office will cooperate with its counterparts in other countries to reduce the local examination process for patents that have already been registered in other countries.



SECTION 3

An Infrastructure Built for Commercial Logistics

Rapid Ground Transportation to Major North American Markets

Baja California is Mexico's most western state located just south of California. The Tijuana/San Diego border region is one of the largest in the world for both tourism and commercial trade. With the enactment of NAFTA, Mexico has invested significantly in infrastructure improvements to maintain existing, as well as attract new commercial trade to the region.



Highways & Transportation

Tijuana and the Otay Mesa Commercial border crossings are located just minutes south of San Diego, California, giving commercial transportation access to all major North American trade corridors and highways. Baja California has a strong network of well-maintained highways with Highway 1 as the major artery connecting the entire state to the US via San Diego. Running east from Tijuana, Highway 2 provides direct connection to eastern commercial land ports of entry like those in Nogales and El Paso.

In addition to several thousand miles of highways and railways used to move raw materials and finished products throughout the region and to major North America, Baja California also has one deep water port located in Ensenada. A mere 63 miles south of Tijuana/San Diego, Ensenada's deep water port is directly linked to major international ports in Los Angeles, Long Beach and Hong Kong. Port to Port, Ensenada is only 140 nautical miles from Long Beach.

Facilities & Real Estate

The Tijuana industrial real estate market offers more than 57.3 million square feet of pre-owned and new buildings throughout the city. From Class A to Class C facilities, companies will find shell, semi-finished and built-to-suit options, as well as inexpensive land for new facility construction. Tijuana has over 60 industrial parks making it one of the top four industrial markets in Mexico. Lease rates throughout Baja California vary depending on term, averaging \$0.28 USD to \$0.48 USD, per square foot.

Utilities Infrastructure

Utility costs include electricity and natural gas costs and represent up to 8 percent of total location-sensitive costs. Mexico has very low utility costs when compared to other major growth markets.³ For example, the city of Mexicali lying just east of Tijuana and capital of Baja California, supplies most of its inhabitants from hydroelectric power provided by the Colorado River.

Within the last 2 years Mexico also made the electrical infrastructure for new facility sites easier to obtain by streamlining procedures, offering training opportunities to private contractors, using a geographic information system (GIS) to map the electricity distribution network and increasing the stock of materials.⁸

A majority of the water supply for Tijuana is obtained from the Colorado River. The Baja Californian State Water Commission (CESPT) opened two new water treatment plants in Tijuana in 2010 for recycled water meant specifically for industrial use. ⁷ These two new facilities were certified by the North American Bank.

NEW, FASTER PROCESSING IN 2013:

Otay Mesa Commercial Crossing

Otay Mesa is located just 15 minutes east of Tijuana and 20 minutes south of San Diego, California. Designated as the only commercial crossing in all of southern California, Otay Mesa sees more than 1.4 million commercial trucks cross into the United States a year.

A new facility located at the Otay Mesa port of entry was recently completed in 2013 by the Mexican government and will have customs officers from both the US and Mexico. From laboratory rooms and cold storage, to state of the art inspection equipment, the purpose of joint operation is to speed processing of produce coming into the US. Its these types of investments in infrastructure and legal process improvement by the Mexican government that continue to prove the country's dedication to increasing efficiency in trade and commerce for its region.

Supply Chain & New Exposure

Medical device manufacturers identify the financial benefit of by expanding or moving operations to Mexico. In addition to lowering costs, medical device companies also enjoy the lucrative nature of being geographically located in the heart of Mexico's largest Medical Device Manufacturing Cluster, giving them access to new clients and new industries.

Companies like DJ Orthopedics found that their proximity to other medical device production and assembly operations opened themselves up to new suppliers and a new supply

Tijuana	Q1 2011	Q2 2012	Q1 2013	Trends
Total Industrial Space Available: (Million SF)	7.3	6.3	5.7	1
Vacancy Rate: %	13.61%	10.45%	9.30%	1
Asking Lease Rates Class "A": \$/SF/Month	\$.36	\$.42- \$.44	\$.42-\$.44	\leftrightarrow
Under Construction (SF)	200,000	180,000	729,000	1

chain. No decision has ever been easier than an expansion of operations for cost-effectiveness that also exposes your business to new markets and an expansive supply chain.

SECTION 4

Mexico's Low Cost, Highly Skilled Workforce

Expect Employees to be University Educated and Technically Trained

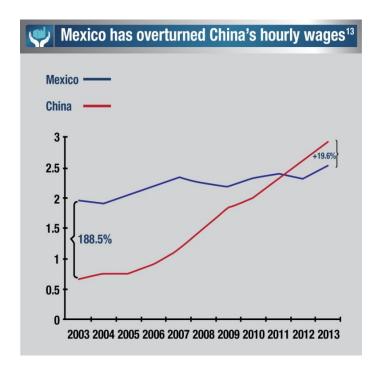
Mexico and Baja California's workforce is educated, plentiful and reliable. Graduating around 115,000 engineering and technical students per year, Mexico produces roughly three times more graduates in the field than the United States.¹⁰ Baja California's medical device industry is responsible for over 41,000 jobs in the state, with nearly 31,000 direct medical device manufacturing jobs in Tijuana.⁶

Tijuana's workforce is extremely reliable with a low average turnover rate of 2.6% reported in 2011.⁷ additionally; executives cite benefits of the closer cultural ties with the mostly bilingual workforce versus that of offshore locations like those in the Asian-Pacific.

Competitively Low-Cost

In the high growth markets, total labor costs account for approximately 30 percent of total location-sensitive costs in manufacturing and approximately 65 percent of total location-sensitive costs in service operations. Labor costs are lowest in India, China, and Mexico.³

In the last 10 years Mexico has significantly closed the gap in labor costs compared to its offshore competitor, China. Labor cost in Mexico went from being 200% more expensive than China, to an impressive 14% difference today. Adding in transportation and logistics time and cost, companies are finding nearshore operations in Mexico dramatically less expensive, even with the very slight difference in labor costs.



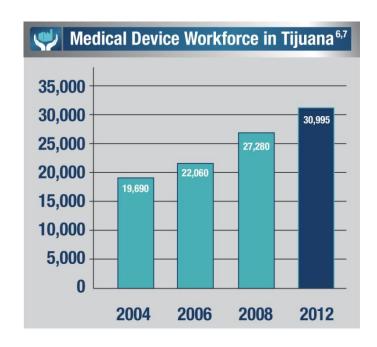
Highly Skilled & Highly Trained

Baja California is home to 35 universities and 14 technical schools offering over one hundred professional degrees including Biotechnology, Physics, Oceanography, Digital Geothermal Technology, Astronomy, Aerospace, Electrical Engineering, and Sustainable Energy. ⁷ Most universities are located in major urban centers such as Tijuana (15) and Ensenada (8) and many participate in direct education exchange programs with the leading universities in Southern California and San Diego.

Higher Education Enrollment in Tijuana 2013 ¹²			
Under Graduate	40,963		
Technical Training Students	6,434		
Graduate Students	3,215		
Total (estimated):	50,612		

Close Cultural Ties to the United States

Strong cultural, economic and familial ties have existed between Tijuana and San Diego for decades, some would say as long back as when California was still a part of Mexico. With over 59 million northbound crossings from Tijuana a year, Executives find that the region is not only largely bilingual, but also engrained with many American customs.



SECTION 5

Nearshore vs. Offshore

World Bank: *Mexico Top-Ranked Global Destination for Doing Business*

Mexico is ranked 48 under the "ease of doing business category, surpassing all the BRIC countries including China (91), Brazil (130), and India (132), according to the World Bank's annual report "Doing Business 2013," which compares business regulations for domestic firms in 185 countries.⁸

Moving operations from the US to Mexico represents an overall savings **up to 23.3%**⁹

Improving five positions since 2012, Mexico's pro-business government made notable improvements including eliminating minimum capital requirements for LLCs, and reducing the number of times a company pays taxes from 27 to 6 times a year.

The cost of manufacturing medical instruments, electronic devices and precision components, concept testing, operating and labor costs in Mexico are all substantially lower than in other countries across all levels of specialization.

Major Medical Device Companies

Nearly 40 major medical device manufacturers operate in Tijuana, including global players such as Medtronic who has had a facility in the region since 1970. Other large medical device companies in Tijuana include Avail, Cardinal Health, Gambro Avantti MediClear and Welch Allyn. Avantti MediClear is expected to complete a new facility for medical device sterilization in eastern Tijuana sometime in 2013. Co-Production International has assisted many major medical device companies including US market giants; Teledyne Medical and DJ Orthopedics.

Tijuana Medical Device Companies

Medtronic	Cardiovascular disease treatment & technology, orthopedic devices, medical instruments		
Nelcor Puritian Bennett (Covedien)	Medical instruments, respiratory therapy equipment		
Greatbatch	Orthopedic devices		
Becton Dickinson	Glass & prefilled syringes, hypodermic products		
Össur	Non-evasive orthopedics		
Medline	Wound care products, medical uniforms, gloves		
DJ Orthopedics	Orthopedic devices, surgical reconstructive implant products		
Teledyne Medical	Surgical kits, syringe packaging		

Certifications & Accreditations

Tijuana's industrial and manufacturing facilities hold many accreditations including ISO9001, ISO13485, ISO/TS16949, AS 9100, Nadcap, Six Sigma, 5S, Kaizen, in addition to major project management and lean manufacturing industry best practices. Of the facilities in Tijuana with over 250 employees, 90% are ISO certified. Where offshore locations in the Asian Pacific may boast similar commitments to international standards for quality, the mere proximity of Tijuana to the US allows for immediate oversight of quality issues and on-site verification of adherence to international accreditations.

Nearshore Logistics Savings

The cost to transport materials and products represents anywhere from 30–40% of your total logistics costs. Contributing directly to your bottom line and the product's final cost, logic dictates having your manufacturing activities as close to your market as possible. Tijuana is only 140 miles from Los Angeles making it 46 times closer to North American markets than the global commercial logistics hub in Shanghai.

SECTION 6

Getting Started in Mexico

It Doesn't Get Any Easier!

Starting or expanding your business in any foreign country can be a daunting decision process for any sized business. Fortunately it couldn't be any easier than it is in Mexico. In addition to the long history of social and cultural ties between the Mexico and the United States, the two countries have also mastered a mutually beneficial and supportive environment for trade and commerce. The US dollar is also widely accepted and used throughout Baja California.

An Industry at Your Service

Considering close geographic proximity, over 20 years of NAFTA, and an established network of industry support services, executives exploring Mexico for their next facility can rely on services and organizations whose sole purpose is to facilitate or handle it all for you. Not only are there many companies such as Co-Production International, to facilitate your operations in Mexico, but also government organizations waiting to get you through the legal steps so you can get up and running as soon as possible.

Security & Safety in Mexico

One last consideration by executives is the safety and security of the country they are considering to do business in. Much of the news reports of violence and drug crime in Mexico, especially along the US/Mexico border, have been shown to be exaggerated. Co-Production International has an expanded paper for executives interested in learning more about issues of security and safety in Mexico.

Visit CPI's website or <u>Click here for your free copy of "Security First in Tijuana, Mexico."</u>

SECTION 7

Summary

Mexico: A New State of Manufacturing

Executives and companies consider a handful of factors when exploring new facilities for medical device manufacturing activities. An almost entirely financially motivated decision, the cost-effectiveness of production (labor & materials) and proximity to major markets, are the top considerations in new site selection, with infrastructure and ease of doing business following closely behind.

Years ago businesses wouldn't hesitate to cite offshore countries such as China as the hands-down lowest cost option for manufacturing. After examining various factors crucial to a low cost, efficient and lean manufacturing supply chain, Mexico has emerged as a global leader for the medical device industry.

References and sources provided for further information. This is not a legal document. Co-Production International, Inc. does not guarantee claims made by sources used in this paper. Every effort to be accurate has been made at the time of publication. Corrections to data or errors should be sent to CPI.

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