UDIMEB Mexico – Sonia Mayra Peréz Tapia, Executive Director

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The executive director of the university spin-off UDIMEB explains the major achievements of the institution, her plans to convert it into a strategic partner to the pharmaceutical and biotechnology industry to conduct pre-clinical tests and the challenges spin-off initiatives face today in Mexico.

In the past pharmaceutical R&D activities in Mexico have been mainly confined to academia. How would you assess the situation today?

In Mexico five to ten years ago the role of R&D in the pharmaceutical and biotechnology field started to change. Whereas in the past it was mainly publicly funded and carried out at academic institutions, researchers increasingly started putting their know-how at disposal of the private industry or creating new forms of collaboration between private sector and university. This happened mainly because of the need for increasing funding, as public resources allocated to R&D in Mexico are scarce and mostly provided only by one major institution, the National Council for Science and Technology (CONACyT).

Today many university R&D labs play a crucial role in completing the development process of products for the private industry, as many companies do not have the infrastructure to perform it

in-house. Outsourcing these R&D activities provides a number of benefits to companies, as they avoid paying fixed overhead costs for a specialized team, which – instead – is hired on demand. This makes companies and, in turn, the industry more competitive, as investors are more prone to use risk capital and R&D service providers are pushed to compete.

Could you please walk us through the main milestones of UDIMEB and tell us how you got involved in the project?

UDIMEB was started back in the 1970s as *Proyecto Factor de Transferencia* (transfer factor project) by Dr Sergio Estrada-Parra, the father of immunology in Mexico and winner of the National Science Award in 2012. Transfer factors were originally discovered in 1949 in the US by pioneer immunologist Dr. Henry Sherwood Lawrence, who discovered that T-lymphocytes played crucial roles in defending against a wide variety of infectious agents. At IPN (the National Polytechnic Institute) Dr. Estrada-Parra deepened research on transfer factors to develop an immunomodulatory drug, which could be used locally.

I started working on the project as a student in 1998. By then research was already advanced but product development still in its early stages, so we developed a strategy to make the drug commercially viable and launch it on the market. Today the immunomodulatory product is registered with the Federal Commission for the Protection against Sanitary Risk (COFEPRIS) and marketed under the brand Transferon as an injectable. The IPN is actually patenting it, because even though the product is not new, the contribution of the institute regards the technology involved. When I started working on the project, you could only obtain one unit of Transferon® from one unit of blood bag; today from 300 blood bags we can obtain up to 2,000 units of product.

So, how does UDIMEB look today?

The project underwent many changes over time, and we decided to change its name to UDIMEB to be more competitive in the market place. As a result of this evolution, today UDIMEB is a three-armed institution which comprises UDIBI, a national laboratory unit offering R&D bioprocess services to the private industry and the academia; USEIC, an institution providing free clinical services in the field of immunology and alternative treatments based on transfer factors to more than 20,000 patients. Last but not least we have FARMA FT, the company in charge of manufacturing the immunomodulatory drug Transferon. It’s impressive to see how we started between two people, while today we are 108, and that besides me, all UDIMEB resources are paid with the institution’s own resources, as by today the project is on its own feet.

What is the strategic importance of the R&D branch UDIBI within the organization?

For us R&D is something carved in our DNA – most of our team are master and PhD students, who have pursued their career either at IPN or at other academic institutions here in Mexico. UDIBI is certified by CONACyT and three years ago obtained a grant as national lab, one of the most important endowments the institution offers to R&D professionals in Mexico. A project for basic science is usually awarded with approx. USD 67,500, whereas the lab got a funding of (nearly USD 2.7 million over three years, which allowed us to put the basis to create a good infrastructure and make a viable business.

What started years ago as an R&D service provided to private firms slowly evolved into a strategic partnership. Today, the private industry comes to UDIBI in search for specialized help to complete their developments in the fields of pre-clinical tests. Our dream is to be able to offer to the industry basic R&D, proof of concept, pre-clinical and toxicological tests and, eventually, Phase I studies for clinical research, with the necessary equipment and infrastructure to perform them in-house.

What is going to be UDIMEB's next step and where would you like to see it in five years from now?

My vision is to spin off UDIMEB outside of the IPN to transform it in a self-sustainable and profitable business, but it's very difficult, as Mexico does not have a culture of university spin-offs. Moreover, since we already have commercial operations, many argue the IPN would lose an important source of financial income. What I always try to make people understand is that moving into the private industry will help – and force – the institution to grow and be more competitive, thus also helping the company and the staff grow. For instance, today our production of Transferon is limited to 5,000 units, but we need to transfer our technology to make sure we can increase it.

In five years from now I would like to see UDIMEB as an autonomous profitable business outside of the IPN, maybe not from a physical perspective, as we rely on state-of-the-art-facilities, but from a business standpoint to make sure it can grow on its own feet. I would like to be an investor of the company I started – something possible in other parts of the world, but not in Mexico.

What would you recommend to government authorities and academic institutions to ensure Mexico can have more success stories as UDIMEB's?

First and foremost, we need to change the law, as today our legislative framework for science and technology is rather an obstacle than a facilitator. The current law states that spin-off initiatives between academia and private investors can be created, though the reality shows it's impossible because the law regulating public servants states that all employees of public institutions – academic or not – cannot start a business and at the same time receive salaries from the

government, as this generates a conflict of interest. Moreover, the general labor law states that your boss is the owner of all your creativity, meaning you are an investor only from a moral point of view, which definitely does not convert it into money. This scenario makes spin-off initiatives almost impossible!

Five years ago the IPN created a trust to make private-public partnerships happen. As a result, today the institute is among the most important service providers to the state-owned oil company Pemex. The trust was created to ensure Pemex could pay the IPN and the institute could use the money. However, the IPN keeps 30 percent of all revenues, which go into a common fund and are not necessarily reinvested in the same project.

Mexico is the only country where private-public collaborations are seen as ‘prostituting’ science. I’m a black sheep within the immunology community, but this mindset needs to change. I think initiatives, which bring together the private industry and academic institutions should be strongly encouraged. So far we have worked along with two pharmaceutical companies and both are very happy about the results. We already are certified as national laboratory and are soon going to be certified as third-authorized party by COFEPRIS, which in the future will increasingly rely on the support of external laboratories, as differently from the FDA and the EMA, it does not have enough resources to have its own labs.

How do your previous experiences help you in your current tenure as executive director of UDIMEB?

I rely on a master’s degree and PhD in immunology, then studied a degree in administration for the pharmaceutical industry, a post-graduate program in technology innovation at the IPN and today I’m doing an MBA at the IPADE Business School – my experience is a bit of everything. However, I think the transfer factor was the most important project of my career so far, as we had to create a production plant to manufacture the product from scratch. Transferon® is a controversial product, as it was marketed twenty years ago without having the clinical trials, toxicology tests and publications, which are requested today by COFEPRIS. So we had to build everything in reverse.

Nonetheless, I must admit one of the activities I must like is being an advisor to COFEPRIS on behalf of the IPN. I enjoy very much being able to help create a better regulatory environment in Mexico, as the committees are formed of experts from different branches and you can really see the impact of your recommendations in the very short term. Many companies complain about the strict rules implied to register a drug in Mexico, though we have to bear in mind that COFEPRIS today does not rely on the necessary resources to conduct vigilance, so the only way to make sure

companies comply with the regulatory framework is to make it stricter from the beginning. I think COFEPRIS has changed dramatically over the past years – and for the better – to become an authority of regional reference and I expect them to increasingly convert national laboratories such as UDIBI in strategic partners to the federal authorities to leverage the infrastructure and human capital already present in the country.

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