A medical devices cluster in Baja California-Mexico: a strategic proposal.

Rodolfo Rubio
Carl Zeiss Vision
Tijuana, Baja California. MEXICO

Mario A. Zurita-Barrón
IBM de México
Ciudad del Carmen, Campeche. MEXICO

Homero H. Contreras
Zelaya Consultores
Puebla, Pue. MÉXICO

Abstract

Mexico is developing and consolidating clusters in different industries. In particular, the medical industry is highlighting for its excellent quality in both products and services and its low cost compared with their counterparts in emerging economies. This research is focused on showing a strategic analysis centered on the Medical Device Cluster of Baja California, from its regional context to its international one, giving center stage to its contribution to the development of the medical industry in Mexico. The assessment tools used are those suggested by Michael Porter, and the results of these tools are presented along with strategic and tactical recommendations to further consolidate and develop the cluster itself as to provide the basis of a benchmarking for other clusters in the region.

Keywords
Cluster, medical devices, Baja California, strategy

1. Introduction

The cluster of the industry of medical devices in Baja California had its beginnings in 2003, after meetings among representatives of the medical manufacturing companies looking to review the common challenges and opportunities. The cluster consists of 67 manufacturers and designers of health care products, all working together with representatives of manufacturing companies, suppliers, educational institutions and economic development agencies. The main exported products of the sector were instruments and medical devices for surgical, dental or veterinary areas, which represented 78% of Mexico's exports of medical devices and to date has remained as the most important in Mexico. These exports account for more than 50% of the sector. Among the major inputs and needs of the sector are: components and plastic processes, electronic components and processes and raw materials, packaging and some other services. The demand is estimated at over one billion dollars.

2. Mexico and its environment

2.1 Mexico on the Economic and Financial Context

The country covers an area of 1,964,375 km$^2$ [1]. According to the International Monetary Fund (IMF), in 2009 Mexico ranked 32 in per capita income among 182 countries, and according to the study of global competitiveness from 2009 to 2012, prepared by the World Economic Forum, the country occupied the position 60 out of 133 countries. As for tax revenue as a percentage of GDP, in 2008 Mexico was in the lower position of the 30 members of the Organization for Economic Cooperation and Development (OECD). This represents that the country cannot
Rubio, Zurita and Contreras

attract the necessary resources for its proper operation. The World Bank, in its Doing Business 2010 study, places Mexico in the 106 position of the 183 countries surveyed in terms of the simplicity of the procedure for the payment of taxes by taxpayers. Regardless, the country continues to attract foreign capital, so it is among the top 10 countries with the highest preference in the confidence index of foreign direct investment in 2010 [2].

2.2. Human Development

Education plays a crucial role in human capital, because it is a key issue to expand and improve the opportunities of people in the labor market; encourages social mobility, and it is a major component of the competitiveness growth of nations [3]. Most of the population of Baja California is located along the international border line with the USA, representing about 90% of the population of the state. People hold a satisfactory level of life (HDI of 0.7717 - Very High), and because of the proximity to the United States, most of them speak English as a second language, which also provides another attractiveness to the State [4].

3. Theoretical framework

3.1 Strategy

Several authors have proposed definitions of strategy; for example, Liddell-Hart [5] consider strategy as the art of distribution and application of military ideas to achieve the objectives of a specific policy; Steiner [6] defines strategy as something made by the top-management that is of great importance for the organization; Tregoe and Zimmerman [7] consider strategy as the framework used to guide the options that define the nature and direction of any organization, and finally, Michael Porter [8] makes a deep meditation about the concept of strategy, emphasizing the competitiveness.

Porter’s concept of strategy [8] might be defined as achieving a unique and valuable position for the company, defining the trade-off that must be made and fitting all the activities within the company towards the strategy. He also suggests that any company must be focused on the strategic position and be different, choosing a specific set of activities to provide a unique value to its customers. He also encourages the use of a tool, named the Diamond, to evaluate the status of any industry and then, support the development of both a strategy and a cluster map.

3.2 Porter’s Diamond

Porter [9] suggests a diamond model which provides support in the definition of the advantages that any cluster should have. This model is based on four attributes:

- **Factor conditions**: Includes factors of production, such as skilled labor, infrastructure, natural resources, geographical position, capital resources, information, and scientific and technological infrastructure necessary to compete in a given industry. It is important to consider both the quality and specialization of these factors.
- **Demand conditions**: These factors are related to the nature of home-market demand for the industry’s product or service. Sophisticated and demanding local customers are a trigger to the cluster, and provide specialized segments that can be served globally.
- **Related and supporting industries**: The presence or absence of supplier industries and other related industries that are internationally competitive.
- **Firm strategy, structure, and rivalry**: Conditions related to how companies are created, organized and managed, as well as the nature of domestic rivalry. It is important the presence of a local context that encourages appropriate forms of investment and sustained upgrading, as well as vigorous competition among locally-based rivals.

3.3 Clusters and cases in Mexico

Porter [9] defined a cluster as “geographical concentrations of interconnected enterprises, specialized suppliers of services, enterprises from related sectors and networking institutions that compete, but also work together”. The creation of clusters promotes the development of a region, and there are successful examples of clusters in developing countries.

In the particular case of Mexico, some incipient clusters have been analyzed in both sophisticated and non-sophisticated industries. Contreras, Cabanas and Nuño [10] have studied a flower cluster in the central region of Mexico, a non-sophisticated cluster focused on ornamental horticulture. Furthermore, Contreras, Nuño, Santillana,
Rubio, Zurita and Contreras and Cabanas [11] developed a cluster map for the automotive industry in Puebla, Mexico, clearly a sophisticated sector. Both cases are still working in their consolidation, but have proven to be successful.

4. The Mexican Medical Device Industry

4.1 Text Sections and Headings

During the last decade, Mexico has become one of the leaders in the manufacturing and assembly of medical devices worldwide [12]. In Mexico, medical devices are classified according to the risk involved in their use. They can be considered as:

- Class I: Those inputs known in medical practice whose safety and efficiency are proven and are not generally introduced to the body.
- Class II: Those inputs known in medical practice that are generally introduced to the body, remaining there less than thirty days.
- Class III: Those inputs recently accepted in medical practice that are introduced to the body and remain there for more than thirty days. It is estimated that the sector's production in Mexico reached an amount of 8,562 million dollars in 2011.

According to Global Trade Atlas, in 2011 Mexico exported 6,072 million dollars, ranking as the eleventh exporter of medical devices globally, the biggest exporter in Latin America, and the main supplier to the United States. The main exported products were instruments and medical devices for surgical, dental or veterinary areas, which represented 78% of Mexico's exports of medical devices. In terms of global ranks, Mexico was the third largest world exporter of tabular metal needles and suture needles; the fifth exporter of instruments and appliances used in the medical, surgical, dental or veterinary areas; the sixth exporter of mechanical therapy devices, massage and psychotechnical devices; and the first exporter of wadding, gauze, and bandages in Latin America.

4.2 Established Companies in Mexico

There are 2,179 economic units specialized in medical devices in the country. In 2011, 744 companies reported exports, mainly located in the states of Baja California, Chihuahua, Coahuila, Federal District, State of Mexico and Jalisco. The most important cluster of this industry in the country is located in Baja California, whose companies represent more than 50% of the national total exports of the sector and are mostly related to the manufacturing and assembly of equipment and components [12]. In 2011, Mexico's public health sector received the largest budget in the history of the country, where the Mexican Institute of Social Security (IMSS), the Institute of Safety and Health for State Workers (ISSSTE) and the Ministry of Health received an annual increase of 10%, 12%, and 12.6%, respectively. Over 107 million Mexicans are enrolled in a health insurance programs funded by the state, an area in which the Mexican government has spent more than six billion dollars. Baja California hosts 440 medical units, 290 of those are public and 150 are private [13].

4.3 Global Competitive Landscape

KPMG Competitive Alternatives 2012 shows that Mexico offers 23.3% of cost savings in the manufacturing of medical instruments compared to the U.S., and that it is the country with the lowest costs compared with 9 other leading countries in the industry. In addition, Mexico offers cost advantages in areas such as plastics, metal components, and precision manufacturing. The global medical devices industry is relatively concentrated; with 15 companies representing 60% of global sales and 45 U.S. firms (e.g., J & J, GE, Medtronic, Baxter, and Covidien) lead the market [14].

Mexico's location allows considerable savings in terms of logistics and close supervision of the manufacturing process, relevant issues in export. It also facilitates the inspection of the facilities by the health authorities and enables a fast response to sudden changes in demand trends [13]. In the last ten years, the number of employees directly associated with the medical device industry has increased from 17,000 in 2002 to over 32,000 in 2011 only in Baja California. These figures are expected to increase as new companies such as Össur and Fisher & Paykel Healthcare start operations. The sector’s imports of about 1.5 billion show the potential to both develop local suppliers and attract traders from other countries to the area. Other states, such as Chihuahua, Mexico City, Jalisco, Sonora, Nuevo Leon, Coahuila, Tamaulipas and Mexico State play an important role in the manufacturing of medical devices; however, Baja California has over 45 years of experience in this industry. Production has grown due to an increased demand, which can be the result of multiple factors, including population growth [15].
5. Baja California’s Medical Devices Cluster

5.1 Cluster Background
The potential medical products cluster can be traced to 2003 after some meetings among representatives of the medical manufacturing companies looking to review the common challenges and opportunities. In addition to these works, Axis Intelligence Center Company was requested to conduct a study about Baja California with the participation of companies like Medtronic, DJ Orthopedics, Alaris Medical Systems and Termofisher, resulting in 2005 in the development of a strategic plan aimed at increasing the economic benefit and the level of industrial competitiveness of the cluster. Since 2004, this cluster has remained as the most important in the manufacturing of medical products in Mexico and its exports represent more than 50% of the industry, comprising 67 companies in the state. They all work together with representatives of manufacturers, suppliers, educational institutions and economic development agencies.

The medical industry in Baja California allocates 1,500 million annually for the purchase of parts and materials to develop clinical instruments. It includes 38,000 employees, who produce a significant amount of daily artifacts such as catheters, pipes, valves, respiratory products, plastic connectors, braces, and other equipment. Based on these figures, the border entity has the largest production dynamics of medical devices in Latin America.

Major product categories include:

- Large size equipment ($500K +) such as mechanic therapy equipment, grilles, and steel doors.
- Small / medium size equipment (<$500,000), such as medical assemblies and electronic products.
- Therapeutic devices, pacemakers, orthopedic implants, (pads, knee pads, elbow pads, girdles, immobilizers), ophthalmic lenses of plastic resins.
- High volume products, such as bandages, plastic supplies (sets to administer solutions, electrical circuits, feeding tubes, dialysis sets, hemodialysis, etc.), wheelchairs, chair backs, thermometers, catheters, urine bags, and others.

5.2 Links with Educational Institutions
Through linkage schemes, responsibility and synergy, there are cooperation agreements with educational institutions like CETYS University and the Autonomous University of Baja California, which provide an institutional commitment to promote the development process of the cluster. The focus is to achieve the established goals and take actions to advance the education and social development of the region.

5.3 Current situation
Some of the most important companies are Tyco Healthcare, Cardinal Health, Pall Life Sciences, Medtronic, Gambro, Medimexico, ICU Medical Inc., Hudson Aci, DJ Ortho, CLP, Sunrise Medical, North Safety Products, Augend, Brag, Lancer Orthodontics, I Flo, Masimo, and Carl Zeiss Vision. In 2010, the export value of the cluster was estimated at 2,030 million.

The year 2012 also faced the construction and setting of ebeam Avantti MediClear sterilizer in Tijuana, the first project of its kind and a trigger for the strategic development of the state in the medical industry. The incubation of the company (focused on providing sterilization services) is one of the main achievements through collaboration between the cluster and government agencies. The association has also set the expansion of the supply chain, the attraction of new investments, the development of the human capital required by the industry and new partnerships in the industry as strategic goals [17].

5.4 Organizational Structure
The Cluster of Medical Products in Baja California has an organizational structure shown in Figure 1. Organizational levels are run by managers from different companies members of the Cluster.
The positions are honorary and renewed every year, but there is a staff of three full-time members that were selected and contracted to lead the work plan, coordinate meetings, and facilitate the agenda of the various committees. It is intended that the representatives of the companies are the highest-level managers, but intermediate level managers are also considered. Government representatives and members of major IFC’s regularly participate in meetings and working groups. Considering that the cluster does not have enough facilities to carry out all its activities, the monthly meetings are alternated between the different companies who offer their support voluntarily.

6. Strategic analysis of the cluster
The proposed cluster is supported by an analysis based on the methodology suggested by Porter and his most relevant tools.

6.1 Porter’s Five Competitive Forces
The analysis of the five forces that can affect this industry are described below and presented in the Figure 2:
- The threat of new entrants is relatively weak because the industry is highly specialized and expertise is crucial; furthermore, there are strict regulations.
- The threat of substitute products has been identified as weak because even if there is availability of products, they are not certified and the formal market has strong regulations.
- The bargaining power of buyers is considered high, since the groups of buyers and distributors are strong due to purchase volume. Government contracts and army purchases are also considerable and dependent on the manufacturer of specialized products.
- The bargaining power of suppliers is also high because they also serve other companies and there are not enough of them. The supplier’s presence is locally limited and some of them are specialized, thus giving them even more bargaining power.
- The rivalry in the industry is moderate, because competition among the companies is weak and their products do not compete with each other.
There are positive issues in every element of the Porter’s Diamond that support the Cluster of Medical Products in Baja California. Figure 3 presents the framework of the diamond.

- **Factor conditions:** include trained personnel, low operating costs, excellent geographical location, capabilities and experience in world class manufacturing, as well as institutions to conduct research and development. However, a lack of specialized talent has been identified.
- **On demand conditions:** it was determined that the cluster has a sophisticated demand and strict legislation. All production is mainly for export and employment generation has grown 8.4% annually since 2004 due to

---

**Rubio, Zurita and Contreras**

**Figure 2: Porter’s Five Forces**

**Figure 3: Porter’s Diamond**
the fact that the sector is the least affected by the economic crisis. However, there is still pressure from state and local governments to reduce costs [18].

- The context for strategy and rivalry of firms is favorable because companies in the cluster are subsidiaries of multinationals operating as maquiladoras, have a good relationship with the unions, their products do not compete with each other and there is intellectual property protection through the free trade agreement with North America. However, the complexity and cost of doing business has increased.
- In related and support companies there are collaborative institutions (IFC) at state, national and international level. Nevertheless, there is a high dependency on the U.S. market and, therefore, city, state and federal governments have supported the growth of the cluster through programs such as IMMEX and NEEC, the program of customs and border protection CTPAT, and tax incentives for job creation.

6.3 Value Chain

One of the strategic objectives of the World Health Organization (WHO) Plan 2008-2013 is to assure improved access to medical products, including medical devices of good quality and user friendly, recognizing these devices as a means to provide health care and improve people’s health. The future of this industry is facing pressures of cost, quality and service delivery of multiple stakeholders so it should focus on all the stages of the life cycle of devices. It is also required to use knowledge, inventiveness and efforts to the pursuit of equitable use and cost effectiveness. The ability of companies and groups to respond to these trends will help to determine whether they will be able to maintain its current competitive position [14].

Lower-cost robotic systems will continue to be developed to be smaller. Synergy and miniaturization are the key principles of innovation in the design of medical devices. Another interdisciplinary technological trend is the convergence of different disciplines related to health care, such as life sciences, nanotechnology, cognitive science, technology information and materials science. However, large companies and transnational corporations operating in the areas of hospitals and health insurance plans may abuse and use their market power to take advantage of the lack of regulations, thus reflecting in higher costs, availability and quality of medical care [19].

Globalization of health services are triggered by the new opportunities of investment in the sector due to factors like the liberalization and deregulation and the general increase in demand for health services due to higher income levels and population age, thus making the sector attractive. The upward trend in production, sales, exports and investments is a reflection of the good position of the medical devices industry in Mexico. According to the National Institute of Statistics and Geography (INEGI) and ProMéxico, the medical device industry represented 8,560 million dollars in 2011 and is expected to increase to 14,910 million in 2020, with an estimated annual growth of 6.4 %, (above projections for North America or countries such as Germany, Japan and Switzerland) [13].

The analysis shows that the human resources issue is the most mature process of the value chain. However, operations is the weakest process, and some recommendations about this key issue are presented in section 8. Figure 4 shows the value chain diagram.

![Figure 4: Value Chain](image-url)
6.4 Cluster Map
The medical devices cluster comprises both supporting and related industries, customers and external entities (like IFCC and government). Figure 5 presents a graphical representation of the cluster.

![Cluster Map](image)

Figure 5: Cluster Map

The cluster serves several customers. Companies such as Medtronic, Welch Allyn, Greatbatch Medical, Care Fusion, and Carl Zeiss Vision are considered.

Supporting Industries are those providing services required by the cluster to perform its manufacturing operations, such as:
- Packaging & Shipping. Companies in charge of delivery of the devices to final destination.
- Plastic Injection Molding. Providing components to manufacturers of medical devices.
- Precision Metal working. A company providing specific components, such as dies.
- Contract Manufacturing. Outsourcing services, both permanent and seasonal.
- Quality Assessment & Control. Focused on the inspection of products and quality assurance.

Related Industries are those related to special, non-manufacturing services required by the cluster, such as:
- Business Services. Mostly focused on banking and financial products, provided by financial institutions, insurance companies and foreign-trade partners.
- Regulatory Services. The official regulations services of the state and federal government are mandatory. These services are provided by both private and public companies located in the state, and there is also direct contact with regulators approved by the FDA.
- Certifiers. It is desirable that all the companies must are certified to ISO standards, an there are plenty of authorized certification companies.
- Marketing. The cluster is promoted by state and federal government to increase the attractiveness of the industry.

Other elements are considered in the cluster, such as IFC, government and external factors.
- External Factors. The skilled and available labor force is a key element, as well as any issue related to the production cost, which represents up to 50% savings versus the USA companies.
- IFC. They contribute to the technological development of the cluster through the delivery, training and promotion of technologies that strengthen the whole production process.
Rubio, Zurita and Contreras

- Government. It provides policies to support the cluster, and one of its agencies, CONACYT, promotes and provides high quality educational and research programs.

7. Conclusions
The study concludes that the cluster is viable, considering:
- There is a critical mass of companies. Baja California encompasses 67 companies manufacturing medical products.
- There are several specific advantages. Costs and labor are competitive; excellent geographical location in relation to major customers in the United States; companies comply with current regulations of the US Food and Drug Administration (FDA); 90% of industrial facilities are certified to ISO standards, and the business has over 45 years of experience in the manufacture of medical products.

Porter considers that at least two conditions must be satisfied to consider a cluster viable to be developed and grow in the future. Therefore, the cluster is feasible.

7.1 Opportunities and Recommendations
Based on the previous studies, some opportunities are found, and recommendations based on them are depicted bellow in the Table 1:

<table>
<thead>
<tr>
<th>Area of Opportunity</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Find alternative markets besides USA.</td>
<td>1. Strengthen ties between the private sector and the Government. 2. Identify companies that are manufacturing in other states and send a group to visit these companies to attract their operations to BC. 3. Do benchmarking for process optimization. 4. Request support from the Government to strengthen the infrastructure, technology, networking and dissemination of the cluster.</td>
</tr>
<tr>
<td>B. Encourage the domestic market.</td>
<td>1. Assess the relevance of the studies that support the manufacturing sector and propose improvements to the studies plan ad hoc to the needs of the cluster. 2. Promote certification of graduates in the labor needs of companies in the cluster. 3. Adjust internships and professionals residences incorporating technology. 4. Promote cultural, scientific and technological exchange between higher education institutions and countries specialized in technologies. 5. Promote postgraduate scholarship (MS and PhD) endorsed by the National Council for Science and Technology (CONACYT). 6. Create jobs in exchange for research and technological support. 7. Linking professional residences to companies from the group.</td>
</tr>
<tr>
<td>C. Promote the incorporation of technological support programs and curricula with educational institutions in BC.</td>
<td>1. Generate research and technological development in order to improve production processes in companies in the Cluster. 2. Hold contests and award prizes to students and staff from the companies recognizing those committed to continuous improvement. 3. The cluster must register at least 5 companies in the IGNITUS initiative (model of incubator of new products or processes).</td>
</tr>
<tr>
<td>D. Request more cooperation with higher education institutions.</td>
<td>1. Seek investors among cluster members and the community of the state to install manufacturing plants deemed necessary.</td>
</tr>
<tr>
<td>E. Encourage greater liaison between local businesses and educational institutions to attract research and technological development.</td>
<td>1. Recommend the application of certification in environmental standards, with the aim that all start-ups have clean and healthy processes for sustainable development of the environment.</td>
</tr>
<tr>
<td>F. Promote the installation of plants for sterilization, clean rooms and automation.</td>
<td>1. Lean on universities or private companies to develop the official website in order to make it attractive.</td>
</tr>
<tr>
<td>G. Certify Cluster companies as socially responsible.</td>
<td>1. Promote the installation of plants for sterilization, clean rooms and automation.</td>
</tr>
<tr>
<td>H. Technological Marketing</td>
<td>1. Lean on universities or private companies to develop the official website in order to make it attractive.</td>
</tr>
</tbody>
</table>
Rubio, Zurita and Contreras

The recommendations can be summarized in three groups:

- **Strengthen relationships with educational institutions:** The model of collaboration with CETYS University has been operating for over 7 years and comprises several aspects shown in this set of specific recommendations. It is intended that the cluster formally expands this model to other institutions such as the Universidad Autónoma de Baja California, Tijuana Institute of Technology, Universidad Iberoamericana and the Technological University of Tijuana. Furthermore, the model can be strengthened by promoting access to training and certification processes in the regulations governing the sector for students.

- **Attracting companies to grow and strengthen the competitive position:** Starting with the website, the cluster can be supported by the before mentioned universities in areas like information systems and marketing, and even by external companies to improve it. Current content does not reflect the vision and objectives of the cluster in a proper manner.

- **Link the cluster with local institutions to attract research and technological development:** The Tijuana Economic Development Corporation (DEITAC for its acronym in Spanish) is probably the IFC that works most actively with some industries in Baja California. DEITAC has recently been promoting a program of innovation in order to link entrepreneurs with consultants to strengthen the development of projects with high technological or intellectual capital as well as facilitating access to risk capital and, finally, marketing the project. The program is being promoted under the name IGNITUS and offers the following services: Incubation Model, Knowledge Transfer Office and High Technology Incubator.

**References**