Designed in Mexico

Roadmap for the Medical Device Industry

MEXICO

MEANS OPPORTUNITY

Designed in Mexico

Roadmap for the Medical Device Industry

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1. Introduction

The Ministry of Economy (SE), the Boston Consulting Group and ProMéxico, in their study entitled "Diagnosis of Advantages and Limitations to the Attraction of Foreign Direct Investment to Mexico", pose the following questions: What are the sectors and subsectors with the highest competitiveness and economic impact? To which of these sectors should federal, state and municipal governments channel a significant part of their promotion and sector development efforts? Through this analysis, productive sectors and subsectors in which Mexico has competitive advantages compared to other countries were identified, with the goal of attracting investments. The combination of the health services and electronics sectors shows that the medical device sector is crucial due to its current high level of competitiveness and potential impact.

During the last decade, Mexico's medical device sector has experienced dynamic and sustained growth, resulting from the development of manufacturing capacities by leading companies, which have found the country to be a key partner for their investment and business strategies. Mexico has become the leading medical product supplier to the most important market in the world: the United States.

In this context, the challenge for Mexico is to turn this window of opportunity into an innovative environment with a high national added value; a sector of highly paid quality jobs, investment and talent attraction, which together generate competitiveness poles that are linked to international innovation networks. To achieve this, ambitious goals must be established with a focus on the country's abilities, as well as the understanding of the environment and challenges facing the sector so as to define strategies that will allow industry, academia and government to build platforms that project into the future.

A roadmap is a comprehensive planning tool that visually connects future goals with the actions and resources needed to achieve them. It also allows planning to be compared with the environment facing the decisions, technology evolution and milestones that may affect the route. A roadmap that focuses on innovation cannot be built in isolation; the leading players of the medical device sector in Mexico must

be invited to define the direction that industry, academia and government must take to make the sector one of Mexico's flagship industries, spilling out technological advantages, methodologies, strategic alliances, talent education and high added value opportunities.

The results are presented in a first map, a complete dynamic plan that gathers the opinions of sector leaders to collectively build their future, to define a project of great vision. By nature, a sector strategy is a process of continuous improvement, under perpetual assessment and that requires the convergence of all added value players. In that sense, it is an unfinished document that must be constantly updated and adapted; a starting point called "National Diagnosis."

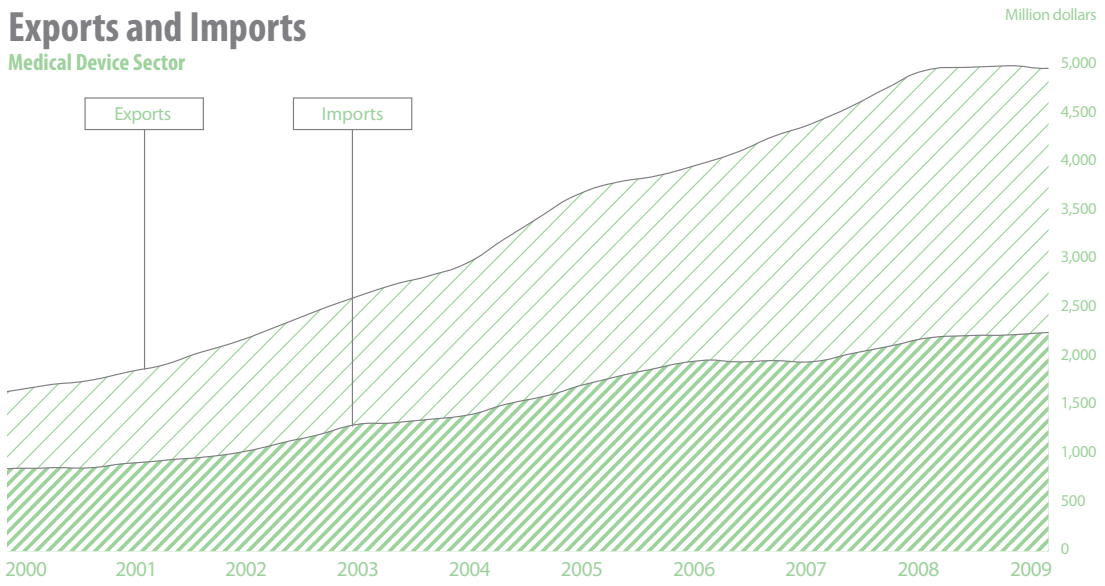

12,5x

2. General Diagnosis

2.1 The Medical Device Sector in Mexico

The medical device industry in Mexico comprises mainly small and medium businesses and, although it has proven to have a successful performance in manufacturing and assembly processes, is still relatively young. It has the potential to develop more advanced technology frameworks with a higher level of integration into the production chain.

In the last decade, Mexico has become one of the global leaders in medical device manufacturing and assembly. Mexico is currently the fifth medical device exporter in the world, the second largest market in Latin America and the leading supplier to the US –the largest market in the world.



Source: Global Trade Atlas (GTA) with information from the Ministry of Economy, 2009.

In 2010 the sector reported exports of 5.798 billion dollars and an average growth of 12% in the last five years.[1]

[1] GTA with information from the Ministry of Economy, 2010.

[2] "Americas Pharma & Healthcare" published by Business Monitor International.

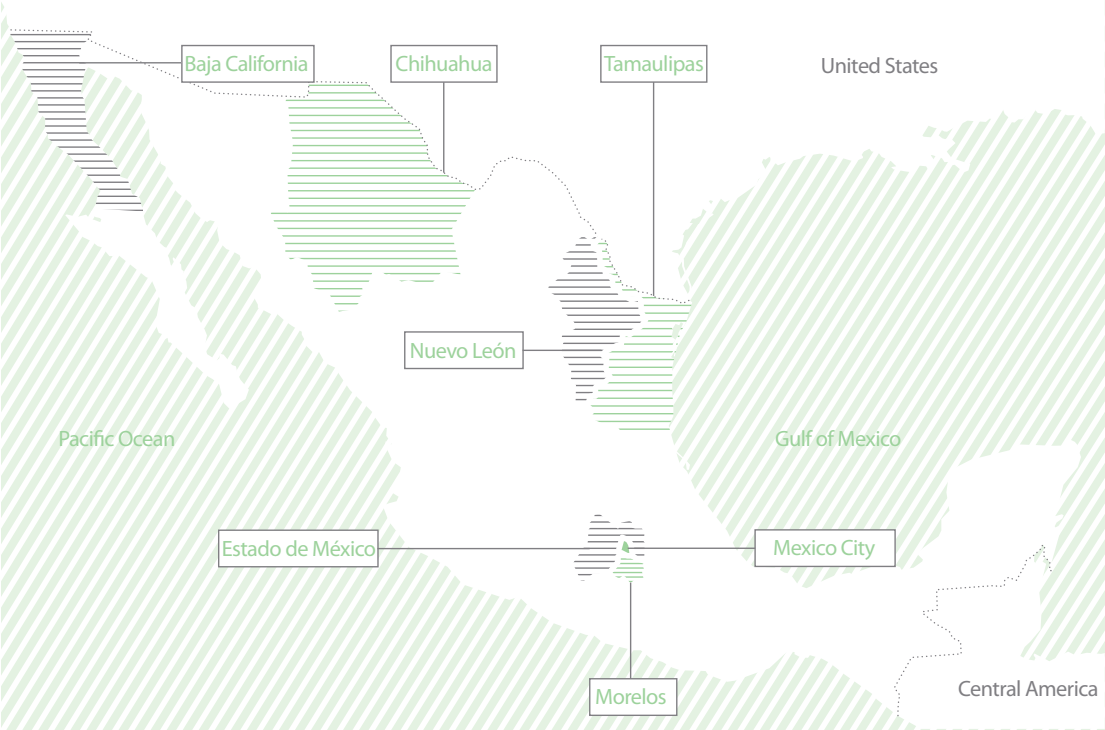
In 2008 the medical device market in Mexico reached a value of 2.31 billion dollars. It is expected that this market will reach a value of 3.72 billion dollars and grow at an average annual rate of 10% by 2013.[2] Some of the sector's leading companies globally are established in Mexico, such as: Beckton Dickinson, Johnson & Johnson and Medtronic, among others.

There are seven clusters for this sector in Mexico, which bring together around 130 companies. The Baja California cluster is the most important given that its companies represent more than 50% of the sector's total national exports. This cluster's main capabilities relate to equipment and component manufacturing and assembly, such as catheters, pipettes, valves, artificial respirators, nebulizers, connectors and orthopedic devices, among others.

In addition, there are manufacturing and design companies in the states of Chihuahua, Tamaulipas, Mexico City, Estado de México, Nuevo León and Morelos.

Medical Device Clusters in Mexico

Life Sciences, Medical and Surgical Equipment and Instruments Industry

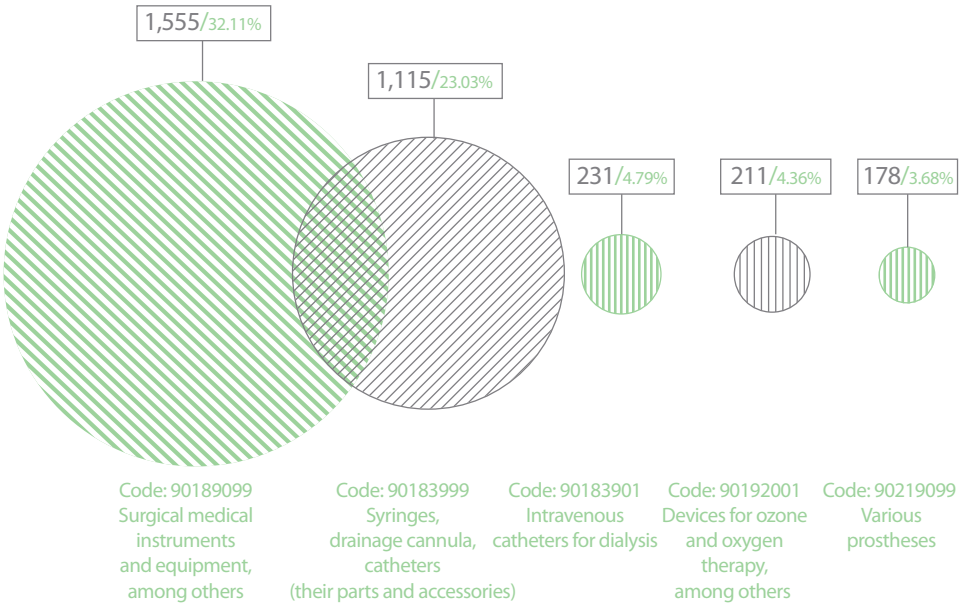


Source: Business Intelligence Unit (UIN), ProMéxico, 2008.

In 2008 the main Mexican products exported by the medical device sector were:

Exports

Main Mexican Products Exported by the Medical Device Sector in 2008
(Value in millions of dollars)



Source: GTA with information from the Ministry of Economy, 2008.

The products mentioned in the previous table represent 68% of Mexican exports by the medical device sector.

In Mexico this sector has unique characteristics compared to other manufactured goods, and it shares many of them with pharmaceutical products. Most notably:

- Medical devices are products with specific and strict regulations dictated by each country's health authorities (the Food and Drug Administration or FDA and the Federal Commission for Health Risks or COFEPRIS, among others). Typically, they must be periodically approved and undergo clinical tests to ascertain their efficacy.

- The industry requires particular manufacturing techniques (e.g., "clean-room standards" to guarantee their sterility) and very high quality standards. National and even foreign health authorities carry out inspections of manufacturing plants.

- This is an industry where intellectual property plays a predominant role and companies, therefore, allocate a large part of their income to research and development (R&D).

2.1.1 Medical Device Innovation in Mexico

Since the beginning of the 1920s, after the discovery of penicillin, research and development has been the driver for the success of the life sciences sector and innovation has been its pillar. The innovation process motivates companies to seek alternatives in low-cost manufacturing areas that simultaneously offer capabilities to develop innovative and market competitive processes.

The medical device sector is divided into two main segments. On one hand, there is the market of conventional products that have a low degree of innovation and simple processes, which is directly related to low profit margins and large sales volumes. On the other hand, there is the segment of high-tech products, which includes sophisticated devices designed specifically for therapeutic treatments and diagnosis. These relate to activities with high costs and risks, clinical trials, and administrative and regulatory procedures for their market launch. Products in this segment have a high growth potential and a high risk of becoming obsolete.

The segment of high-tech products is characterized by constant innovation and improvements that are based on science, technology and material availability. Product design is generally based on mechanics, electrics, engineering materials and biotechnology.

The global innovation center for this sector is located in California's Silicon Valley, where more than 50% of medical equipment manufacturing companies can also be found. As it relates to this region, it is noteworthy to mention the Medical Device Initiative (FUMMDI) implemented by the United States-Mexico Foundation for Science (FUMEC). Its main goal is to support product developers in Mexico and connect them through TechBA to companies and clusters abroad (such as Silicon Valley), where there are companies that need low-cost manufacturing. Tijuana, which is only a mile away from the California border, has become the main manufacturing center for medical devices in Mexico.

Although R&D investment in the life sciences sector in Mexico has grown, the investment quota is comparatively low in original research. Currently, Mexico has

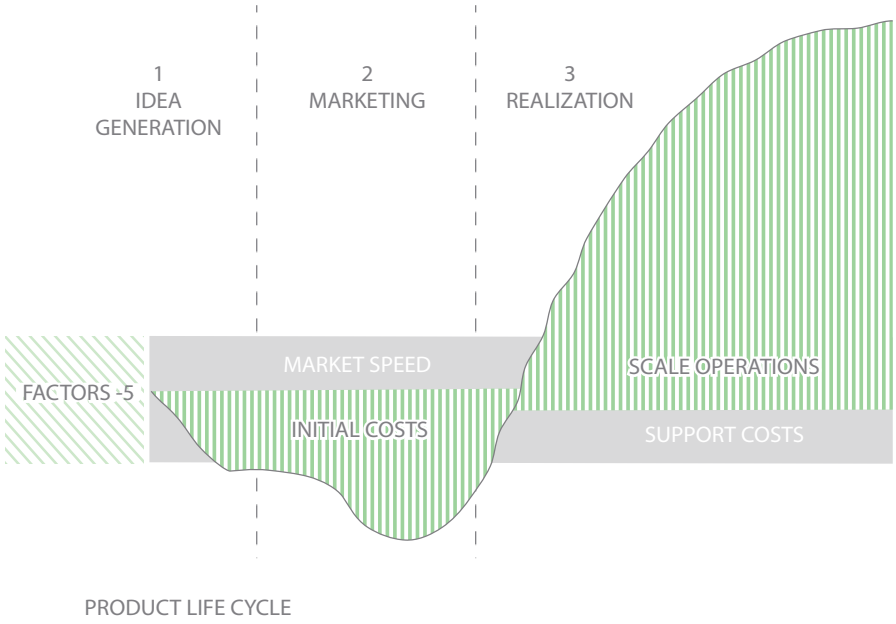
one professional researcher per 2,000 workers, compared to the Organisation for Economic Cooperation and Development's (OECD) average of 6.39.

In this area, resources are mainly invested in the primary product assembly process and not in R&D activities, which means that there will be more imports of new technologies that are not developed in the country. In addition, only a few companies established in Mexico perform R&D and innovation activities in the sector.

In some Mexican companies, R&D activities are surfacing in two areas: analytics (bioequivalence studies) and technology (related to product manufacturing).

The Money Curve

Main Mexican Products Exported by the Medical Device Sector in 2008
(Value in millions of dollars)



Source: Harvard Business School Press, "Payback: Reaping the Rewards of Innovation" by James P. Andrew and Harold L. Sirkin, 2007.

Medical device companies commonly have their own research centers where they do field work. However, they also hire research services from Mexican university institutes.

The main innovation projects in Mexico, which revolve around the medical device sector, focus on software; information technology and communications; hardware design and engineering for medical applications; and biotechnology. In this context,

centers and institutions such as the Monterrey Institute of Technology and Higher Education (ITESM), the National Institute of Astrophysics, Optics and Electronics (INAOE), the Autonomous University of Nuevo León (UANL), the Metropolitan Autonomous University (UAM) and the Center for Mathematics Research (CIMAT), are developing significant capabilities in device design and development for areas such as disease detection and diagnosis, as well as information systems in health institutions. Examples of such projects are:

- Technology for the automatic detection of leukemia based on the morphological image analysis of medullary bone developed by INAOE. This technology was transferred to the Mexican Social Security Institute (IMSS) and the State Workers' Social Security and Social Services Institute (ISSSTE).

- Microelectromechanical systems (MEMS) for telecommunications and biomedical applications developed by the ITESM.

- Microstructural influence on biocompatible surfaces in the tribological[3] behavior of surgical implants developed by UANL's Department of Mechanical and Electrical Engineering.

- New materials (mainly polymers) for biomedical applications, developed by the Center for Applied Chemical Research (CIQA) and Yucatán's Center for Scientific Research (CICY).

- Nanotechnology applications for medical needs, developed by the Center for Innovation, Research and Development in Engineering and Technology (CIIDIT) of the UANL.

- Technology for computer vision-assisted diagnosis of cervical cancer, developed by INAOE.

- Medical Imaging Laboratory, managed by the UAM in collaboration with the National Council on Science and Technology (CONACYT).

[3] Editor's note: Tribology (from the Greek *tribos*, which means to rub) is the science that studies friction, wear and lubrication that occurs when two solid surfaces in movement come into contact. The term has been universally used since the late 20th century.

2.2 Definition of Strategy and Scope

The effective integration of technological considerations into the strategy is key to business planning, especially when it is developed in a highly competitive technological environment, such as the medical device sector. In these sectors, a technological and innovative orientation is vital due to its strategic implications and its role in the generation of value and competitive advantages. These are very important factors, as are cost, complexity, changes in technology platforms, globalization of competitiveness and talent.

The essence of the business strategy and planning is directed towards the alignment of the industry's, academia's and government's activities and available resources, in order to create sustainable competitiveness in the market. This requires the full understanding of the nature of medium-and-long-term change in the business environment as it applies to opportunities and external threats, and the set of weaknesses and strengths of the industry and its environment. Technology impacts external and internal strategic aspects in terms of technology and innovation platforms and competitors' strength.

The TRM work group, which includes the industry's leading players, was established with the goal of defining a dynamic strategic vision that is aligned with the sector's various strategic milestones.

In that sense, the strategy's main lines of action in the medical device sector must focus on:

- National product design and integration.
- Incorporation to international networks.
- Foreign direct investment (FDI) and company attraction.
- International certification of Mexican design companies.
- Specialized talent management systems.
- Consolidation of specialty niches.
- Supplier development.

Leveraging and developing the following value premises and axes will support this strategy:

Intellectual Property

Mexico has a modern framework for intellectual property. Unlike China and other Asian countries, there are no requirements for technology transfer or association with local companies.

Costs

According to a study by AlixPartners, which calculated production costs to place several industrial products in the American market, Mexico stood at a level 25% below that observed in the United States, while savings in China were only six percent lower (Brazil and India also presented higher costs than Mexico). In turn, KPMG's "Competitive Alternatives" study (2010) pointed out that for medical device manufacturing projects, Mexico offers total costs that are 20.8% lower than those in the United States.

Location

Mexico's geographic location allows considerable savings in terms of logistics, enables close monitoring of the manufacturing process and facilitates plant inspections by health authorities. It is worth noting that just less than half of the American medical device companies are headquartered in California, which is why the largest medical equipment cluster in Mexico is located in Baja California. This cluster includes more than 60 companies and 30,000 workers. Furthermore, this proximity provides easy access to specialized services, such as "cleanroom" maintenance.

Supply Chain

Mexico has a wide world-class industrial base, particularly in the automotive and electric-electronic sectors. This guarantees the availability of experienced labor, local suppliers of key inputs (molding, plastic injection, metallic parts, etc.) and the basic industrial infrastructure required by the sector.

Human and Scientific Capital

The country has a vast pool of skilled workers. Every year, over 100,000 students graduate from engineering and technical programs. There are universities and research institutes related to this sector, such as the Institute of Biotechnology of the Universidad Nacional Autónoma de México (UNAM), as well as various universities that offer biomedical engineering courses.

3. Methodology

3.1 Technology Roadmap (TRM)

The TRM is a dynamic analysis tool to develop strategies based on innovation and technology. Companies, industries, geographic regions or countries use it to support their strategies. It involves the graphical representation of the main aspects of the strategy to be followed and the definition of milestones and the actions and resources needed through time for their implementation. The graphical representation offers a framework to respond to questions such as: Where is the industry now? Where does it want to go? What does it need to get there?

TRMs can take many forms; however, the most common is a graph through time (horizontal axis) of a set of activities (vertical axis) that are typically grouped into four large areas: market, product, technology and the relationship between them.

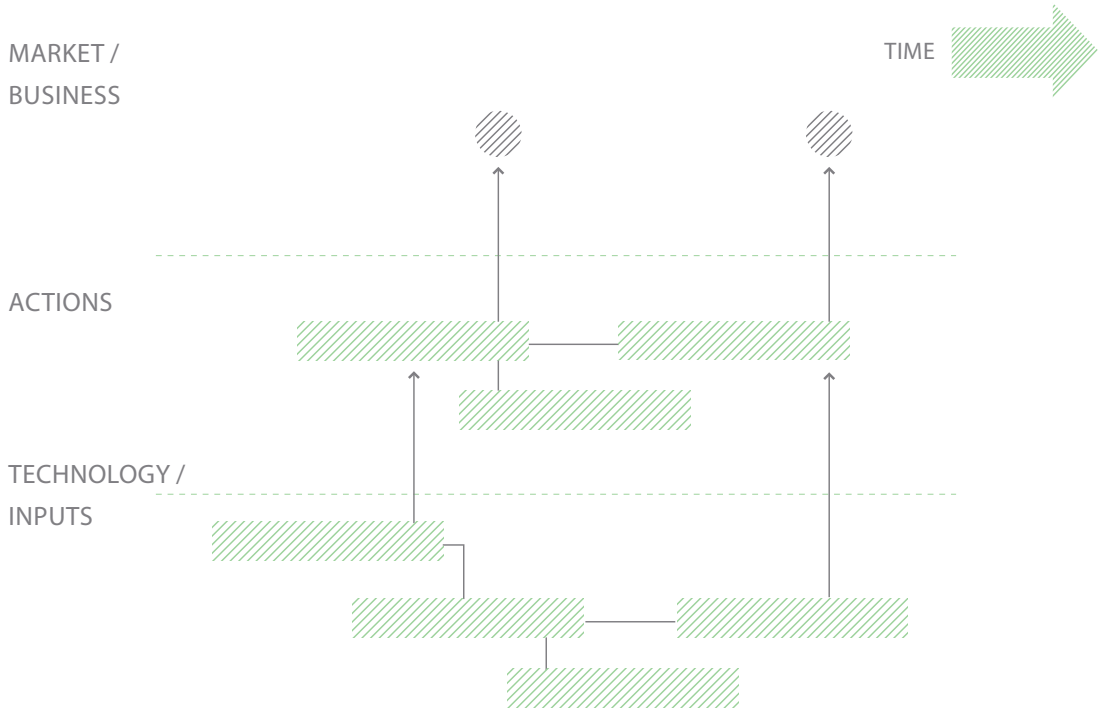
Planning horizons can be short term (less than one year), for sectors such as information technology, due to the speed with which changes occur. Given the complexity of the medical device industry, its horizon is usually medium-to-long-term; 10 years with intermediate horizons of three to five years and the immediate actions required to achieve them.

The graphical representation of the TRM is very effective in communicating the strategy to follow and reaching the defined vision and goals. The purpose of this process is not to predict the future, but to create an agreed or well-argued vision of the medium-and-long-term technological development, to identify the research lines and technology development that must be followed. Furthermore, it is important to note that a complete planning system is dynamic and current, and that it must adapt to changes in the environment and the players, a situation that requires the periodical and consensual revision of the plan.

As for the medical device TRM, a six-month planning horizon is foreseen, after which the confidence group must meet to tune and adjust the preliminary version of the map.

3.1.1 TRM Methodology

TRMs can have many forms, but they are generally presented based on the following figure:



Source: Cambridge University, "Fast Start-up Technology Roadmapping", 2009.

The upper part of the map shows the milestones and market goals, as well as important trends that must be taken into account in the analyzed sector. This is related to specific programs or technology developments that appear in the graphic representation of the map. In this way, services are linked to future products and market and/or business opportunities.

The process for creating the TRM depends on the dynamic participation of the leading industry players, which constitute the social capital that validates the planning.

3.1.2 TRM Process

The TRM process focuses mainly on three stages, as shown in the following figure:

Source: Greater Philadelphia Chamber of Commerce, "Connecting the Greater Philadelphia Innovation Economy", 2003.

Stage 1

Regional analysis of clusters' capabilities and opportunities

- Information from one-on-one interviews.
- Innovation inventory by universities.
- Recent information that considers federal, industry, jobs, salary concentration, risk capital, and other related topics.
- Inventory of technology programs aimed at workforce and capabilities.
- Identification of potential opportunity targets.

Stage 2

Design and implementation of the TRM

- Creation of a work group with 18 to 22 players from the industry, academia, the government and business leaders, to design the TRM appropriately.
- Leading the work group to identify and review windows of opportunity.
- Creation of a business plan, identifying project champions, resources and sustainable mechanisms to launch initiatives.

Stage 3

Launch of initiatives, sustainable implementation and performance/progress report

- Creation of a work group that joins federal, local and state efforts, as well as other critical resources for the launch to sustain regional innovation.
- Implementation of the roadmap for the analyzed sector.
- Ensure sustainability, pressure and resources to complete the efforts.

3.2 Cambridge University Approach

3.2.1 TRM Launch Process

The central element of the process is a set of meetings in which the industry's leading players actively participate: customers, suppliers, federal and state government entities, universities and research centers. Their participation is essential to define the scope of the TRM (vision and desired goals), as well as key aspects of the industry related to market, product and technology, in order to support the design and instrumentation of a common strategy and, therefore, increase the probability of success.

The fast-start approach to create a TRM seeks to facilitate its startup; establish the primary relationships between technological resources and business drivers; and identify the most important gaps in the market, product and technology dimensions.

The main goals of the launch process are to:

- Support the process of specific companies within the TRM.
- Establish key links between technological resources and business drivers.
- Identify important gaps in the market, products and technological intelligence.
- Develop a first cut of the TRM.
- Support the technological strategy and planning initiatives.
- Support communication between commercial and technical functions.

– Benefits of a roadmap –

The main benefits derive from the creation process, not from the TRM itself. By gathering the industry's leading players, they are given the opportunity to share their information and perspectives.

The largest benefit of this first TRM is the establishment of communication channels among the players and a common base to develop the industry's strategy.

The graphic representation of the TRM facilitates the analysis of the information obtained and synthesizes results from the meetings.

TRMs efficiently illustrate the road that the industry could follow from its current situation to the long-term vision and goals to be reached.

3.2.1.1 Launch Stages

Stage 1

Market Analysis

- Find and prioritize a set of markets.
- Outline the sector and business drivers.
- Analyze social, technological, economic and political-legal trends.

Stage 2

Sectors / Niches / Product

- Establish a set of sector niches that can satisfy the drivers identified in stage 1.
- Draw a bridge between milestones defined by the way the market evolves and sector and product niches that can satisfy these demands.

Stage 3

Technology and Technological Platforms

- Identify possible solutions and technology platforms that are aligned with the niches and markets, defining a second frame of analysis.

Stage 4

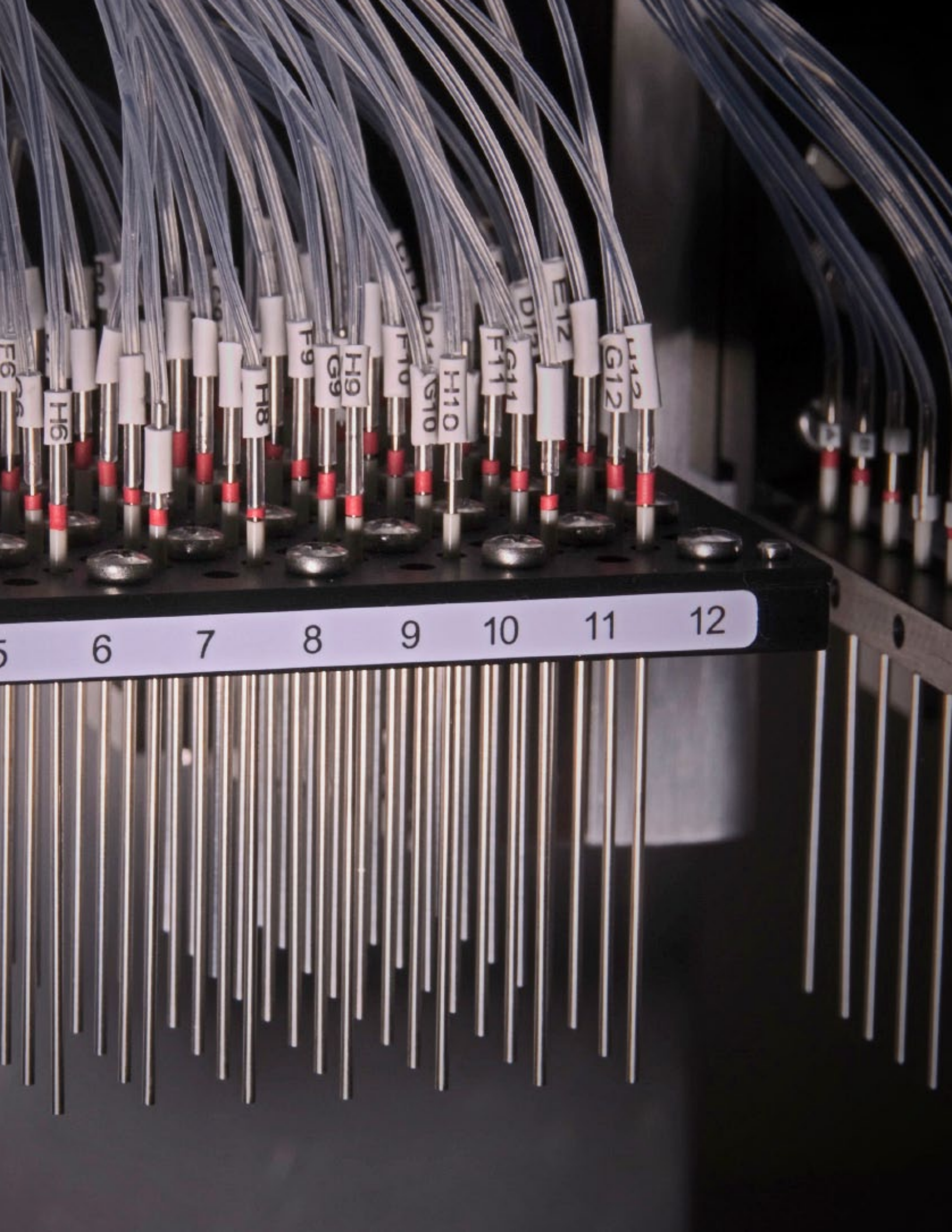
Mapping

- Trace the technology and marketing lines to produce the first TRM.
- Define the format of the TRM in terms of time scale, levels and strategy for sector products and niches, considering the following: identification of main milestones, outlining of the product's and technological programs' evolution and primary market drivers.

Stage 5

Implementation

- Identify gaps in terms of market, product, sector niches and technology knowledge as a whole.
- Evaluation of the best implementation of the TRM in the industry.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4. Stages of the TRM of the Medical Device Industry in Mexico

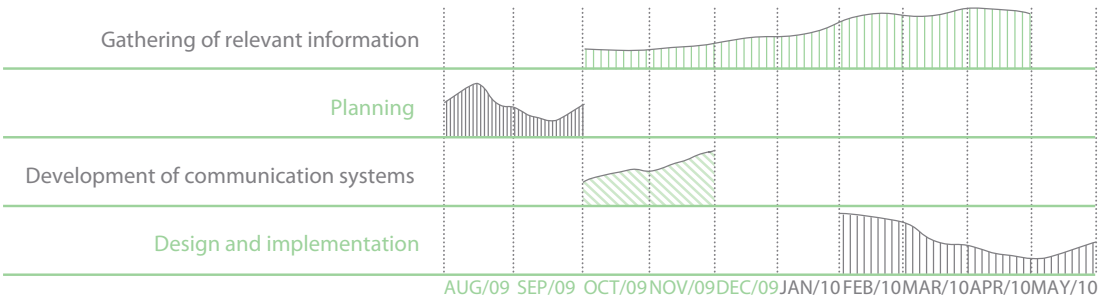
Based on Cambridge University's aforementioned approach, the work group established the stages needed to create the Medical Device TRM, which will focus initially on general tactics to develop the sector in Mexico and will therefore have the scope of a tactical roadmap. The work was divided into four main stages: planning, development of communication systems, gathering of relevant information and design and implementation.

4.1 Planning

The TRM planning stage covered defining its goal, scope and focus. In addition, a work group was created with the main players from government, industry, chambers, academies, research centers and other entities needed to properly approach the subject. Representing academia were the Mexican Association of Applied Research and Technological Development Directors (ADIAT); the Pan-American Research and Innovation Center (CEPii); ITESM; FUMEC and the Pan-American University (UP). Representing the industry were the National Chamber for the Transformation Industry (CANACINTRA) and the Baja California Cluster, while the Ministry of Economy, ProMéxico and CONACYT represented the government.

In order to achieve an organized management, a calendar of sessions was defined for the work group with specific goals:

TRM Schedule



Source: UIN, ProMéxico, 2009.

4.2 Development of Communication Systems

During this stage, a communication system was developed using a SharePoint-type platform where players accessed the various efforts carried out by each industry participant. This virtual library contains defining documents that epitomize the industry and individual projects carried out by participating entities.

Creating a common platform for industry players to communicate with each other is one of the main goals of the project because it is a way to direct and join efforts to find synergies and common goals. The first stage of integration depends on each party's knowledge and encourages the shared use of information and collaboration to produce documents.

4.3 Gathering of Relevant Information

During this stage, the members of the work group exchanged both defining and informative documents on the projects on which they have worked. These documents covered various topics, as shown in the following table:

National Studies on the Industry

- Producen (2009) Collaboration between the government and private sector.
- Boston Consulting Group (2009) Strategy to promote investment and transfer of operations to Mexico.
- Datamonitor (2008) Market profile for bone marrow implants in Mexico.
- Producen (2005) Medical product cluster in Baja California.
- Producen (2007) Update of the program to develop the medical product cluster for the Californias.
- ProMéxico (2010) Promotional brochure for the life sciences industry.
- ProMéxico Business Intelligence Unit (2009) Links to the leading companies in the Mexican medical device sector.
- San Diego Dialogue (2005) Innovation without borders.

International Studies on the Industry

- HEC Montreal (2007) Medical device sector in the northeastern region.
- Centre for the Promotion of Imports from Developing Countries (CBI) (2009) The medical device and disposables market in Germany.
- Economy and Trade Office of the Spanish Embassy in Berlin (2004) The medical equipment market in Germany.
- Government of Canada (2009) Invest in Canada - Medical Devices.
- KPMG (2009) Competitive Alternatives: Guide to International Business Location.
- Deloitte Consulting and the BioBusiness Alliance of Minnesota (2009) Destination 2025 - focus on the medical device sector.
- Datamonitor (2009) Profile of the global healthcare, equipment and inputs industry.
- Export Promotion and Investment Attraction Office of the Business Hub in Switzerland (2009) The American medical device market, opportunities and challenges for Swiss companies.
- Association Agreement between Central America and the European Union (2007) Definition of the medical equipment sector.
- Deloitte Consulting (2007) The future of the life sciences industry 2015.
- National Research Council Canada (2010) The medical device sector in Canada.
- National Research Council Canada (2009) Profile of the medical device sector in Canada.

Legal Framework and Industrial Directory

- World Health Organization (WHO) (2003) Regulations for the global medical device sector.
- CANACINTRA (2005-2009) Statistics for the medical device sector.
- Axis Business Intelligence Center Directory of the medical device industry in Baja California.
- Producen (2007) Directory of medical device products.
- Producen (2008) Directory of the medical equipment industry.

Methodology

- Cambridge Methodology for the creation of an aerospace TRM (2010).
- TRM for the United Kingdom's aerospace industry (2009).
- TRMs in Canada (2009) Development guide.
- National Research Council Canada (2001) Medical imaging device TRM.

4.4 Design and Implementation

The TRM design and implementation stage was divided into several workshops in which members of the work group discussed relevant topics to create it. This led to workshops on markets, products and subsectors, technology platforms, and R&D and talent inputs.

4.4.1 Market Workshop

During this workshop, the members of the work group performed a SWOT analysis. In addition, they studied competitors, partners, market segments, sector drivers and performance measurements related to the industry.

4.4.2 Product and Subsector Workshop

This covered the study and analysis of basic concepts, market matrices and product and sector strategies.

4.4.3 Technology Platform Workshop

This workshop included discussions on topics related to technological solutions for the sector, classification of technology areas and a matrix of the areas and their main attributes.

4.4.4 R&D and Talent Input Workshop

The workshop covered the grouping of R&D areas and a matrix of the areas that focus on R&D and the existing technology for these.

With the information gathered and discussed during the various workshops, the work group began to establish a first approach to the TRM, where variables obtained became the main input for this draft. Similarly, this first cut of the TRM integrated market factors (drivers, trends, triggers, strategic milestones, legislative events and activities of the competition) and key resources (talent, knowledge, alliances, investment and matters to discuss).

The final stage of the TRM required an analysis process where the various players that constituted the national strategy could validate the information obtained. Once this was done, it was crucial to identify "champions" for each project to help develop a mechanism to sustain initiatives.

To summarize, specifying and underlining the dynamic nature of a TRM is essential, since initiatives and conclusions are changing in conjunction with both internal and external aspects. In addition, it must be recognized that team work and information exchange make the strategy an extremely valuable tool for the industry that will help align the individual efforts of each of the sector's players in a way that leads the industry to development and evolution.

5. Innovation Economy

5.1 Innovation Life Cycle

The international financial consulting firm, New Economic Strategies (NES), states that the concept of innovation is not based solely on the adoption and development of new technological tools, but rather on a concept that must include new governing models, innovative team work schemes and the innovative use of technology that enable new challenges to be addressed and new opportunities to be exploited to achieve a continuous working model. The appearance of this new model -of a knowledge-based society- has turned innovation and talent resources into the new capital of countries and companies, even more strategic than economic resources. This transformation is only the gateway to a more complex and dynamic society that is driven by talent and intellectual capital: a social network based on knowledge.[4]

[4] UIN, ProMéxico, "Digital Creative City. Business Plan", 2009.

"Corporations are defining their value more in terms of intangibles - the creativity of their designers, the proficiency of their software architects, the knowledge of their marketers, the strength of their internal organization or culture, and their links with external partners. These are the assets, which are recognized on a global basis, in the search for efficiency gains. Pooling technology and know-how is currently more important than the combination of plant and equipment or the construction of new facilities. To extend their reach, firms are buying access to brand names and specialized niche markets. The "dematerialization" of much economic activity underlies the new patterns of globalization."[5]

[5] Organisation for Economic Co-operation and Development (OECD), "New Patterns of Industrial Globalization", 2001.

In this new society of multiple connections and sustainable development, the level of competitiveness is defined by the capacity to integrate various players in a synergistic system that promotes innovation and continuous learning. This new environment poses new challenges and opportunities for companies, higher education and research institutions, business support organizations and government.

From a market standpoint, this network economy shifts the perspective of competition and competitiveness from a local company vs. company vision to a global vision of trade block vs. trade block.

The reference point is no longer the regional or local leader. Companies must compare themselves to global leaders more frequently and penetrate deeper into the markets that were once considered exclusive to local or national suppliers.

Transnational companies invest millions in understanding local markets and adapt their products and services to the needs of countries and regions, at times to small groups and even individuals. This combination of global vision and local actions allows them to see themselves as part of a wide and global market with the flexibility to act based on local needs: "Glocal".

And while these transnational companies penetrate deeper and deeper into economies that were traditionally out of their reach, local companies with their short-reach and short-term vision lose competitiveness and the local business ecology vanishes due to a simple Darwinian matter of survival of the fittest.

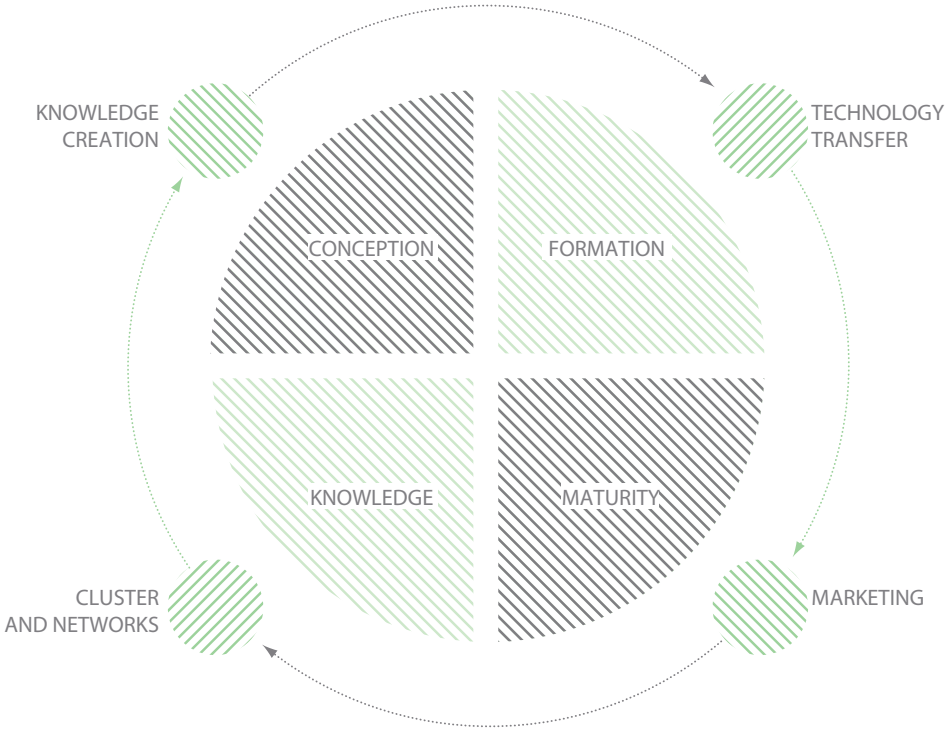
Thus, we must define a strategy that promotes and improves competitiveness among Mexican companies to strengthen the national economy and the sustainable social development of our country. We believe that this strategy must focus on: increasing the systemic competitiveness of businesses; on productive articulation and teamwork; on the development of business communities that pursue goals of great vision and that promote the creation of a new generation of "glocal" Mexican entrepreneurs.

5.2 The Importance of Innovation

Innovation is currently a critical concept for any industry, especially those in which technology is crucial. The medical device industry is one of them.

Science and technology require leadership and an action plan driven towards achieving goals that result in innovation. For innovation to be an effective concept and a useful tool, it must complete a multiple stage cycle in which leadership is effectively transmitted from one stage to the next, otherwise, the process may be interrupted at any stage and pose the risk of not achieving the goal of innovation.

The Innovation Cycle



Source: Greater Philadelphia Chamber of Commerce, "Connecting the Greater Philadelphia Innovation Economy", 2003.

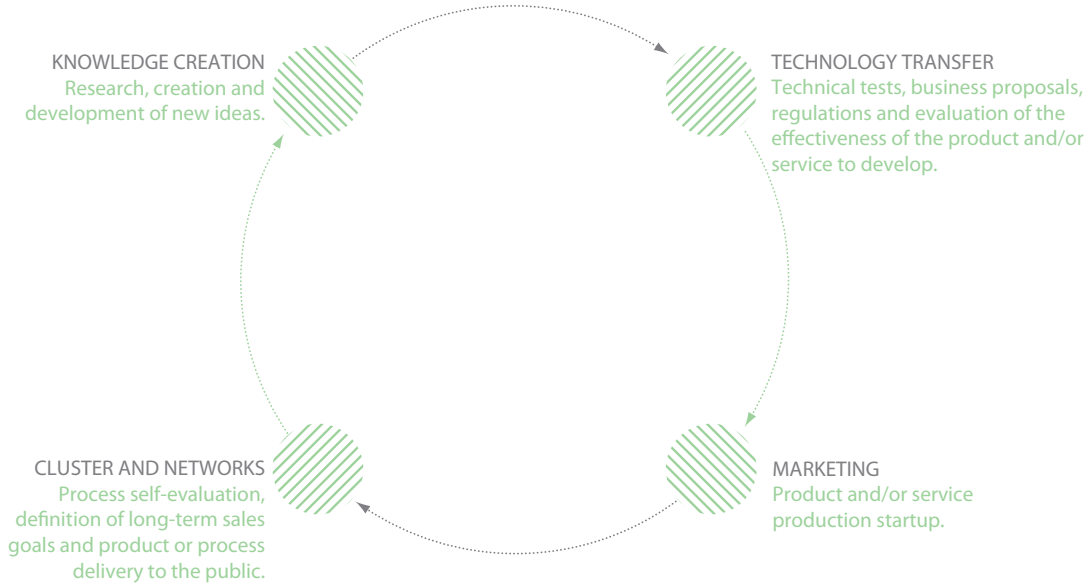
The purpose of the innovation cycle is its continuity; it must self-generate and every repetition must result in an innovative process, product or service.

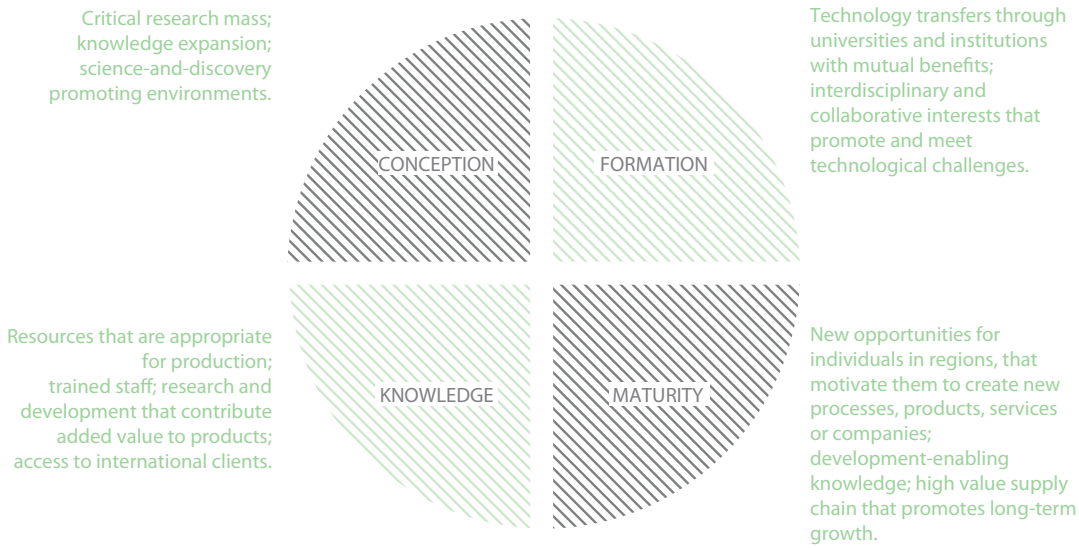
A large part of the success of an industry relies on the connectivity of its individuals, which results from the ability to transform economic, political and social relations to a regional or global scale, giving the industry a longer projection. This is achieved through effective transmission from one stage of the innovation cycle to another.

For the cycle to be complete, each stage must have the following ingredients: intellectual, human, economic and social capital, as well as connectivity.

These ingredients are crucial for the development of the innovation cycle; however, each one has its own significance that must be evaluated individually to determine whether its capabilities should be improved and so increase its contribution to the innovation cycle.

Stages of the Innovation Cycle





6. TRM Work Group

6.1 Data Gathering, Analysis and Scope of Studies

The work group gathered data and performed the analyses required to develop a joint strategy to learn about the current situation of Mexico's medical device industry and establish short-and-long-term strategies and way forward.

This was performed using a collaborative working system, which enables the opinions of work group participants to be obtained simultaneously since each person has a keyboard connected to the central computer. The advantage of this system is that it is able to receive anonymous arguments and, therefore, does not inhibit the players and creates a platform of uncensored trust.

6.2 SWOT

Aiming to learn about the current situation of the medical device industry, a SWOT analysis was carried out to diagnose and make the proper decisions for the sector.

*See table in page 40

6.3 Allies and Competitors

For analysis purposes, the participants defined the clusters or networks that could be identified as allies and competitors, to help create collaboration opportunities and competitive evaluation mechanisms. This definition is more of an analysis tool rather than a model to position the country among other economies and countries.

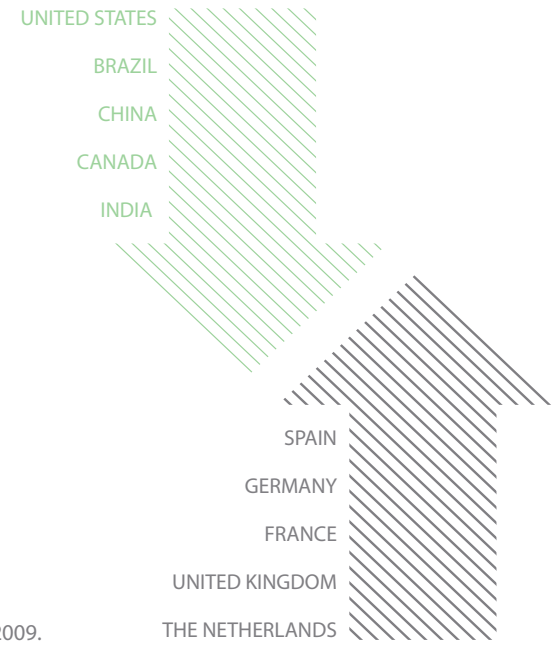
SWOT Analysis

Threats | Opportunities | Weaknesses | Strengths

- Development and leverage of new technologies
- Leverage of international relations
- Human resources
- Mexican talent capacity
- Growing market
- Increasing demand
- Lack of supply
- Market expansion
- Ability to transfer knowledge and technology from other sectors
- Competing countries
- Cartel oligopolies
- Insecurity in the country
- Geographic location
- Competitive costs and quality
- Non-tariff legislation
- Free trade agreements
- Dynamism in the sector's exports
- Production capacity
- Human resources
- Lack of joint vision
- Lack of investment in R&D
- Lack of innovation
- Lack of specialists
- Lack of knowledge of the industry
- Lack of support for new projects
- Lack of knowledge of the composition, subsectors and players
- Lack of information sources
- Lack of leverage of existing talent
- Low national added value
- Lack of industrial policy
- Lack of access to financing
- Long response times from regulating authorities
- Lack of professionalization of Mexican SMBs
- Asymmetrical logistics costs
- Comparatively high time to market
- Lack of a wide talent and skills management system

Source: UIN, ProMéxico, "Focus Group Session Results", 2009.

Allied clusters and competitors



Source: UIN, ProMéxico, "Focus Group Session Results", 2009.

6.4 Definition of Strategic Milestones

The analysis of national clusters and their capabilities identified the need for deeper analysis. The main strategic milestones were established on which the medical device industry must focus on in the coming years. As a result, the following strategic milestones were identified:

Short Term

- 2012. There is a federal fund in Mexico for R&D and innovation grant programs and funding and to finance the development stages of medical devices or their lines.
- 2013. Mexico joins six of the leading medical device innovation networks (two national and four international) in the Americas, South America, the European Union and Asia.

Medium Term

- 2015. Twenty-five of the leading companies in the sector globally have

manufacturing alliances with Mexican companies and make two percent investments in R&D and innovation.

- 2015. Industry and academia join efforts to help Mexican designers of electrical and biomedical equipment and software obtain national certifications in accordance with international standards (ISO 14000, FDA[6] and CE[7]).
- 2015. The integration of several sectors is consolidated through a central R&D and innovation network for the sector, which groups 7 AERIS[8] to increase medical device competitiveness under the guidance of CONACYT.
- 2015. Mexico has a specialized talent management system (IT, Software, Imaging) for the sector, which integrates academia with the industry.
- 2015. Mexico has two medical device clusters that are interested in FDI, which are internationally renowned for their innovative development and advanced manufacturing.
- 2015. Increases in exports and the Supplier Development program established in Mexico (FDI and national investment), determine the creation of 2,500 new jobs (with higher wages than the national high mean) per cluster.

[6] Editor's note: Food and Drug Administration (FDA).

[7] Editor's note: The CE certification is the manufacturer's guarantee that the product fulfills the requirements of every relevant European guideline.

[8] Editor's note: AERIS is the Spanish acronym for Strategic Alliances and Innovation Networks for Competitiveness.

Long Term

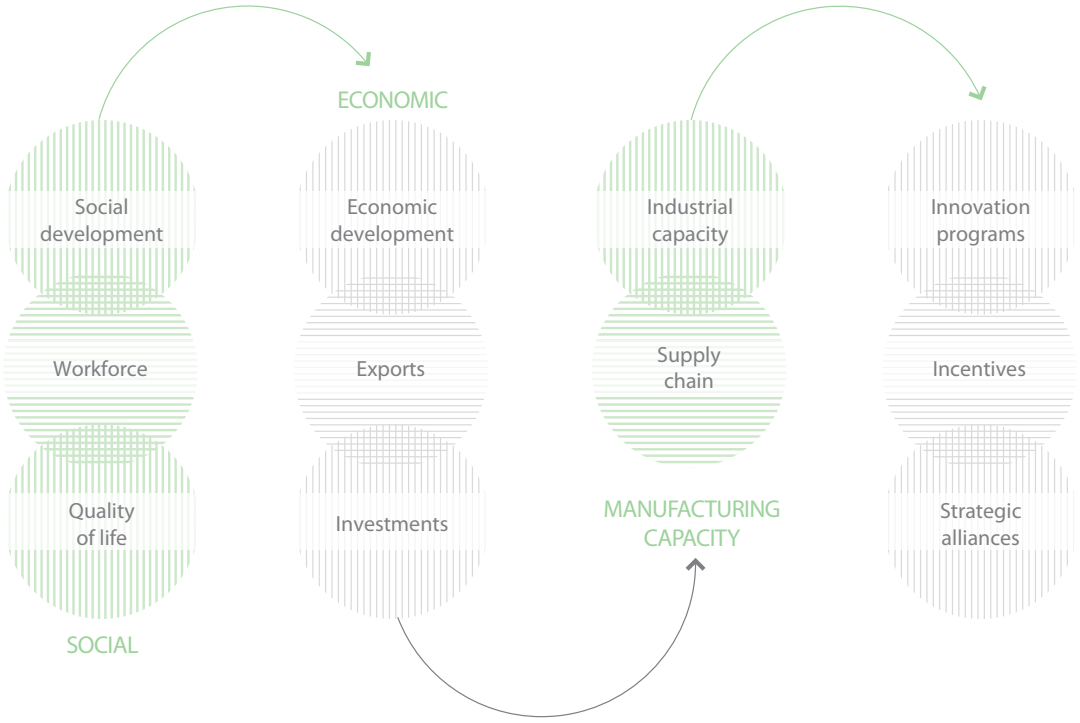
- 2020. The national industry designs, develops and manufactures medical devices that are registered in Mexico, with at least 49% of national integration and recently developed Mexican technologies, with an export value of one billion dollars.
- 2020. Through a Supplier Development program, national internal consumption increases by 10%, particularly by Public Health Institutions (IPS) such as the IMSS and ISSSTE, among others.

6.5 Performance Variables

Performance variables are used to evaluate the regional evolution and development of the sector by defining performance criteria in areas of economic, social, manufacturing and innovation impact. This allows technological and innovation goals to be related to strategies for the sustainable development of regions. A comprehensive plan must be beneficial for both the region and the country.

It was agreed to determine the main performance variables for the defined clusters, so that the plan would take into account the correct measurement of each region's sustainable development.

Performance Variables and Regional Development of the Sector

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7. Technology Insertion Roadmap

7.1 TRM

The TRM is the result of analyzing the medical device industry on both a global and national scale over a 15-year period, beginning in 2004 and projected until 2019. It comprises four sections: trends and drivers, technology platforms, critical success factors and resources.

7.1.1 Trends and Drivers

This section introduces the main trends and drivers of the global medical device industry, which provide a general overview of the various market drivers and trends that must be taken into account to define future lines of development.

Social

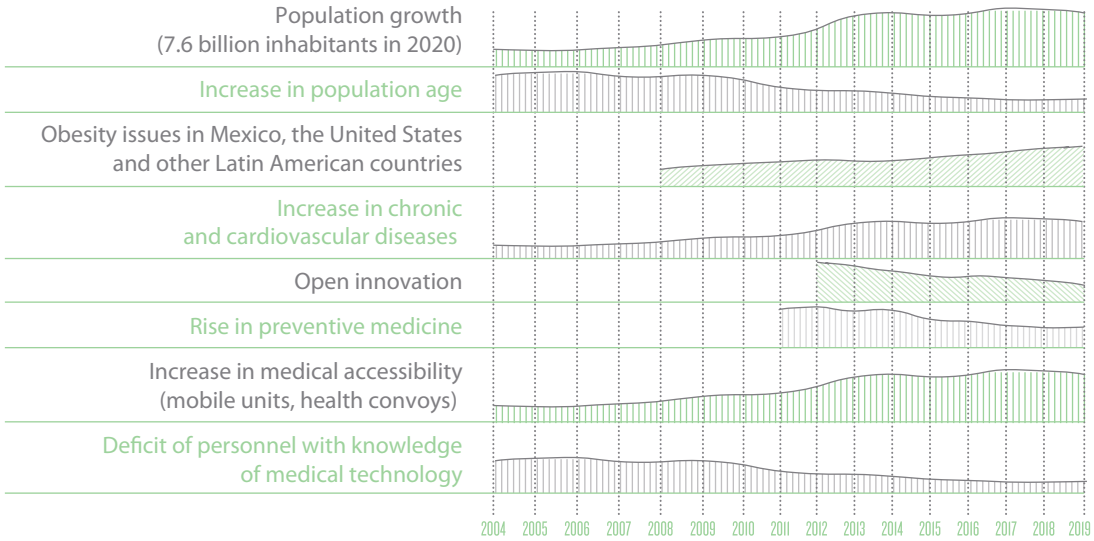
The main social trends that will arise in the following years are population increase and aging. The increase in age of the global population will result in a rise in chronic degenerative diseases (mainly in North America and Europe), so that preventive medicine will become a more common alternative for health care. Innovation will play a crucial role in the sector, allowing convergences between medicine and new technologies in the areas of biotechnology, mechatronics and electronics, among others, to increase access to health services and medical devices for a larger percentage of the population, resulting in an increased demand for these services.

Another important window of opportunity for Mexico is the foreseen scarcity of engineers and technicians in the leading developed countries (mainly the United States and Canada), as well as the significant student population growth in engineering and technology programs in Mexico.[9] If this opportunity, which will peak in 2013, is seized, Mexico will have a competitive advantage not only in terms of manufacturing costs but in innovation and design. Various analysts show that this scarcity will also increase due to the

[9] Businessweek and the National Association of Universities and Higher Education Institutions (ANUIES).

fact that technical professionals in the industry are mainly "baby boomers" who are in the process of retiring and there are insufficient replacements. For Mexico, this window will mean specific actions to strengthen the quality of graduates, adapt programs to industry needs and placing special emphasis on the negotiation of the North American Free Trade Agreement's (NAFTA) mobility programs.

Social Trends for the Sector on a Global Level

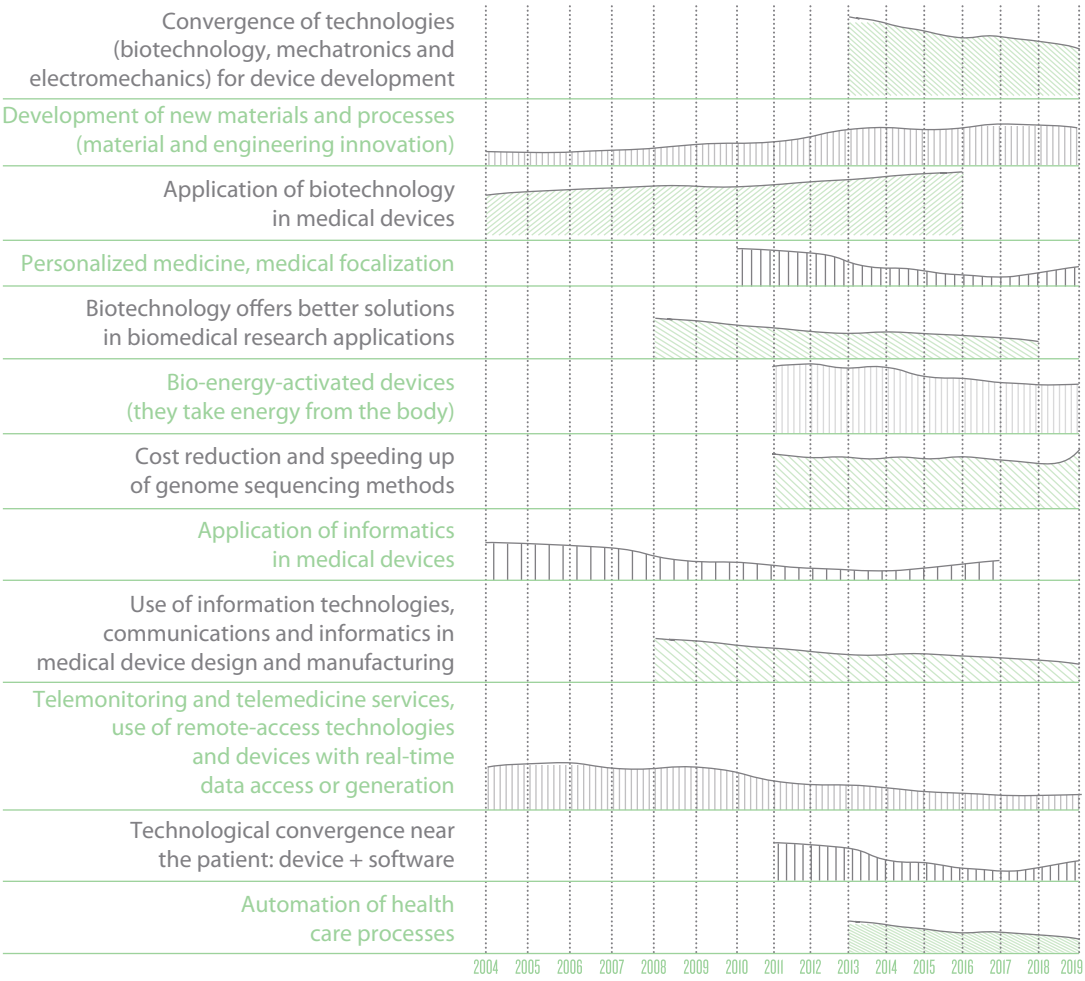


Source: UIN, ProMéxico, 2010.

Technological

In the technology field, the main trends relate to the production of medical devices using new processes and materials. Similarly, the application of information technologies and computer systems will result in the production of medical devices with the ability to give medical diagnoses through real-time information and the automation of health care processes. Therefore, methods such as telemedicine and focalized medicine will become more accessible. Furthermore, biotechnology-and-nanotechnology-related applications will drive the manufacture of smaller devices, less invasive treatments and devices that generate power by capturing the energy of the human body.

Technological Trends of the Sector on a Global Level



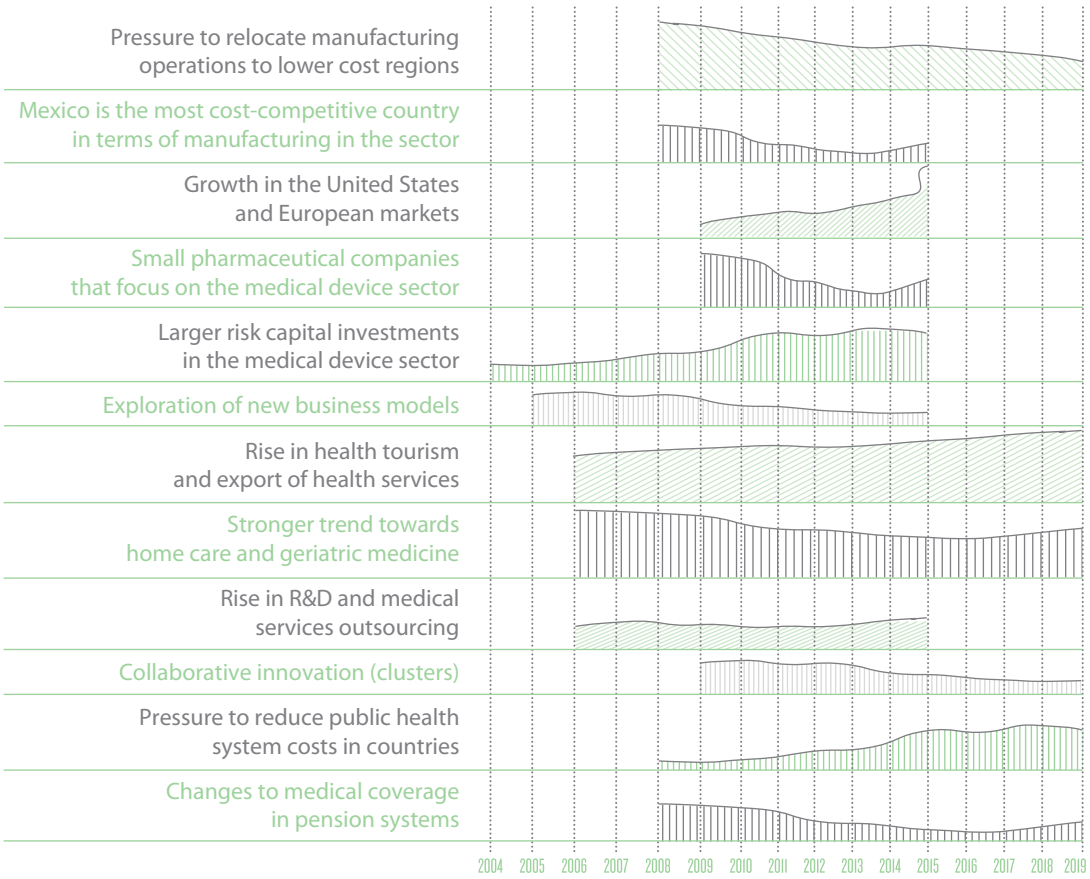
Source: UIN, ProMéxico, 2010.

Economic

Economic trends pose important challenges and incomparable windows of opportunity. Undoubtedly, the global crisis will force leading companies in the sector to reconsider their positioning strategy, especially in terms of manufacturing. This situation is both an opportunity and a risk. The rise of new low-cost regions implies the need to understand and strengthen our competitive advantages, and to develop strategies to drive our areas of opportunity. Mexico is and will continue to be, at least for the next five years, the most competitive country in terms of manufacturing costs for the sector; therefore, the main opportunities - in addition to this advantage - must focus on innovation and talent training capabilities.

In addition, large companies will focus their capacities on manufacturing medical devices, therefore, market growth will create new opportunities in cross markets for the sector, such as health tourism and export of health services.

Economic Trends for the Sector on a Global Level

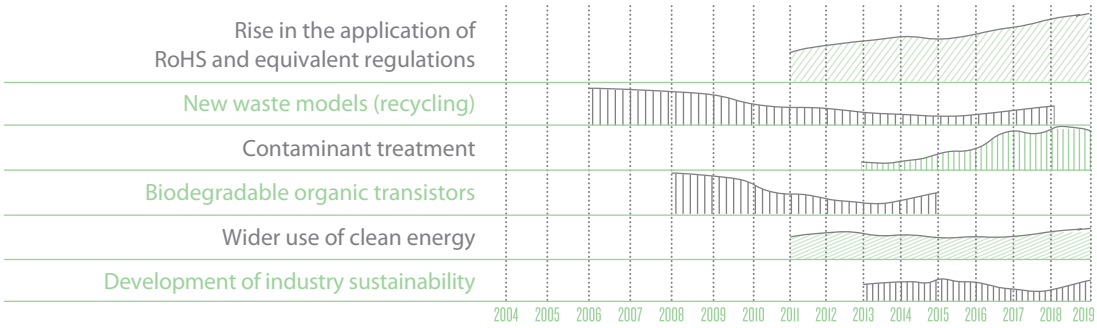


Source: UIN, ProMéxico, 2010.

Environmental and Political-Legal

The medical device sector must obtain certifications and regulations issued by the WHO. The development of new environmental regulation models and international regulations is foreseen for the medical device manufacturing industry to be sustainable. Particularly, there will be regulations on new medical waste recycling models. Furthermore, the Restriction of Hazardous Substances (RoHS) will undergo changes to obtain better management of potentially harmful waste.

Environmental and Political-Legal Trends for the Sector on a Global Level



Source: UIN, ProMéxico, 2010.

7.2 Strategy and Action Plan

Following the approach of this TRM, which was defined in previous chapters, the work group established action lines that support this plan, as well as the projects required to reach strategic milestones in Mexico's medical device sector.

The strategy's main lines of action in the medical device sector must focus on:

- National product design and integration.
- Incorporation to international networks.
- Strategic plan to attract FDI.
- National certification of Mexican design companies.
- Specialized talent management systems.
- Consolidation of specialty niches.
- Supplier development.

7.2.1 National Product Design and Integration

The work group defined as one of its main milestones for 2020, the consolidation of a national industry capable of designing, developing and manufacturing medical devices registered in Mexico using Mexican technologies.

The group, therefore, decided to focus on a strategy that includes a higher national integration of medical devices and creates a Mexican industry that is not limited exclusively to product assembly, but rather has the capacity to design, develop and manufacture devices with Mexican technologies. Through competitiveness

factors such as cheap workforce, R&D by large corporations and improvements to designs made in the country, this renewed industry contributes a larger percentage of integration, which creates more added value and the associated acquisition of knowledge and technology that favor the sector's evolution.

The realization of this milestone will depend on the development of integrating companies, the ties of academia with industry to generate highly skilled human resources and drive innovation; these factors are closely related to the level of complexity and added value of national products.

The prior requirements for this evolution go beyond technological and manufacturing capabilities; in fact, several multinational companies reiterate the need to change Mexico's business culture to world-class practices.

For this reason, the projects proposed by the work group for the medical device TRM focus on topics such as: greater incentives for companies for innovation; streamlining of administrative processes; more and better funding sources; and efficient coordination between public and private sectors. This led to the definition of the following projects in the TRM:

- Create a map of the sector's relevant players.
- Lobby to substitute the formula published in the Federation's Official Gazette regarding the national integration of medical devices.
- Trigger linkage cycles between academia, research centers and industry.
- Drive financing mechanisms to develop prototypes, promote R&D investments and projects in development.
- Establish federal programs of national purchases that motivate supply to the medical device industry.
- Create the comprehensive mold design and tooling program.
- Consolidate a legislative framework that facilitates the development of pilot plants and/or industrial parks for testing and development, with a model of plants authorized to market products.
- Work with COFEPRIS to make regulations for launching new medical device products in Mexico more efficient.

7.2.2 Incorporation to International Networks

Innovation networks are tools that promote articulation between research institutions and

companies, which by using their synergies increase the competitiveness of their respective production sector. These networks are constituted by innovation in specific topics and groups that establish associations between education and both research institutions and companies.

The main purpose of this proposal is to motivate the creation of a network of networks for the medical device sector that contributes to raising its competitiveness in Mexico, and to promote research, technology development and innovation projects in the industry.

Some of the benefits of creating a network of networks are:

- Skill formation and their medium-and-long-term permanence, seeking their self-sustainability.
- Resource training in accordance with productive demand, and their involvement in production processes, considering professionals with masters and PhDs.
- Direct ties between industry, research centers and education institutions.
- Setting up innovation technology lines that will be developed or strengthened through the creation of said network.
- Coordination of a joint vision of the industry in favor of obtaining new support.
- Increased added value to the sector.
- Job evolution; those with higher levels of knowledge and responsibility.

The projects' main topics are:

- To establish a network of strategic alliances to coordinate CONACYT's AERIS for medical equipment microelectronics.
- To implement a network of R&D-oriented technology labs.
- To perform market studies of target countries with higher added value developments.
- To identify innovation networks that better represent the sector with the aim of joining them.
- To integrate the 25 leading companies of the sector to the networks.

7.2.3 Strategic Plan to Attract FDI

The world's medical device industry is relatively un-globalized; most original

equipment manufacturers' (OEM) production and Tier 1 supply is centered on the companies' countries of origin. In addition, the outsourcing process is still limited. However, a few specialized manufacturing destinations of medical equipment have emerged in countries with low production costs such as Mexico, Ireland, China and Costa Rica.

Mexico has a strategic advantage after receiving recognition by several consulting firms (KPMG and Alix Partners, among others) as the country with the most competitive operative costs, compared to the leading countries in the industry. For example, KPMG's study "Competitive Alternatives: Guide to International Business Location 2008 Edition" placed Mexico as the country with the highest percentage of savings in production costs for pharmaceutical products and biotechnologies, clinical tests and medical devices. In addition, Alix Partners' study "Index of Manufacturing Costs 2009" determined that Mexico is and will continue to be – at least for the next five years – the most competitive country in terms of manufacturing costs for the sector.

Because of this, the process of attracting FDI to the Mexican medical device sector must continue in order to create a critical mass of companies in the clusters that is sufficient to improve efficiency. Savings in the total costs of the supply chain must be the main driver to attract companies, since Mexico offers savings of up to 35% compared to countries such as Germany or Japan.

The main target countries in the investment attraction strategy are: the United States, France, Switzerland and Germany.

The TRM work group identified the following main projects:

- To develop medical device manufacturing clusters by specialty and region.
- To carry out a competitive diagnosis of Mexico as an investment destination in medical devices.

7.2.4 International Certification of Mexican Design Companies

Currently, medical device manufacturers face stricter regulatory requirements, which raise product development costs and risks. The stringent standards of medical device regulatory institutions require careful and complete work documentation and the maintenance of a design history that includes the outcomes of the analyses that gave

rise to a concrete decision. This strict regulatory environment increases the likelihood of unsatisfactory product testing, which may put development costs at risk. Success in today's strict environment requires a quicker innovation process with shorter design and validation cycles that reduce time-to-market and engineering costs.

In the medical sector, innovation is one of the fields with the highest growth at international level, especially in recent years in emerging markets that have electronic design activity such as Mexico, Brazil and Argentina, to name a few.

The work group of the Medical Device TRM recognized that Mexican engineers have extensive skills in the fields of innovation and technology development. In addition, national regulations are aligned with international standards, increasing the possibility for Mexican designs to be marketed, both nationally and internationally.

To leverage these advantages, Mexico needs to offer a favorable regulatory environment (aligned with international standards) that includes intellectual property approval and protection. The TRM work group, therefore, identified the following main projects:

- Define a Standardization System in Mexico, supported by norms and monographs.
- Certify academic centers such as authorized labs with national and international certifications.
- Create a Master's program in Medical Device Design and Development through specialized postgraduate studies.
- Promote and publish specifications, certifications, standards and regulations with a trend towards international equivalence.
- Organize national design awards by congress.
- Promote the multinational bilateral negotiation of certifications.

7.2.5 Specialized Talent Management System

Talent development and management are crucial for the activities described here, especially those related to R&D. The availability of a multidisciplinary talent pool must be ensured as the sector continues to develop.

A talent management program aims to identify individuals who have the potential to integrate successfully into the sector, manage their integration into the industry and procure their development and permanence in the sector.

To that end, the work group outlined the actions required to implement a talent management program that can help identify current and future human capital requirements. By identifying these needs, the existing gap between the medical device sector's requirements and the existing human capital capacities can be identified.

By developing an identification platform with a software system and approach based on business intelligence, the program will be put into action.

Identifying the gaps will enable a long-term linkage program between Mexican industry and academia through higher education programs, namely graduate and postgraduate studies, curriculum evaluation and ongoing monitoring of human resources.

7.2.6 Consolidation of Specialty Niches

As a strategic action, the work group for the Medical Device TRM decided to focus on the sector's current capacities, more specifically on the exploration of new business niches. Some of these potential niches are:

- Medical tourism.
- Convergences in technologies (biotechnology, mechatronics and electromechanics).
- Focalized medicine.
- Telemonitoring and telemedicine.

These and other identifiable niches must be studied and analyzed more thoroughly to recognize the main opportunities that they can offer the medical device sector in Mexico.

7.2.7 Supplier Development

The development of the Mexican supply chain for the medical device sector will enable the integration of products with a higher national added value. The substitution of imported parts with parts that could be manufactured by Mexican companies, promotes the pushing of SMBs and a greater transfer of technology in design, development and advanced manufacturing processes in the country.

Furthermore, supplier development must take into account the significant gaps in the sector's supply chain, which will not have capacities from other sectors to convert and that must start by creating national companies in these niches or attracting companies from other regions and developing strategic alliances with

Mexican companies. The TRM work group identified the following main projects:

- Creation of a supplier integration program.
- Consolidation of a National Supplier Development Council for the Health Sector.
- Promotion of sector events that allow the presentation of structural projects to opinion leaders.
- Replication of the R&D Investment Program by bid purchases model (YSSEMYM).
- Implementation of the Supplier Development Program in companies that are affiliated to the chambers and with government tractor companies.
- Promotion of the national development of high specialty medical devices.

Source: UIN, ProMéxico, 2010.

Source: UIN, ProMéxico, 2010.

8. Participating Entities

National Council on Science and Technology (CONACYT)

CONACYT was created in 1970 according to Congress, as a public, decentralized body of the Federal Public Administration. Its main goal is to consolidate a National Science and Technology System that responds to the country's primary demands; provides solutions to specific problems and needs; and contributes to better the population's well-being and quality of life.

CONACYT, as the entity responsible for creating science and technology policies in Mexico, is involved as the leader of the work group of the Medical Device TRM.

ProMéxico

ProMéxico is the Mexican federal government's agency in charge of strengthening Mexico's involvement in international economy. It supports export activities of businesses established in Mexico and coordinates actions aimed at attracting foreign direct investment to national territory. ProMéxico was established by presidential decree in 2007, as a sectored public trust fund of the Ministry of Economy. It has a network of 26 offices in Mexico and 33 offices abroad.

ProMéxico has invited leading public and private players of the medical device industry to form the work group of the TRM to facilitate the definition of a national strategy, in order to increase the industry's exports in Mexico.

Ministry of Economy (SE)

The Ministry of Economy is the federal government's entity that promotes quality job creation and Mexico's economic growth, by supporting and implementing public policies that trigger competitiveness and productive investments.

National Chamber of the Transformation Industry (CANACINTRA)

CANACINTRA is an autonomous and public interest institution made up of industries from all around Mexico. It is a non-profit institution that has its own legal personality and acts as a consulting and negotiating body before government entities and public and private organizations. CANACINTRA is involved in the work group as a representative of national industry.

Baja California Cluster/Axis

Axis is an intelligence body that was developed in 2001 to promote medium-and-high-tech sectors in Baja California. Its goal is to support the development and generation of value within the medical product-manufacturing group in Baja California, with the purpose of increasing economic spillover and industrial competitiveness. Axis is involved in the work group as a representative of national industry.

Innovamédica

Innovamédica is a company that focuses on the research, design and development of new medical devices with an interdisciplinary approach. The company brings together engineers, scientists and doctors to develop their tests and projects. Innovamédica is involved in the work group as a representative of national industry.

United States - Mexico Foundation for Science (FUMEC)

FUMEC was created at the end of 1992 to promote and support science and technology collaboration between Mexico and the United States. FUMEC is involved in the work group to support the development of science and technology projects for the medical device industry.

Monterrey Institute of Technology and Higher Education (ITESM)

ITESM is a private education institution that offers study programs focused on technology and innovation. ITESM is involved in the work group as a representative of academia.

Pan-American Center of Research and Innovation (CEPii)

CEPii is a business accelerator created in 2004 by the Pan-American University (UP) and the IPADE Business School. Its mission includes business acceleration, applied research and research promotion. CEPii is involved in the work group as a representative of academia.

The Mexican Association of Directors of Applied Research and Technology Research (ADIAT)

ADIAT is an institution that, together with public and private research centers, works to promote applied research, technology development and the publication of best technology management practices. ADIAT is involved in the work group as a representative of academia.

Designed in Mexico

Roadmap for the Medical Device Industry

RECYCLED RECYCLABLE

FEDERAL GOVERNMENT
SE
PROMÉXICO
Trade and Investment