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Biograft is the first private tissue bank in Mexico meeting the increasing demand for implants of human musculoskeletal tissue. The general director and founder discusses the vision behind the creation of Biograft, how the company mastered to overcome skepticism and the plans to expand exports and transform the company in the tractor of a biotech cluster.

Biograft is focusing on a very specific niche of the healthcare industry: implants derived from human muscle skeletal tissue. What was the vision behind the creation of the company and what have been its most important achievements so far?

Biograft was founded in 2003 because we identified the growing need for these kinds of implants in the Mexican market. Imported products were of poor quality and we were aware that companies were even introducing this kind of tissues into the country without complying with any kind of regulation. After the creation of the company it took us three years to acquire the necessary license, the sanitary registrations for the products and start the operations, during which we received a lot of support from the Federal Commission for the Protection against Sanitary Risk (COFEPRIS), which believed in our vision.

From the beginning the most important priority we had was patients' safety. For this reason we decided to comply not only with the local regulation of COFEPRIS and the Mexican National Center for Transplants (CENATRA), but also with the guidelines of the American Association of Tissue

Banks (AATB), the Food and Drug Administration (FDA) on human tissue derived products as well as with ISO 9001-2008, ISO 13485- 2003 and TÜV certification. All other tissue banks in Mexico are public, so it took us a lot of efforts to convince the Mexican authorities that we were a viable organization, that we were not doing anything illegal and that we were actually interested in setting the standards for tissue banks in the country. Today we can proudly say we are the first private tissue bank in Mexico.

What kind of advantages do these types of implants offer?

Our products offer a number of advantages. First, they are not intended to replace other type of implants, but rather to be combined with these products to help them better and faster integrate in the patient's body. Also, before the boom of our products, the main source for bone was the body of the patient himself, which implied a second surgery and, thus, longer recovery time for patients.

In a recent interview you mentioned that in the past "there was a lot of reticence toward Mexican-made products of this type, which were very scarce". What did you do to build up trust in medical circles?

Unfortunately locally manufactured products suffered from a very poor image because of low quality standards. In order to overcome this negative perception we decided to implement an open house policy, whereby we invite the surgeons to visit our facilities and see how we produce our implants. The first three physicians that visited us were among the top key opinion leaders in Mexico and after visiting our state-of-the-art facilities and seeing our production process they all changed their mind. As a result, Dr. Clemente Ibarra, traumatologist and orthopedist at the National Rehabilitation Center, is now doing clinical trials and protocols with our implants, and all key opinion leaders in Mexico are using our products. We may not have the size of American tissue banks – we only have four clean rooms, while in the US most banks have at least 30 —, but the quality is the same, our certifications prove it and this is what matters.

A further differentiator is that we manage Biograft as a medical devices company, with customer service always being top priority. Our sales force is very close to physicians to make sure we can supply them the products they need in the shortest time. That's what makes us successful.

Biograft received financial support from the National Council of Science and Technology (CONACyT) to finance R&D activities. What was your experience with CONACyT and what needs to be done in Mexico to foster such successful stories?

Being a young company we did not rely on the resources to be self-sufficient in terms of R&D, so we decided to apply for government funds CONACyT offers to start-up companies to support innovation. Thanks to the company's successful trajectory we received five grants, which allowed us to consolidate our product portfolio, enter the demineralized bone matrix (DBM) segment – today the only one produced in Latin America –, the market of human cartilage derived products for maxillofacial and plastic surgery, to leverage the innovation culture within the company with trainings and, last but not least, enter the cadaveric skin derived implants segment, which is a growing need in the country and we hope to start very soon.

When I presented the DBM project to the CONACyT committee evaluating the projects to be funded I was very nervous. While most of the applicants were presenting the financial forecast for their projects, I decided to break the paradigm and show the final product. I had only ten to fifteen minutes to present the project, but the interest was so high that the project was approved right away. Alas, Biograft is an exception in Mexico: we are and innovative, young and paradigm-breaker company, but not many are like us in the country.

Education is the key to have more of these success stories. Today, the government has the huge responsibility to decide which education model it wants to have in the future. Recruiting the correct staff is a challenge in Mexico: today we have open positions, but face difficulties to fill them because most of the candidates do not have the appropriate academic background.

You already export products to South Korea, Spain, Switzerland, Guatemala and Peru and have plans to start exporting to Germany. What competitive advantages does Mexico offer to manufacture this kind of implants at international scale?

We receive tissues from other countries, process and send them back, meaning we actually export technology and knowledge – which is way much better than exporting products. The advantages of being in Mexico are many. First of all, Mexico has a very strategic position from a logistic standpoint, being close to both the largest market of the world, the US, as well as to Latin America and having access to both oceans through ports and good infrastructure, which is not the case of Brazil for example. Besides elements such as hard working and creative people, a further factor we should not underestimate is weather, as the favorable weather conditions help you keep costs down.

Despite relying on a national organizational system for transplantation, according to the Global Observatory on Donation and Transplantation Mexico still ranks way below the average, with 0 – 2.4 transplantations per million people. Why do you think it is the

case?

My experience tells me that Mexicans are convinced and willing to donate when they see that the pass-away of their beloved ones can help someone else's lives. Our main barriers – believe it or not – are mostly the lack of adequate infrastructure and healthcare professionals who do not understand that all the efforts and technology involved in the transformation process to assure safety, quality and supply are costly and that we need to recover these costs to operate and expand our presence in the market.

Biograft expects to diversify its portfolio of solutions with the introduction of human cadaver skin tissue, cartilage and stem cells. Where are we going to see Biograft in five years from now?

One of our competitive advantages is that we are an innovation-driven company – we have innovation running in our blood, brain and everyday activities. Thanks to the technology partners we have around the world, who feed us with the newest developments, we have a five-years strategy plan and a pipeline of new products until 2020. When we identify new products, which may be interesting for the Mexican market, we first go to key opinion leaders to understand and assess their potential before we develop a business and marketing plan for the launch.

In five years I'd like to see Biograft as a tractor of a biotech cluster – I'm actually already working on the project –, having a more international presence, leading the Mexican association for tissue banks and being finally recognized by the skeptics. I think we can combine public and private tissue banks because the needs of the country are much higher than the personal interests. As for the cluster, we are receiving the support from the government agency ProMéxico and from the development bank Nafin, already have a ground where we plan to develop it and a company interested in joining – so are definitely on the right track. We are also working closely with the Tecamac Technological University of the State of Mexico, which has provided us with 30 percent of our current staff, as we have strong partnerships for intern and scholarships.

We are also committed to give back: we donate a very significant percentage of what we manufacture to hospitals where we have rehabilitation programs and to pediatric hospitals. It's a great combination: we are innovating, we are fostering medical R&D, we are generating employment and we are supporting the society – maybe not at the pace we'd like, but we are.

As an entrepreneur what would be your piece of advice to investors thinking of starting a business in Mexico?

Mexico is much more than what you see today on the newspapers and offers a fertile ground for investment also due to a strengthened regulatory environment thanks to COFEPRIS. There is still room for improvement, but the authority is moving in the right direction and is much closer to the needs of the industry.

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