

# TIJUANA: NORTH AMERICA'S MEDICAL DEVICE MANUFACTURING CAPITAL



# TIJUANA'S MEDICAL DEVICE INDUSTRY

## ABOUT THE MEDICAL DEVICE INDUSTRY

Medical devices have a great impact on a day to day life since they have become fundamental for the detection and treatment of many health conditions. Lifestyle, an aging population and new advances in science are just some of the factors that drive the continued use of medical devices among the world's population. It is estimated that, this market has a value of 96.5 billion dollars worldwide, being the United States, Germany, Holland, China, Japan, Ireland, and Mexico among the main competing countries in production and export of medical devices, according to data by the Observatory of Economic Complexity (2017).

In Mexico, there were 2,494 economic units that employed around 170,000 people and contributed to 13,811 million dollars' worth of production in 2017 (ProMéxico, 2018). Among the states with the highest concentration of the medical device industry are Baja California as themain state, Mexico City, Estado de Mexico, Jalisco, Chihuahua, Coahuila, Morelos, Nuevo Leon and Tamaulipas.



Due to the health risk posed by the use of medical devices, the medical manufacturing industry in Mexico requires that even the simplest processes and products are regulated by a rigorous regulatory framework stipulated by the General Health Law, Regulations on consumables related to Health, Supplements for medical devices of the Pharmacopoeia of the United Mexican States, and Official Mexican Norms such as:

**NOM - 001 - SSA1-2010**

That institutes the procedure by which it will review, update and edit the Pharmacopoeia of the United Mexican States.

**NOM - 137 - SSA1-2008**

Labeling of Medical Devices

**NOM - 241 - SSA - 2012**

Good Manufacturing Practices for Medical Devices,

**NOM -240 - SSA1 - 2012**

Installation and Operation of Techno-surveillance

It should be mentioned that, although products manufactured in Mexico must adhere to national standards, they are also subject to international certifications, in the case of devices that will be marketed abroad, such as the ISO 9001, ISO 13485, ISO 140000 and ISO 17025 standards, as well as the CE marking (Conformité Européenne) for products destined to the European Union, Canadian Medical Device Regulations (CMDR) in the case of Canada, and the requirements established by the Food and Drug Administration (FDA) of the United States, to mention some examples. Among the institutions that regulate the products and processes of the industry within the Mexican context are the Ministry of Health, COFEPRIS, the FDA and its Center for Devices and Radiological Health (CDRH) in the United States, and Health Canada in the case of Canada.

The fact that manufacturing companies and their suppliers have abided and complied to international regulations and certifications established by different Mexican and foreign entities, has granted a competitive advantage to the medical device industry in Baja California, situating it as a world class destination and offering additional advantages for potential foreign investment in this area.



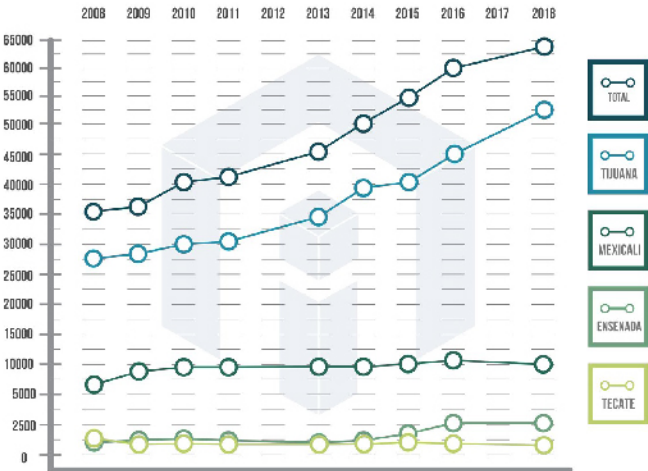


# THE MEDICAL DEVICE INDUSTRY IN NUMBERS

The history of the medical device industry in Baja California is one of success, characterized by a process of constant learning, sustained growth, increased confidence in regional capabilities, rising as one of the most important industry hubs of this sector in Mexico and Latin America.

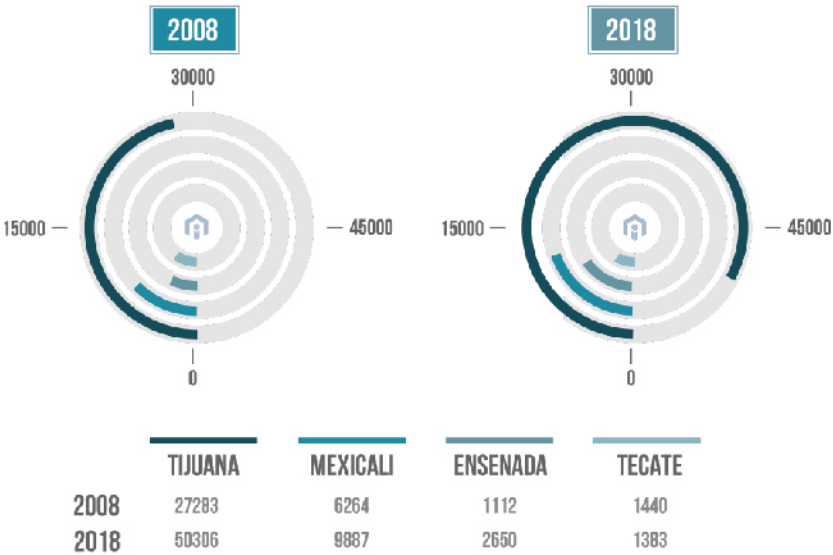
EMPLOYMENT DISTRIBUTION OF THE MEDDEV INDUSTRY BY CITY 2008 - 2018

## EMPLOYMENT



Source: AXIS Centro de Inteligencia Estratégica

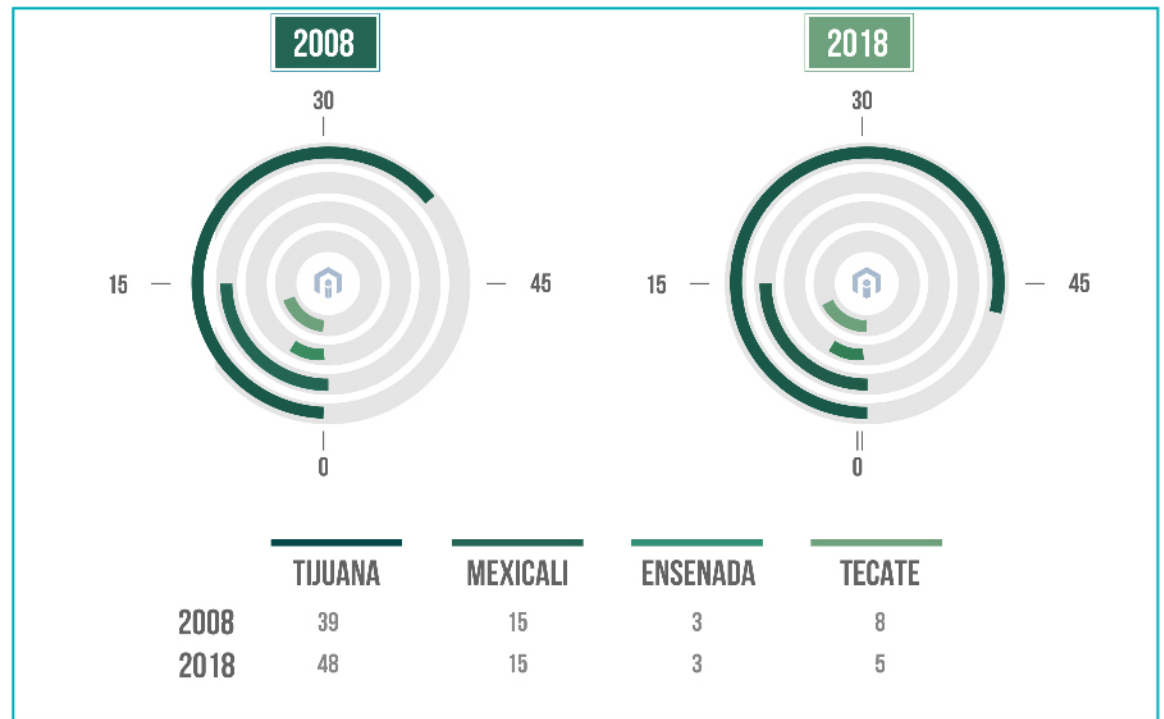
## EMPLOYMENT



Manufacturing plants in Baja have become strategic assets to their headquarters



# COMPANIES



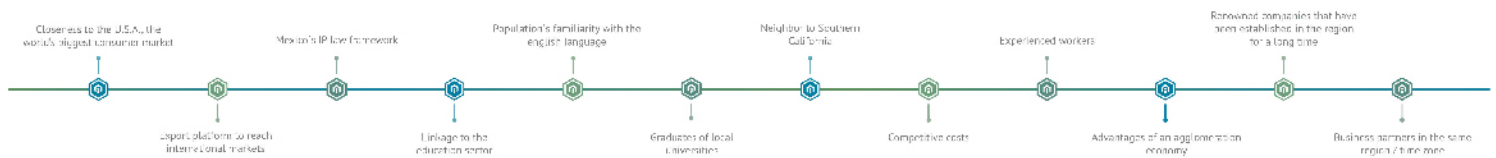
In addition, since its establishment in 2006, the Industrial Association of Medical Products of the Californias A.C., (hereinafter, “cluster”), has been promoting the development of the regional industry. This milestone was achieved with AXIS’ support, which played a key role in developing and managing the strategy to boost the medical device industry in Baja California, as well as acting as coordinator in the cluster’s beginning, and to the participation of private initiative through the Development Council of Tijuana (CDT).



Nowadays, the cluster represents and promotes the sector, works with public and private organizations, and represents an added value for the promotion efforts of the regional industry, by looking after the companies interests and facing shared problems through lobbying and strategic collaboration.

Likewise, the industry’s growth and development has been accompanied by a greater integration of processes to its production chain, which include plastic molding and operations of clean rooms. According to the magazine Business Conexión, 23 companies had clean room facilities in the range of Class 100 to 100,000 in 2014, in comparison to 2007, where only six companies had this type of facilities. This increase represents an industrial specialization regarding manufacturing facilities, as well as a greater rigor in practices specific to the sector.

# BAJA CALIFORNIA'S ADDED VALUES ACCORDING TO GOVERNMENT OFFICIALS, ACADEMIA AND INDUSTRY REPRESENTATIVES



The gradual development, consolidation and competitiveness that Baja California's medical device industry has proven to Mexico and the world, has led to upgrades in the production process from assembly and manufacturing to venturing into increasingly complex products. Now more and more, devices that require additional technology and technical operation expertise are being seen.

The medical device industry's relevance in Baja California has reached such levels, that the State Government, as well as local governments and development agencies, have promoted the sector both in the national and international context.

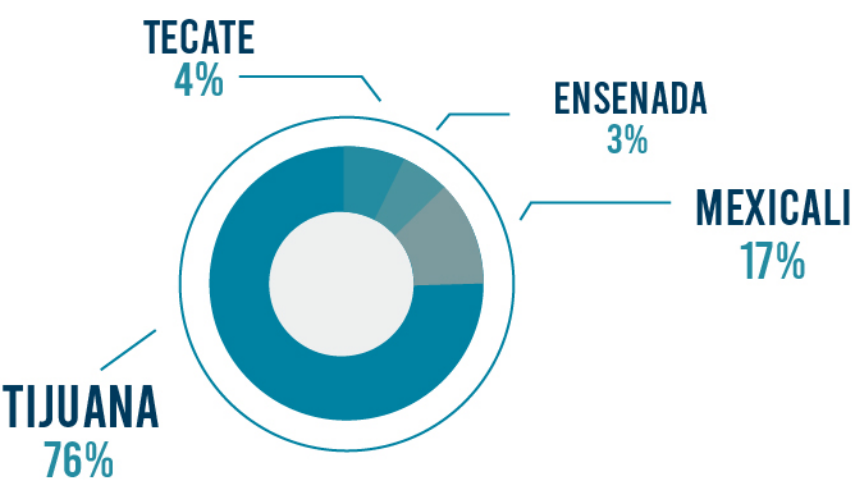
Among the actions aimed towards supporting the industry is the creation of a team of promoters specifically for the medical device industry, where organizations such as Tijuana Economic Development Council (Tijuana EDC) and Mexicali Economic Development Corporation (Mexicali EDC) participate.

The state's industry has been promoted in international events of the industry such as the MEDICA Trade Fair in Germany and the MD&M East and West in the United States.



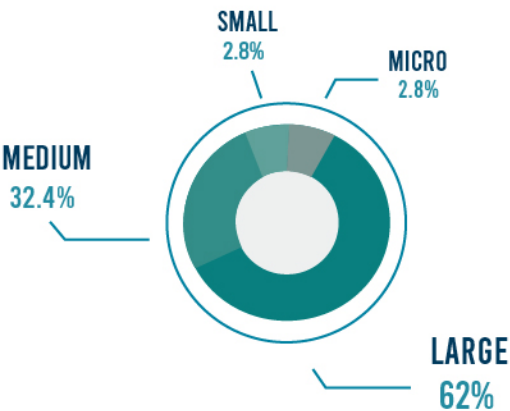
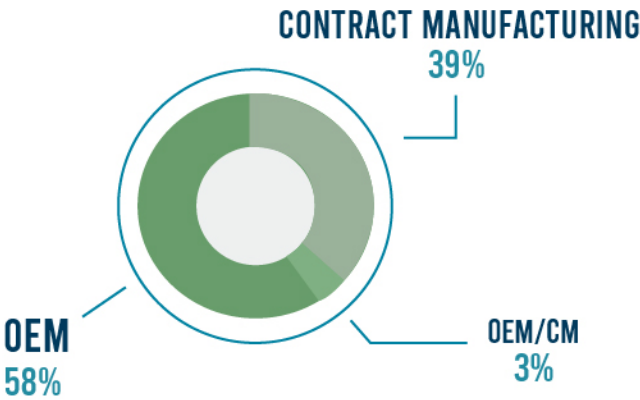
# CHARACTERISTICS AND CURRENT DIMENSION OF THE INDUSTRY

The regional industry currently participates in different actions that allow it to continue to develop and position itself in the international context, including promotion activities, investment attraction, supply chain integration, institutional linkage and even research. However, there are still areas of opportunity that must be addressed in order to continue consolidating the industry and face obstacles that may hold back its performance.



Tijuana is the city with the highest employment concentration in medical device companies, compared to other cities in the state.

42% of medical device companies in Baja participate in contract manufacturing activities by assembling and manufacturing products under the brand of another company.



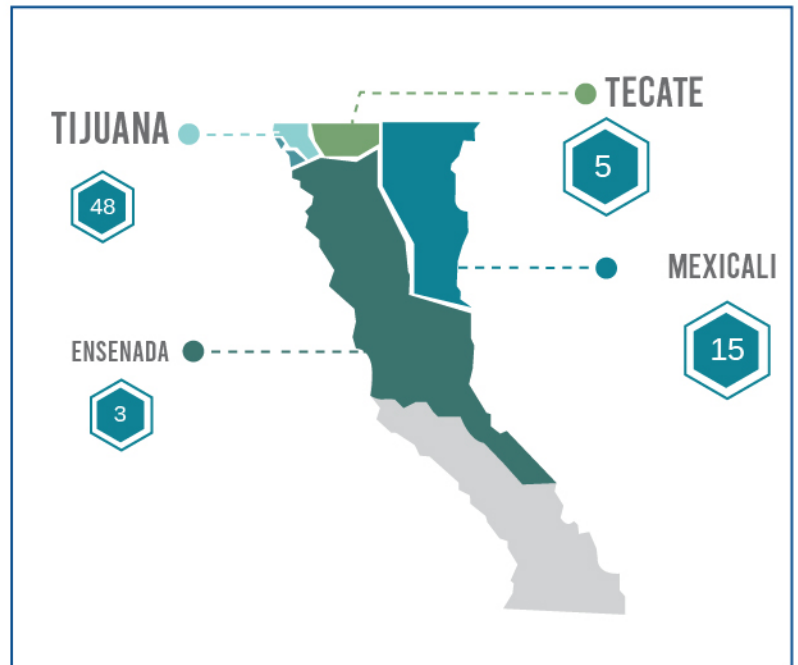
More than half of medical device companies in Baja are classified as “large” by INEGI, for employing over 250 workers.



Baja California has 71 companies established and operating in Tijuana, Mexicali, Tecate and Ensenada. About 80% of the companies come from U.S. investment, followed in second place by 8% of companies of Mexican origin. Other countries that have a presence in the region include companies from Germany, Canada, France, Great Britain, Iceland, Japan, and New Zealand.

Among the medical specialties that manufacturing activities are focused on include respiratory, orthopedic, cardiovascular, ophthalmological, gastroenterological products, as well as equipment and material for hospitalization and surgery, pharmacology, biotechnology, among others.

## BAJA CALIFORNIA HAS 71 COMPANIES OPERATING IN THE MEDDEV INDUSTRY



### GLOBAL LEADING FIRMS ESTABLISHED IN BAJA CALIFORNIA

Around 40% of companies are contract manufacturers, and the most recent investments in the region point towards an upward trend.

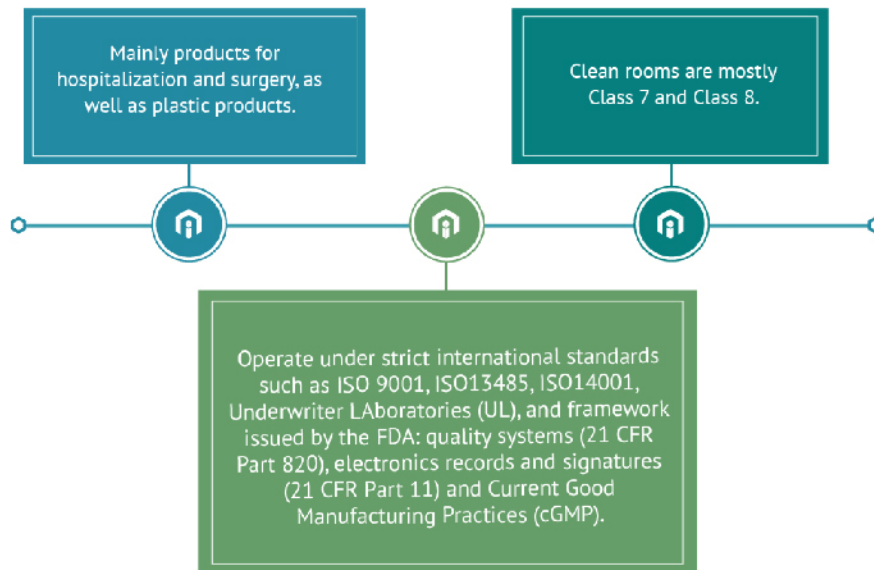


In terms of the devices complexity, there are different approaches between plants, since there are companies that manufacture relatively simple products in large volumes, as well as companies that handle reduced production volumes due to the sophistication of each device.

The companies installed in the region include original equipment manufacturers (OEM), contract manufacturing companies (CM), and even a combination of the two aforementioned, as there are companies that design and manufacture their products under their own brand and for other companies.

It is worth highlighting an interesting phenomenon of outsourcing that is taking place in the state, since currently around 40% of companies are contract manufacturers, and most recent investments in the region point towards an upward trend.

# MAIN CHARACTERISTICS OF MEDICAL CM IN BAJA CALIFORNIA



## MAIN CHARACTERISTICS OF MEDICAL CM IN BAJA CALIFORNIA

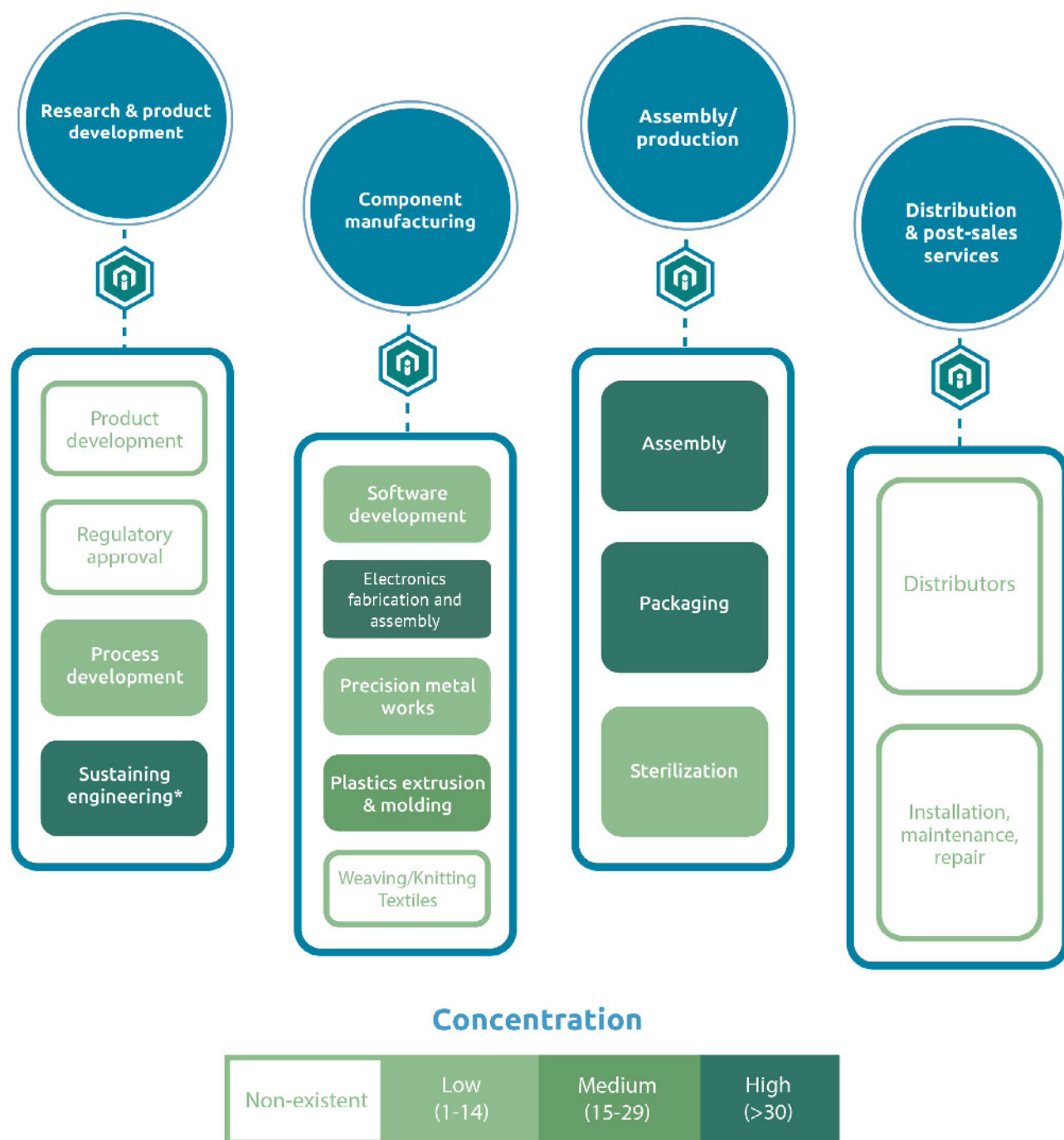
### MOST REQUESTED SPECIALIZED PROCESSES AND SERVICES

- Process automation
- Injection molding
- High precision machining
- IT services
- Software development
- Maintenance of clean rooms

- Maintenance of air conditioners, compressors, production equipment.
- Calibration services
- Treatments for metal parts
- Sterilization

# ANALYSIS OF THE PRODUCTION CHAIN

## PARTICIPATION OF BAJA CALIFORNIA IN THE GLOBAL VALUE CHAIN OF THE MEDICAL DEVICE INDUSTRY



\* Note: Although the exact data is not known, a common practice among the majority of manufacturing plants in Baja California is process engineering which through adjustments to operations allows the increase in the company's efficiency and productivity.



## IN AN INDUSTRY DOMINATED BY LARGE MULTINATIONAL COMPANIES, ENSAMBLES DE CALIDAD MÉXICO, S.A. OF C.V. STANDS OUT AS A MEXICAN SME CONTRACT MANUFACTURING COMPANY.

There are cases of companies that have expanded their internal operations to activities of higher added value, such as Thermo Fisher Scientific, which in addition to manufacturing medical products, the company has opened a Software Development Excellence Center in Tijuana to carry out design processes that involve the fusion of software and hardware for different medical products that they develop. This type of trends prone to vertical integration in the value chain, as well as the participation of companies with more specialized services, adds to other trends in the sector such as the optimization and automation of processes that require other types of personnel specializations.

## THE INDUSTRY AND ITS INSTITUTIONAL ENVIRONMENT

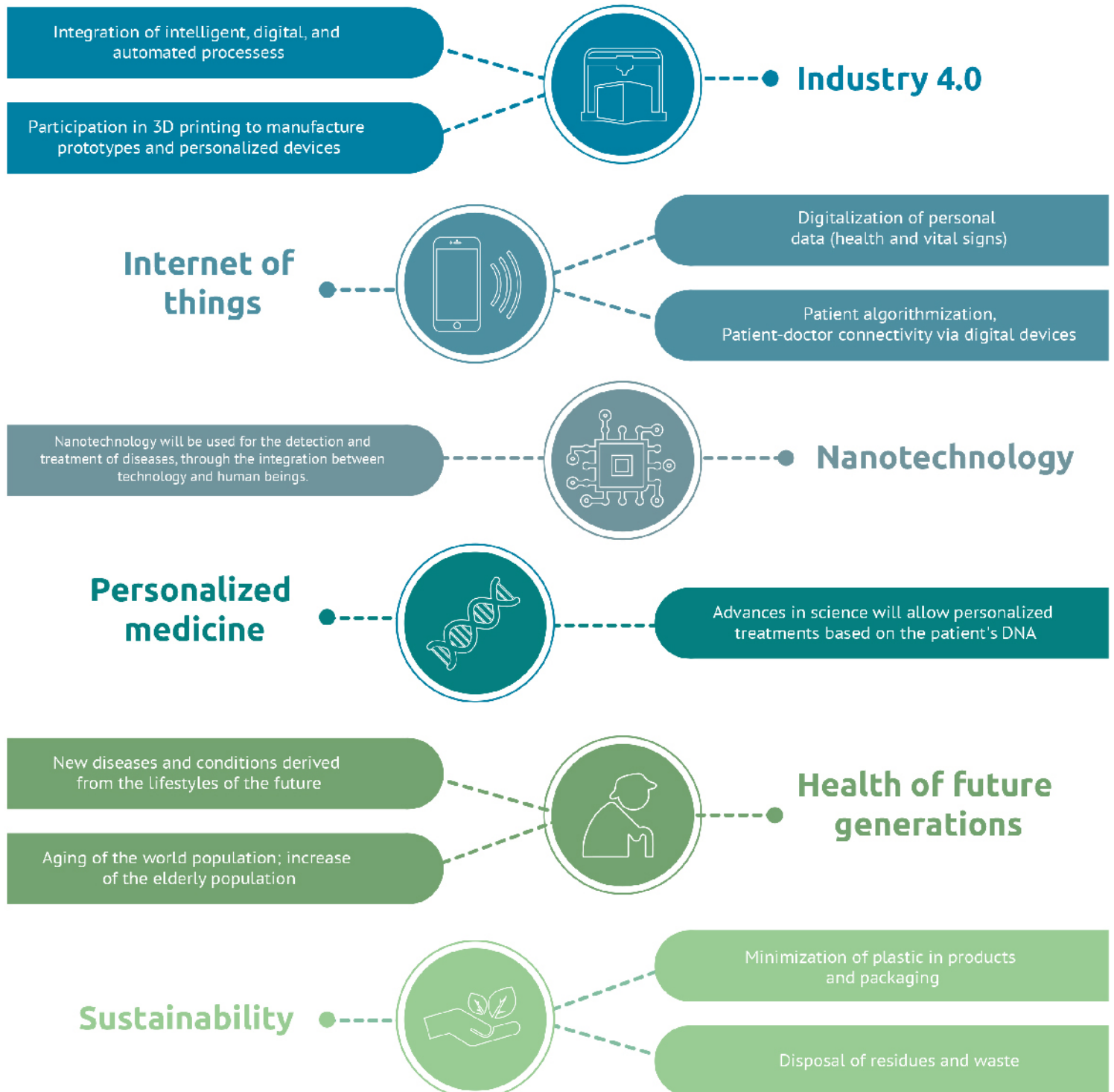
The cluster manages events that bring together established companies in the region, including the MedSummit, the college forum for medical engineering and the forum for the regulation of medical devices, which act as platforms for interactions between stakeholders, suppliers, government authorities and industry professionals. One of the cluster's challenges is to consolidate the participation of all companies in the state since, although this business association operates state-wide, it is recognized that it is difficult to bring together the companies that operate in Mexicali.

One of the most important alliances is the one established between the cluster, companies and the main universities in the region such as UABC, CETYS Universidad and UTT. This educational linkage has fostered the development of study programs, technological services, application projects and the Dual Education Model, which are intended to address the training of professionals profiles oriented towards the industry, updating and continuing education of personnel, and the implementation of solutions for companies by academia and students.

The universities' new approach  
Plastics  
***Advanced manufacturing  
Innovation and technological  
development***

# THE INDUSTRY FACING MEGATRENDS

## MAIN MEGATRENDS THAT WILL IMPACT THE MEDICAL DEVICE INDUSTRY OVER THE NEXT DECADE



# BAJA CALIFORNIA'S OPPORTUNITIES

## **CAPITALIZE ON THE TRAJECTORY OF THE REGION AND THE SECTOR (KNOW-HOW)**

Baja California has a favorable image as host of the manufacturing industry in Mexico, and as an export platform to the largest consumer market in the world, the United States, so the eyes of potential investors are already directed towards this region. The state's inherent advantages, such as its geographical location, as well as those developed through decades of experience in manufacturing activities, such as knowledge and skills of the workforce, must be taken advantage of to begin to highlight other qualities that allow the attraction of activities of higher added value and develop new projects involved in the next industry trends.

## **BI-NATIONAL SYNERGY**

The strategic location of Baja California, should be exploited not only to reduce time and cost of raw materials and goods that go across the border, but for the agreements and cross-border collaboration projects that exist between institutions and the intellectual capital of both sides of the border. Higher education institutions and research centers should strengthen links with their US counterparts to facilitate joint projects, exchange of students and professionals, and use of facilities such as laboratories, which will allow them to increase technology transfer and development of capabilities.

The plants established in Baja California have the opportunity to interact closely with corporate offices in California, and to consolidate capacities on the Mexican side through the transfer of knowledge between engineering groups of the two countries.

## **TECHNOLOGICAL CONVERGENCE**

The trend towards smart and connected devices, as well as a greater use of wearable technology, implies a technological convergence that is visualized towards the next decade between medical devices and electronics. Baja California has a great advantage in this aspect as it is the host of renowned companies in both the medical device industry and the electronics industry, so it is an opportunity to create a dynamic relationship between companies from both industries that generate synergies and projects that can capture the next technological trends.



# ACCES TO CUSTOMERS

## AND SUPPLIERS

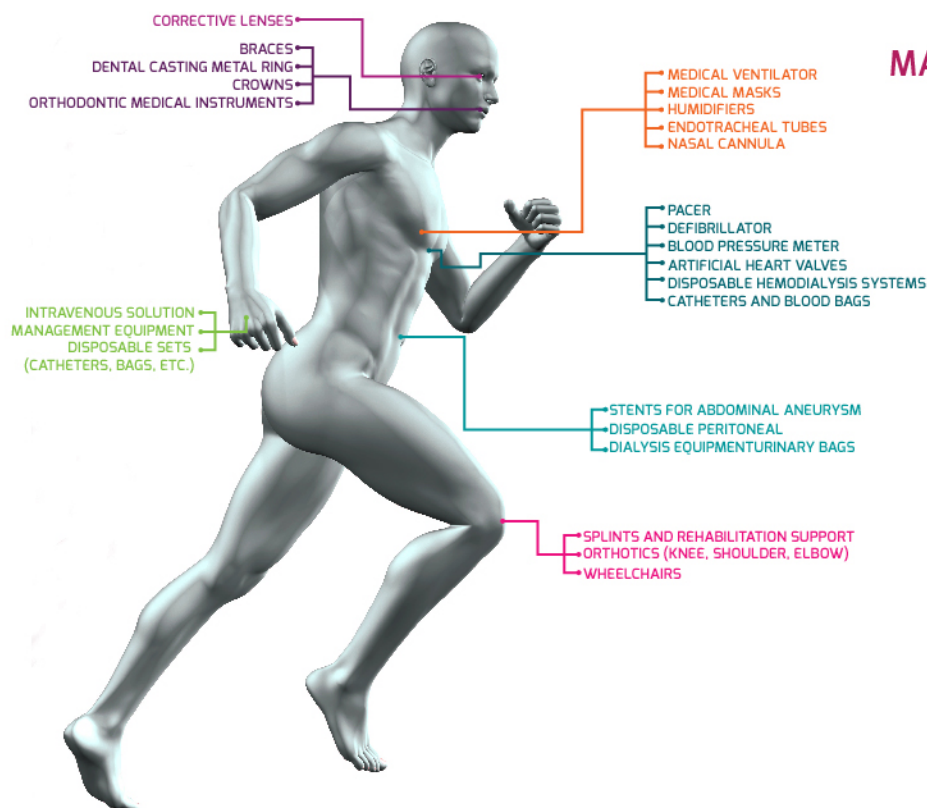
■ Tijuana is also only minutes from Downtown San Diego, and (with nearly 1.7 million residents) it's the second-largest city on the West Coast of North America.

- 2 border crossings
- CBX
- 3 international airports
- 1 binational airport terminal
- 2 specialized marine ports
- Rail links

■ The City of Tijuana is part of the Cali Baja Bi-National Mega-Region and because it's composed of San Diego, Imperial Valley and Baja California, it is home to more than 800+ companies operating in the biotech industry.

Over the past 5 years Tijuana Medical Device Industry has created over **71,000+** employees, reaching a growth of 10.6% in the sector.

## MEDICAL DEVICE MANUFACTURE IN BAJA CALIFORNIA



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## MANUFACTURING PLANTS

- PREGNANCY AND OVULATION DEVICES
- ELECTRONIC AND EAR THERMOMETERS
- SURGICAL TOOLS
- HEALING MATERIALS
- SYRINGES
- ANESTHESIA CIRCUITS
- PERSONAL PROTECTION FOR OPERATING ROOM
- FIRST AID KITS

- STERILIZATION METHODS:
  - ETO
  - E-BEAM



# TIJUANA EDC

Is a private non-profit organization dedicated to facilitating the soft landing of manufacturing operations in Tijuana, Mexico and the CaliBaja Mega-Region.

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International Economic Development Council