

2016

Medical Device Manufacturing in Tijuana and Mexico

*Advantages of Nearshoring in Mexico,
Key Highlights and 2016 Industry
Overview*

WHITE PAPER



CPI CO-PRODUCTION
INTERNATIONAL

Co-Production International
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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, Free Trade Zone
- Maquila Duty-Free Temporary Imports
- Strong Intellectual Property (IP) Protections
- Established Infrastructure

This white paper will assist executives in understanding the benefits of **manufacturing in Mexico** by analyzing Mexico as a potential site for medical device manufacturing activities. Important factors such as proximity to major markets, infrastructure, labor cost and supply, transportation and ease of doing business, will be covered. Additionally, this paper will also focus on the established medical device industry of both Mexico and Tijuana, Baja California.

SECTION 1

Mexico an Attractive, High-Growth Market to Watch

Mexico grew from third in 2012 and is now ranked first for lowest business costs according to the annual KPMG Competitive Alternatives: Guide to International Business Location Costs 2016.³ Mexico's exports of medical equipment and supplies were valued at \$8.5 billion in 2015, of which exports to the US accounted for \$6.45 billion.^{1,9}

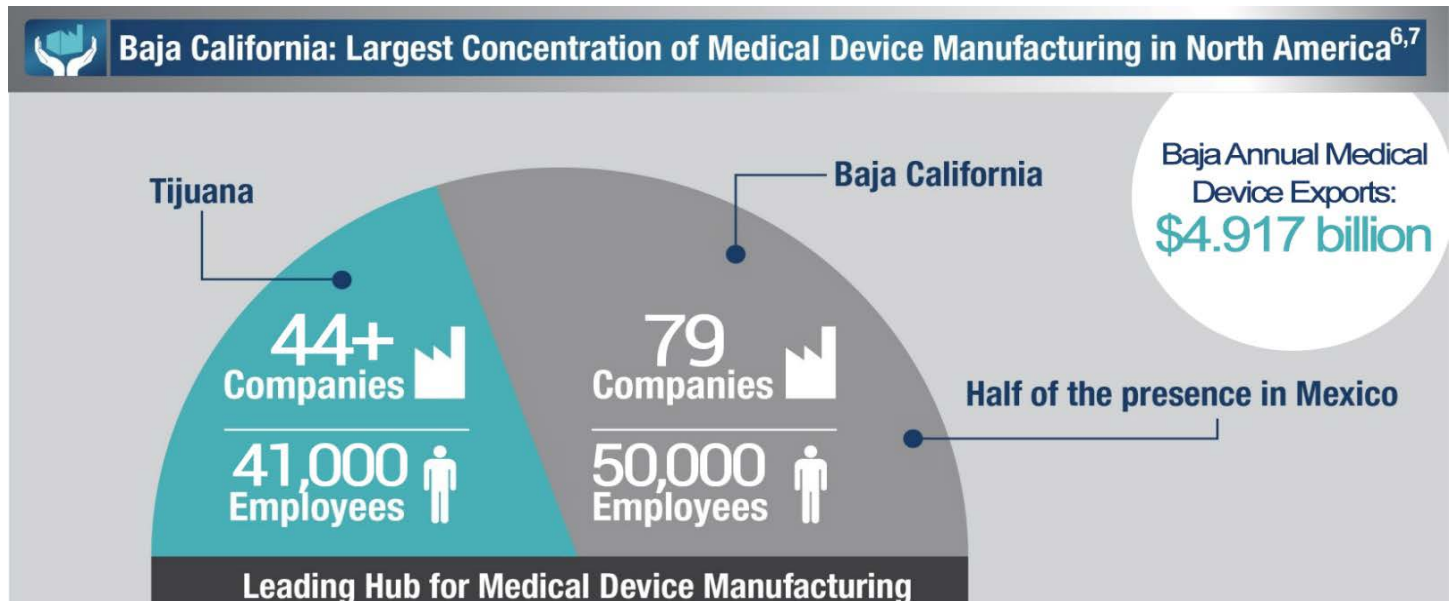
SPOTLIGHT

\$8.5 billion

Mexico's Medical Equipment and Supplies Exports in 2015¹

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.

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.



TIJUANA, BAJA CALIFORNIA:

Mexico's Medical Device Industry Capital

Baja California is home to 79 of the 740 manufacturing companies that comprise Mexico's medical device industry. Though Baja California has approximately 10% of Mexico's medical device manufacturers, it is responsible for half of the country's exports in the industry, reaching \$4.917 billion for 2015.^{2,7}

With more than **44** 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 industry direct foreign investments (DFI) coming from the United States.

SPOTLIGHT

92.5%

Medical Devices Manufactured in Tijuana that are Exported to the US¹⁴

Medical Device Cluster of Tijuana

Over 44 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 Avanti MedClear** and **Welch Allyn**.⁷ In 2013, Avanti Medclear opened their 30,000+ square foot facility in Tijuana becoming the first company in Mexico to offer sterilization services to medical device companies using the modern "E-Beam" technology.

Co-Production International has assisted many major medical device companies including US market giants; **Teledyne Medical** and **DJO Global** with establishing operations in Tijuana, corporate framework, administrative tasks and other business process outsourcing (BPO) services.

TIJUANA SUCCESS STORY: DJO Global

Operating in Tijuana for over 17 years, DJO Global (DJ Orthopedics) has become a shining regional success story for nearshore expansion. Starting with 20 employees and 3 SKUs, DJO has now grown to manage over 11,000 SKUs and 2,000 employees.

DJO Global's Tijuana facility has received US and international awards for quality and operational excellence, including AME's Manufacturing Excellence Award, IndustryWeek's Best Plants, and the Shingo Prize for Operational Excellence. After analyzation, DJO has realized a lead time reduction of 80% and an inventory reduction from 84 to 14 days.

Major Medical Device Companies in Tijuana

Medtronic	Cardiovascular disease treatment & technology, orthopedic devices, medical instruments
Nelcor Puritan 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
DJO Global	Orthopedic devices, surgical reconstructive implant products
Teledyne Medical	Surgical kits, syringe packaging

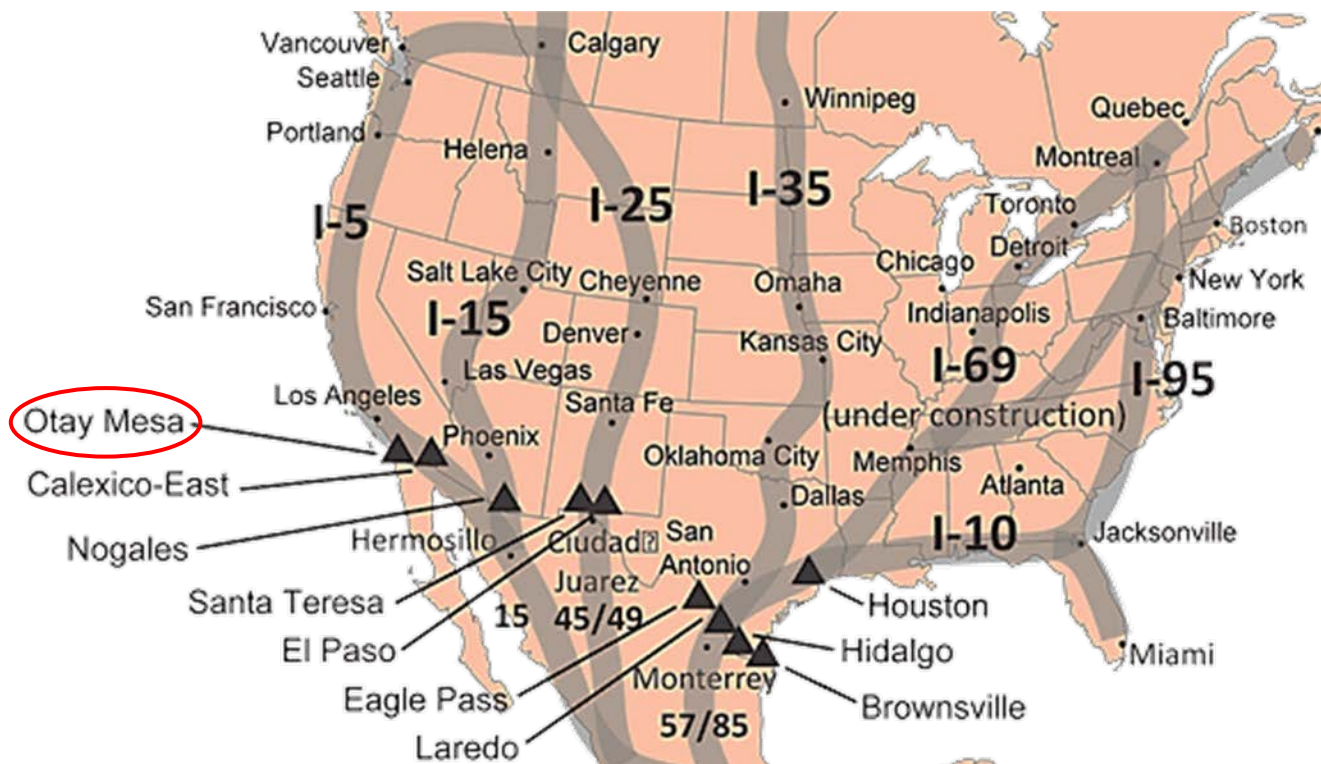
San Diego Biotech Cluster

San Diego, located just minutes north of Tijuana, is considered the top National Biotech Cluster for the United States 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. Additionally, the now called Cali-Baja Megaregion includes over 800 biotech companies. These two sister city's geographic, economic and cultural ties make the region rich in industry and industry support services.

High Quality, Safe & Sterile Facilities

Many industrial facilities carry international and industry recognized accreditations and comply with global standards for quality and safety. Companies will 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.

NAFTA Corridor & Major Commercial Routes



SECTION 2

NAFTA: How Manufacturers Get It Done for Less

Welcome to an Effortless, Free Trade Zone

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 13 major free trade agreements giving preferential treatment to 51 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 international 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 the same KPMG report, with trade to the US and Canada nearly tripling since its signing in 1994.⁴ 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 [service companies](#) such as legal consulting firms and administrative services outsourcing, as well as call centers and trade and logistics specialists, a long-established network of support services are available for medical device manufacturers to consult or contract.

Most support service companies carry decade's long expertise in leaning operations by nearshoring to Mexico, shortening the supply chain, and assisting your business in maximizing benefits from trade agreements such as NAFTA. For businesses looking to establish operations in Mexico, [Co-Production International \(CPI\)](#) is one of these whose purpose is to take on the logistical and legal tasks of establishing your new operations, managing day to day administrative activities, along with trade and logistics support.

Free Trade 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.

TPP: Benefits for Manufacturers in Mexico

The establishment of a free trade zone for 12 countries under the Trans Pacific Partnership in 2016 will open up NAFTA-style preferential tariffs or liberalization of tariffs. The member states include the USA, Canada, Mexico, Peru, Chile, Australia, New Zealand, Japan, Malaysia, Singapore, Vietnam and Brunei. Ratification is expected by 2018 and is expected to boost exports in strategic sectors such as vehicles & auto-parts, aerospace, medical devices, electric equipment, cosmetics, tequila, mescal, beer, avocado, beef, pork and orange juice.¹⁵

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 rapid 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, AZ and El Paso, TX.

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 American markets, 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.

Industrial 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 52 industrial parks making it one of the top four industrial markets in Mexico.

	'14 Q1	'15 Q1	'16 Q1	Trend
Total Available Industrial Space (Million SF)	4.97	4.48	2.89	↓
Vacancy Rate %	8.06%	7.00%	4.40%	↓
Asking Lease Rates Class A, \$/SF/month	\$0.45	\$0.45	\$0.46	↑
Under Construction (SF)	497,327	800,556	833,242	↑

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:

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 crossings into the United States annually.

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.

LOGISTICS SPOTLIGHT

2,000

Loaded Truck Containers that Cross
at Otay Mesa each Day

In the summer of 2013, US Customs and Border Protection began two new pilot programs at the Otay Mesa commercial crossing for empty trucks heading both north and southbound. These pilot programs are meant to help ease traffic and wait times. Now, the northbound import facility will open at 5am (instead of 6am) and the southbound export facility will open at 7am (instead of 8am). Investments by the US in these types of pilot programs also show the country's commitment to its commercial trade relationship with Mexico.

Supply Chain & New Exposure

Medical device manufacturers identify many financial benefits of 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 industry sectors.

Companies like **DJO Global** found that their proximity to other medical device production and assembly operations opened themselves up to new suppliers and a new supply 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, per capita, in the field than the United States.¹⁰ Baja California's medical device industry is responsible for over 50,000 jobs in the state, with nearly 41,000 direct medical device manufacturing jobs in Tijuana.⁶

The Baja California State University (UABC) is located in most major urban centers of the state and offer Bachelor of Science degrees in Aerospace, Electronics, Electrical, Mechanical, and Industrial engineering fields. The manufacturing industry in Tijuana represents 47% of the permanent private jobs in the city.²

TRADE SPOTLIGHT

IMMEX Program for Temporary Import

This program is ideal for medical device manufacturers who are looking for low cost manufacturing and assembly solutions that also shorten the supply chain to major markets.

Under the Manufacturing, Maquiladora and Export Service Decree, the IMMEX Program allows for goods, raw materials and components to be imported into Mexico on a temporary basis, **duty-free and VAT-free**, as long as they are returned abroad within the established timeframes (most are 18mos).⁴

Over the years of NAFTA and the IMMEX program, three main types of maquilas have emerged; service maquilas, manufacturing maquilas, and maquilas operating under manufacturing agreements or shelter operations.

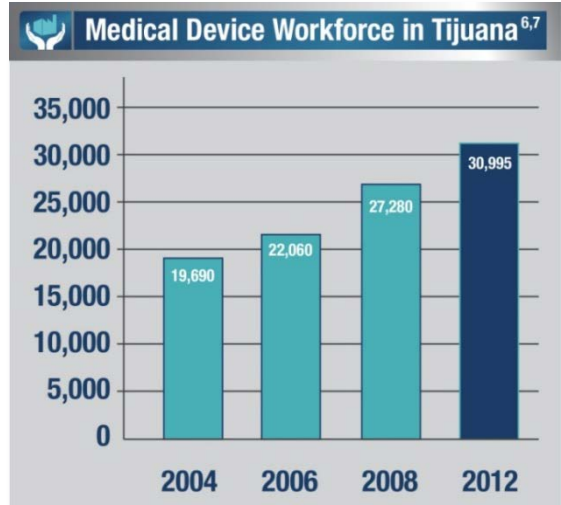
Tijuana's workforce is extremely reliable with a low average turnover rate of 2.6% reported in 2011.⁷ Additionally, executives cite benefits of the closer cultural ties with the mostly bilingual workforce versus the difficulties observed in offshore locations like those in the Asia-Pacific.

finding nearshore operations in Mexico dramatically less expensive, even with the very slight difference in labor costs.

Higher Education Enrollment in Tijuana 2013 ¹³	
Under Graduate	40,963
Technical Training Students	6,434
Graduate Students	3,215
Total:	50,612

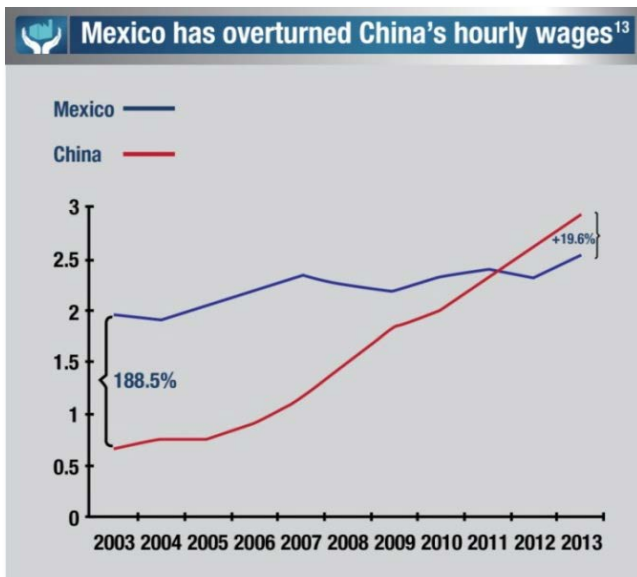
Highly Skilled & Highly Trained

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 and technical schools are located in major urban centers such as Tijuana (35) and Ensenada (12) and many participate in direct education exchange programs with the leading universities in Southern California and San Diego.



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 to San Diego a year, executives find that the region is not only largely bilingual, but also engrained with many American customs. Additionally, the US Dollar is a widely accepted and used form of currency, especially along Northern border regions and in city metropolises. It also the main currency for most trade in the region.



SECTION 5

Nearshore vs. Offshore

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

Mexico is ranked 38 under the "ease of doing business" category, surpassing all the BRIC countries and also including Costa Rica (58), China (84), Brazil (116), and India (130), according to the World Bank's annual report "Doing Business 2016," which compares business regulations for domestic firms in 185 countries.⁸ This represents a marked improvement of Mexico's rank of 48 in 2012.

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.

Globally Competitive Labor Rates

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

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.

Mexico is the largest exporter of medical devices to the US and Latin America

International 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.⁷ 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.

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 established and experienced 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 \(CPI\)](#), to establish and 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 unrest in Mexico, especially along the US/Mexico border, have been shown to be exaggerated.

Co-Production International has an expanded paper that covers of security and safety issues in Mexico. Please see the last page of this white paper.

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.

2016 EVENTS HIGHLIGHTS

Upcoming Regional Medical Device Events

CPI Baja Manufacturing Tours

Tijuana, Baja California

Want to see it first hand?

Get a chance to see manufacturing in Mexico up close! Tour includes visits to manufacturing OEMs, industrial park and sites, and meetings with government officials specializing in setting up operations in Mexico.

**Contact us today to set up a tour date
that works for you!**

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FURTHER READING

CPI invites you to read more about manufacturing in Mexico with its series of White Papers on the following industries. Requests to: Denisse Martinez, Marketing Director, Email: denissem@co-production.net Phone: (619) 429 4344 Ext. 231

NEW! Industry Fact Sheets

2016

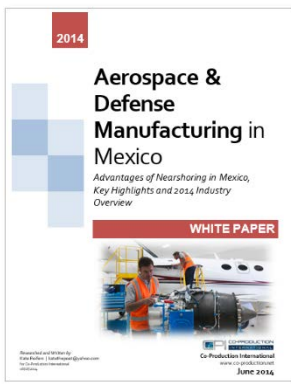
- Medical Device
- Aerospace & Defense
- Electronics
- Automotive & Auto Parts



Manufacturing in Mexico

2016

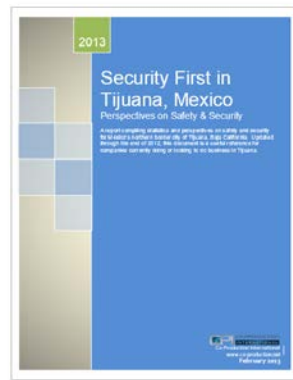
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Aerospace & Defense Manufacturing in Mexico

2016

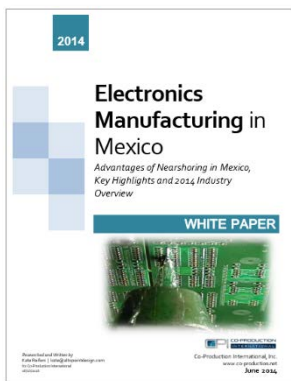
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Security First in Tijuana, Mexico

2013

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Electronics Manufacturing in Mexico

2016

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Medical Device Manufacturing in Mexico

2016

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