Interview: Francisco Kuri Breña, Director of New Developments & Irma Aguilar Delfín, Head of Genomics Research, Landsteiner – Mexico



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Landsteiner is betting on biotech and genomics. The head of new developments and the head of genomic research share their views on the future of the company as well as the importance of embedding new technology in new product developments to better adapt to the changing needs of the Mexican population.

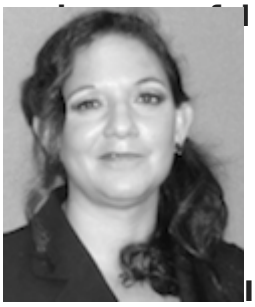
Landsteiner is one of the very few Mexican pharmaceutical companies that actively invests in R&D and embeds biotechnology and genomic medicine in its product development. When was the company established and what are some of its most recent milestones?

Francisco Kuri Breña (FKB): In its origins Landsteiner Scientific was a distributor of hemoderivatives and was named in honor of Karl Landsteiner, a biologist and physician from Austria, who won the Nobel Prize for distinguishing the different blood types. Landsteiner is a very young company – turning 17 years this year – but has been growing significantly over time. It first started with distribution and development of generics. Shortly after, it started focusing on innovation, mostly on new combinations. Today the company employs 1,000 people, has two production plants in Mexico, business offices in the US and a branch in Spain that is primarily focused on genomics.

Landsteiner drugs are produced under the highest quality standards, with certified procedures based on good manufacture practices. Furthermore, everything is continuously supervised under an internal audit program carried out by our quality control area. The company's key strengths lie in the specialty drugs and the diverse pipeline of products, 18 of which are currently under regulatory review for approval. Our R&D is carried out in cooperation with strategic alliances from technology suppliers worldwide, while in biotechnology we are focused on biosimilars.

We also have our own generic brand called Elite Medical, which is mainly focused on the private market and has been reporting interesting growth. In the past, 90-95 percent of our sales were focused on government; however, in recent years we have started focusing more on the private sector and exports. The therapeutic areas we focus on are immunosuppressive drugs, osteoporosis, diabetes and biotech for degenerative and chronic diseases.

The Mexican government is interested in increasingly promoting the collaboration between government, academia and private industry—the triple helix. Given that you work very closely with the Biotechnology Institute of the UNAM and the Institute for Genomic Medicine (INMEGEN), what do you think is missing in Mexico to have more of [illegible] collaborations?



Irma Aguilar Delfín (IAD): The lack of successful collaborations between academy, private sector and government it is not a problem unique to Mexico; it is happening all over the world. One thing that could help foster more successful collaborations would be if the governments were to give more tax incentives. This would give more companies the ability to invest, hire specialized people with higher salaries, and make innovative products. The problem with Mexico is that even when we do produce highly skilled and specialized scientists, we lose them to the US.

What are some of the most important challenges the industry in Mexico faces to invest in biotech and R&D?

FKB: Besides the investment being so high, it's a huge risk. Furthermore, it's a long-term bid, which is why most of the pharmaceutical companies in Mexico that sell biosimilars also sell generics to finance R&D. The second major difficulty with biosimilars is human resources. We have

people that know biotech but not necessarily industrial biotech. For example, at the Institute of Biotechnology we have excellent people that have significant knowledge. However, when you want to move them from academic to industry biotech there is a huge gap. There is certainly room for many more biotech companies in Mexico. It is a very good thing for Mexico that the law has been redefined because it will help us align with the rest of the world. Biotech sounds like science fiction but it's not. I think we all need to focus more on this.

How did Landsteiner decide to incorporate genomics into its medicine, and what was the vision behind this?

IAD: Landsteiner started its adventure with genomics back in 2013, when the company entered an agreement with the Spanish firm Neopharm Obesity. Back then, nobody was doing genomic medicine; but we knew genomics was going to be the name of the game in the near future and that research had to be done in Mexico because the genetics of Mexicans is different from the one of Caucasian people in the US. The idea behind genomics is to develop more specialized medicine, what is called "precision medicine", to identify therapies with higher probability of success in a particular patient. Landsteiner is orienting the development and production of drugs for highly prevalent diseases in Mexico and Latin America like cardiovascular, oncologic and neurodegenerative diseases, as well as obesity.

What markets are you looking at entering in the near future?

FKB: We are aiming at the internationalization of Landsteiner's products while also taking advantage of the different agreements the regulatory authority COFEPRIS has signed with other ministries of health in different countries in Latin America. It was very good for Mexico that COFEPRIS was recognized as a regulatory authority of regional reference. It is also good for Landsteiner because it means our generic brand will soon be exported.

Brazil is a key market in Latin America, but Brazil and Mexico have very different approaches to technology. The first is very protective and you need to have a multinational partner that produces in Brazil to enter the market. On the other hand, Mexican rules are very open: anyone can sell in the country as long as you have a Mexican partner. This difference in approaches creates competition. However, I think in the end Mexico will be the biggest winner. We are also looking towards Europe and the US, ideal markets for this industry, but it all depends on the growth of the company.

What are your ambitions for Landsteiner in the future? Where do you see Landsteiner in the next five years?

FKB: Here at Landsteiner, ethics, quality, excellence and social responsibility are crucial to fulfill our objectives, and one of our main focuses is to contribute to the wellbeing of the Mexican population through products and services that allow a better quality of life. The strength of Landsteiner lies in its ability to participate in the market changes. We are very flexible, we can quickly adapt, and we give the patients and the healthcare system whatever they need.

We also want to increase our exports in the future. We currently rely a lot on government sales so we want to even out the participation of the private sector and the public sector, which can be done through exports and innovation. We are trying to build an innovative company.

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