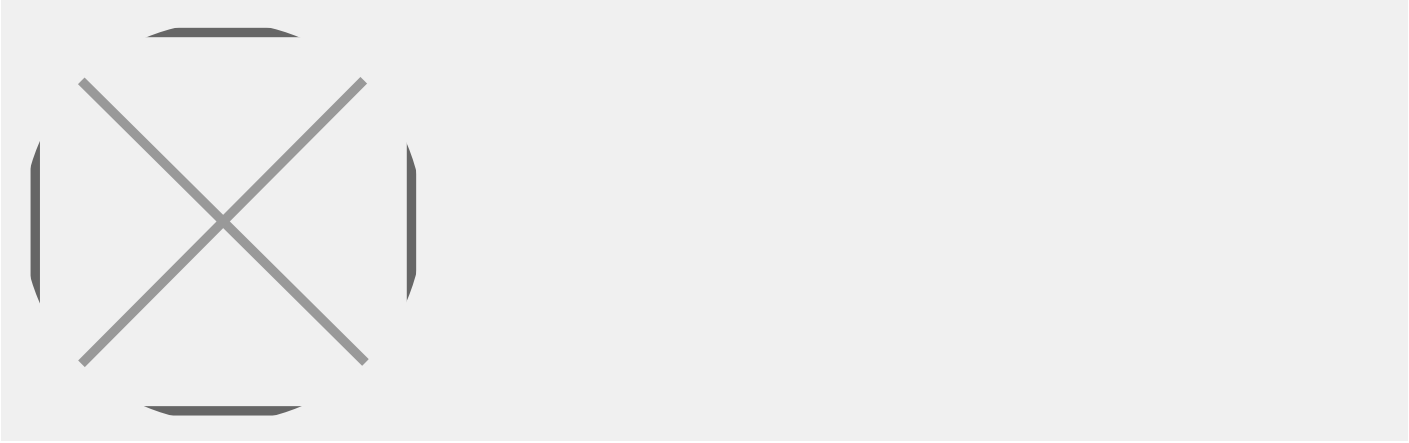
Interview with German Garcia, Regional Director Mexico and Central America, Medtronic México



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Medtronic is the global leader in medical technology. The company has 2 manufacturing facilities in Mexico and the Mexican subsidiary was officially set up in 1970, but could you give us a brief rundown of Medtronic Mexico's current activities within the global operations?

Medtronic was founded in 1949 in a garage in Minneapolis by Earl Bakken, and started as a medical equipment repair shop, specialized in pacemakers. The vision of Earl Bakken was to alleviate pain, restore health, and extend life and today this is still our mission statement.

Medtronic currently employs 40,000 employees worldwide with operations in more than 120 countries, and has revenues of 16 billion USD for the fiscal year ending April 2012.

Medtronic treats 8 million people every year, and we are aiming to treat 25 million per year by 2020. How are we going to achieve this ambitious goal? Our CEO, Omar Ishrak, is the first non-American CEO of Medtronic, and he has a very interesting vision for global growth. His argument is that Medtronic has been very successful for 60 years selling to 5% of the population. Today, we need to address the 95% of the people who could benefit from our therapies but don't have access to our products yet. Therefore, our strategy is threefold – focusing on developing new therapies, growing internationally, and acquiring companies to help us achieve our vision of tripling our number of patients by 2020.

Latin America – and Mexico in particular – are therefore at the core of this new strategy. In Latin America Medtronic is one of the fastest growing regions for the company.

Medtronic has 2 manufacturing facilities in Mexico – one in Tijuana and one in Empalme Sonora, which follow the maquila business model. Both facilities are approved by all the health authorities worldwide, including the FDA. They employ a total number of more than 2500 employees and growing. Mexico is the country outside of the US where Medtronic has the most facilities.

The commercial office currently employs 70 employees. We traditionally sell through a distribution network – except for the insulin pumps in the Diabetes division that we sell directly.

Medtronic is also the company with the broadest and most innovative product portfolio among the industry. Could you give us an overview of the therapeutic areas Medtronic covers?

Innovation is in the DNA of the company. 2/3 of the company's revenues come from products developed in the last 2 years – so if we didn't innovate constantly, we would be out of business.

Regarding the therapeutic areas, Cardiac Rhythm Disease Management (CRDM) represents 33% of all sales; spinal and biologics 22%, cardiovascular 18%; neuromodulation 10% ; diabetes 8% ; and surgical technologies 6%.

CRDM is our oldest business division and we have an ample portfolio of pacemakers, defibrillators, and monitoring systems. In cardiovascular, Medtronic recently acquired ATS Medical, a manufacturer of mechanical heart valves, and this is a welcome addition to our portfolio of stent grafts and angioplasty technologies.

Spinal & Biologics is a business division where Medtronic is developing the new standards of care. We have a full range of highly innovative products, and we are moving towards minimally invasive therapies.

The Neuro division uses the same technology as pacemakers – except the leads are connected to the brain. We are having excellent results to correct diseases such as Parkinson's, Dystonia, epilepsy, and is advancing in the treatment of other diseases such as depression or obesity. Many devices are rechargeable and monitored wirelessly.

Our diabetes division has two main products: our insulin pumps, which are small catheters implanted under the skin to deliver the exact amount of insulin, and our continuous glucose monitoring systems.

Last but not least, we have surgical technologies like navigation equipment which is mainly used in neuro and spinal surgeries and ENT devices.

What is the strongest selling product in Mexico?

Each therapeutic area has a different maturity level in Mexico. The coronary stents are the most developed market segment because stents have become the standard of care. On the other hand, the use of pacemakers is highly undeveloped in Mexico. To give you an idea, in Mexico around 123 pacemakers of all brands are implanted per year per million inhabitants versus 400 in Argentina, around 1,000 in the US, and more than 1,000 in Europe.

How can you explain this discrepancy?

There are several factors. The first one is the patient. Patients believe implanting a pacemaker will be a complicated procedure, and refuse to do it. Our main challenge is that Mexico is a country of pills – so we are working on providing information to the population. Another important point has to do with referrals. Clinical cardiologists who do not perform surgeries have to refer to an implanter – and this referral system hasn't been working. The last factor is that half the Mexican population has limited coverage – Seguro Popular has recently approved some devices, but with some limitations

Since innovation is the name of the game, how soon are you able to launch your products in the Mexican market?

We now have three entry doors to the Mexican market: the traditional registration process that has been taken up to two years, the equivalence agreement (approved last year) or "fast track" for devices that have FDA from US or Canada (this has been working much faster) and recently the use of "terceros autorizados", firms approved by COFEPRIS that pre-check the dossiers, so they can be approved faster.

In Medtronic and some other medical devices companies members of AMID (Mexican Association for Innovative Medical Devices), we still have an important backlog of submissions waiting to be approved.

On the bright side, in some cases, we have even been able to launch prior to the US – thanks to the Fast Track Health Accord. For example, we have just launched in Mexico the latest technology for insulin pumps, VEO. This product still doesn't have US FDA, but it has Health Canada's approval so it qualified for the Fast Track.

With the Fast Track Health Accord in place, which regulatory hurdles are you still facing in the Mexican market?

Despite being a US-based company, not all our products are FDA approved. We manufacture some products in the US that we do not sell in the US, but that are already sold in the rest of the world – like the insulin pump I mentioned. This is also partly due to the time that it requires to obtain the US FDA.

For the products not falling under the Fast Track, the process is still very complex. First, COFEPRIS has a major backlog of registers and not enough people to review the dossiers, which leads to very lengthy approval times. We expect that with the use of “terceros autorizados” we could accelerate the approval timing.

Regarding distribution, the “integrators” have been making the headlines recently. What is your perception of their role?

70% of Medtronic’s sales are institutional and 30% are directed to the private sector. We have a long history with distributors, and trust them. We are now expanding exponentially our presence in the Mexican market, but we are only 70 employees. The complexity to provide service to a public hospital is very high, and requires a lot of personnel and infrastructure to provide a good service. Also, there is an important trend towards integrated services, where institutions issue tenders asking for a cost per procedure, integrating for example the pacemaker, the anesthesia, and the surgery tools. No company has such a broad portfolio of services. Therefore, the integrators provide one single point of sale which has helped the institutions improve the control of their inventories. It might be priced a little higher, but the complete requirement for the procedure is provided.

As a high technology medical device company, how do you assess the quality of healthcare in Mexico – and what could be done to improve it?

I see room for improvement in two areas: the first is a move towards effective universal coverage and the second is training and education for physicians and patients.

Seguro Popular is a fantastic initiative to move towards universal coverage, and 42% of the population has been insured by Seguro Popular over the current administration. You fill out a form and you are covered: that was the easy part. Now we need to deliver – and the implementation process is complicated. Since Seguro Popular doesn’t provide the infrastructure, the service has to be provided at this moment by public institutions. Mexico does not have enough health infrastructure to cover this drastic increase in insured population and this is an important backlog that has to be solved. Also, we need to increase the breadth of services covered by Seguro Popular. For the moment, Seguro Popular has been focusing heavily on prevention, but this is changing, and now catastrophic diseases and some chronic diseases are starting to be covered.

Seguro Popular hasn’t really started having an impact for us. For example, stents have just been included in Seguro Popular, but the hospitals doing the procedure need a certification they don’t have yet; patients do not know well how to be directed to the right centers… The implementation hasn’t been smooth.

Beyond Seguro Popular, IMSS also needs to broaden their services and adopt a long term cost benefit approach to treatments. Diabetes is a good example. About 1% of the total population has diabetes type 1 – and the two competing therapies are insulin pumps or an insulin injection two to three times a day. IMSS provides the insulin to the patients, but they don't even provide the syringes – so you can imagine they will not provide a pump – plus consumables! However, on the long term, patients who don't monitor their diabetes closely end up going to the hospital once or twice a year, so in the end, it is cost effective for the government to provide pumps – not to mention the wellbeing and quality of life of the patient. But there is a long way to go before we see the Mexican government taking this into account.

The second angle we need to work on is education. The pharmaceutical companies have done a very good job on this aspect and today the penetration of drugs in Mexico is comparable to developed countries. However, in terms of surgeries, we are by no means comparable to developed countries, and this is something that medical devices companies need to work on together as an industry. It is of course due to a combination of factors – but I believe the patient's fear of surgery is an important factor. Our industry need to communicate more on products, procedures, and how safe surgeries are, especially with some of our minimally invasive procedures.

If we come back in 5 years, where will we find Medtronic in Mexico?

We will be a significantly bigger company. We are currently growing at 20% , and the goal is to continue with double digit growth rates in the coming years. We will achieve this goal thanks to a combination of factors. The first is further penetration of existing therapies thanks to better education of the physician and better communication to the patient. The second is the inclusion of the devices within Seguro Popular – which will simply double our market potential. Last, Medtronic acquired recently a company called RDN which produces devices in renal denervation which is used to treat hypertension. Hypertension is a very large market in Mexico so we have high hopes that this product addition will fuel our future growth. In conclusion, Medtronic will be a larger company with a stronger product portfolio covering larger therapeutic areas.

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