Interview: Dra. Sonia Mayra Pérez Tapia – Executive Director, UDIBI, Mexico



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The university spin-off UDIBI continues its unstoppable ascension: after being recently recognized by Cofepris, Mexico's sanitary agency, as an authorized laboratory to assess biotech treatments entering the Mexican market, UDIBI has no started to develop its own, innovative compounds. Sonia Mayra Peréz Tapia, executive director of UDIBI, highlights the ambitious development path followed by an organization which steadily becomes a true, research-driven biotech company, while its remarkable scientific capacity and its cost-efficient service offering also draws the interest of an increasing number of customers, in Mexico and abroad.

UDIBI truly showcases how, with the right approach and the right people, it is possible to turn a Mexican university spin-off into a success-story holding promising developments and opportunities. As a matter of fact, in April, 2015, UDIBI was officially recognized by Cofepris as an authorized laboratory for market pre-approval. What does this recognition mean for UDIBI?

Being recognized as a laboratory that holds the technical expertise to conduct pre-approval market authorization on behalf of Cofepris, Mexico's regulatory agency, indisputably stands a formidable achievement. As part of this recognition, UDIBI will moreover be specifically in charge of assessing new, complex biotech treatments entering the Mexican market, according to the NOM-257 regulation that Cofepris released in 2014.

This prestigious recognition comes as a logical consequence of our ongoing progresses, as UDIBI probably holds one of the most experienced scientific teams in Mexico in the biotech and biosimilar fields. Since our beginnings, we have been claiming that our scientific capacity to design credible evaluation assays was aligned with the most exigent quality and technical standards in the world, and Cofepris' recognition clearly validates this statement.

Furthermore, our overall responsibility *vis-à-vis* Cofepris has also been recently evolving and expanding. As a matter of fact, UDIBI as a third party is not solely in charge of pre-evaluating new biotech molecules on Cofepris' behalf, as they also entrusted us with the responsibility to develop and design new evaluation processes and guidelines that would be ultimately implemented by all authorized laboratories in the country.

How have you been adapting UDIBI's capacity to handle this new responsibility?

Since we received Cofepris' recognition, the number of pharmaceutical companies approaching us has been rapidly increasing month after month. A year ago, we initially started with the approval of only five different molecules, while now we are simultaneously conducting more than 10 different product authorizations. This tremendous success obviously means we had to hire new researchers and acquire new research equipment to cope with this increasing demand.

[Featured_in]

In the meantime, UDIBI has had to learn dealing with the largest variety of different clients that our new, expanded service offering entails. In the meantime, UDIBI however boasts a competitive advantage that most our private counterparts doesn't hold: we are way more flexible in terms of payments conditions than our competitors. Mexican companies sometimes struggle to meet their payment deadlines, which sometimes hinders their capacity to pursue sound business relationship with their suppliers and services providers. Nevertheless, as UDIBI still operates as a university spin-off, we are able to offer our customers more advantageous than our private counterparts and competitors.

Your progresses are particularly impressive as only two percent of all authorized laboratories recognized by Cofepris are education institutions or university spin-offs. What could be the impact of this recognition on the private-public sectors relationship in the country?

First, this recognition positively foster private players' openness to conduct business with us. More importantly, pharmaceutical companies are increasingly approaching us as a *normal* service

provider, which means they consider we hold the scientific credibility and display performance levels to be a relevant business partner in our own right.

In this regard, I deeply believe this recognition will also contribute to steadily change the perception that pharmaceutical companies have of Mexican university spin-offs as a whole: even in Mexico, research organizations emerging from an academic background can truly develop themselves into a credible, cost-efficient and competitive pharmaceutical laboratory.

In turn, this achievement may also change the perception that other academic institutions have of their own development opportunities. In this vein, we deeply hope the recent achievements UDIBI has reached will trigger a virtuous circle of commercial successes for our academic counterparts, which actually truly need these additional and commercial incomes to further develop their research capacity and remain competitive.

Do you see private-public partnerships as the way out of the conundrum for public research organizations that struggle to gather the financial resources they need to grow?

In Mexico, it remains particularly difficult for academic institutions to obtain the amount of public funding that conducting cutting-edge research requires, despite the outstanding efforts of CONACYT (National Council of Sciences and Technology) to financially sustain innovative research developments in our country. Nevertheless, developping commercial partnerships between private companies and public research institutes could provide the latters with the funding they lack to further modernize their research capacity and conduct more ambitious research programs.

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Furthermore, by developing their research capacity and conducting contract-based research in partnerships with healthcare companies, public institutions would also be able to offer greater opportunities to their students, researchers and employees. Public research institutes could for example tremendously increase employment opportunities offered to their post-graduate students, which is something Mexican universities still critically lack of.

If research institutes accept to pragmatically analyze the situation, before we started to collaborate with the private sector, the overall research budget we received from the federal government amounted to around six million pesos [around USD 330,000]. By developing our commercial branch and increasingly partnering with the private sector, this research budget is now fifteen times higher than a few years ago.

Some general directors of Mexican public research institutes described to us the difficulties they face in reaching out to the private sector. What would be your advice to the public research institutions that strive to draw the attention of the private sector and follow UDIBI's path?

To make their scientific capacity more appealing to the industry, the most fundamental aspect is to radically transform these institutes' research processes – without compromising their scientific credibility. You don't build research protocols nor display research outcomes in the same way whether you want to publish a scientific article in an academic publication or render them attractive and useful for a pharmaceutical company. This means Mexican research institutes cannot continue to conduct academia-centered research and expect pharmaceutical companies will eventually knock on their door to start partnering with them. Mexican research institutions have to fully integrate their ambition to partner with the private sector within their research approach, from the very first phase of their projects.

Furthermore, the recent amendment of the Mexican legislation related to public-private research partnerships can become a formidable catalyst to develop the two sectors' relationship. In Mexico, public researchers were historically not allowed to receive complementary resources or salaries from private companies. Nevertheless, in November 2015, the Mexican Congress released a new Scientific and Technology Law, which upgrades public researchers' status and gives them a greater freedom to partner with private companies, alongside their public sector responsibilities.

Finally, as teachers and researchers, it is also our responsibility to nurture the desire and instill the reflex to partner with private companies among our students. For too many years, in Mexico, the only funding option considered was CONACYT's public resources. We need to change researchers' mindset, and notably ensure that the next generation of Mexican public researchers will more naturally consider partnering with the private sector when they start designing their research programs.

Beside your approval activities conducted on behalf of Cofepris, what are the other priorities on top of UDIBI's agenda?

Following the aforementioned legislation released by the Mexican Congress, UDIBI will have a new legal status and fully operates as a private organization. Furthermore, we have been evaluating over the last two years the opportunity to develop our footprint outside the Institute's walls, as our current offices prevent us from following all the promising business opportunities that are currently arising.

Being recognized as an authorized laboratory by Cofepris stands as a very interesting but only first step within our ambitious development plan. Our fundamental objective is to evolve towards a modern laboratory structure, which holds the in-house technologic platform to develop its own compounds. In this regard, our strategic approach would be to bring innovative molecules from an academic, basic research phase to a more business-ready stage.

Over the past months, we started developing with our own resources our first three compounds – in oncology and infectious diseases. Our objective is now to develop these compounds until they reach pre-clinical study phase, before partnering with a big pharma company interested in the development potential of these molecules. In this regard, UDIBI now follows the same development model as any other biotech company in the world: we look at promising compounds targeting unmet medical needs, we start developing them with our own resources from the initial to the pre-clinical stage, before looking for a bigger partner to step in and bring these products to the final steps of their development.

How developing your own compounds can help you enrich your current service offering?

Transferon® is a blood derived product but the composition is like a non biological complex drug because of the mixture of peptides. To characterize and also evaluate all the possible immune mechanisms that Transferon® could be involverd, our R&D team has the duty of the evaluation in different cell systems and animals models in order to develop another kind if transfer factor or certain peptides.

Before entering pre-clinical or clinical study phases, a laboratory must ensure it holds the perfect assays to test its compounds and clearly demonstrate their therapeutic impact. In this regard, our expertise to design pre-clinical and clinical assays also stands as a service that we can offer to external clients.

Leveraging our academic network, we collaborate with the most reputed clinical doctors and pharmacologists of the country to design cost-efficient and more precise assays, which will allow to better highlight the therapeutic outcomes sought by our clients. For example, if their clinical protocols are more precisely designed, pharmaceutical companies can expect to make substantial savings by reducing the patient population that will need to be enrolled for the clinical trials.

Talking about the pharmaceutical companies you already worked with, what specificities and competitive advantages of UDIBI attracted them to partner with you?

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First, UDIBI is part of a prestigious institution, the National Polytechnic Institute, which continuously provides us with the best researchers of the country.

Second, our customers and partners value the fact we offer one of the most competitive service offering in Latin America. If they didn’t start partnering with us for this exact reason in the first place, this competitive advantage always counts toward their decision to renew our collaboration. For example, the research cost difference between Mexico and the United States is absolutely mind-blowing, especially when it comes to PhD researchers. Although UDIBI already offers among the highest wages within the Mexican research sector, Mexico’s research wages remain four to five times lower than in the United States. Of course, this favorable cost difference also positively impacts the price of services.

Considering this competitiveness, we currently look at increasing our visibility beyond the Mexican borders, starting with the United States. This internationalization strategy is already paying off, as we recently bound a partnership with a biotech company based in Boston, to which we appeared way more competitive and cost-efficient than our American counterparts.

What are the main challenges that you face in offering such quality of services in Mexico and how do you overcome them?

The design of protocols to evaluate efficacy, safety and biosimilarity demands to have well trained scientists capable to develop analytical techniques and animal models. For this reason, to have well trained human resources is one of the challenges in our lab we provide to our personnel to take national and international trainings in quality, regulatory affairs and biotechnology products in order to improve our operations, develop new models, keeping focus on the client satisfaction.

In Mexico, one of our main challenges still relates to the supply of the raw material needed to conduct cutting-edge research. For most research-driven companies, it remains challenging to access these indispensable resources in a timely manner, mainly because of the approval timelines displayed by the different regulatory and custom agencies. When you have to wait for two months before receiving the required reagents, it becomes extremely difficult to be competitive from an international standpoint.

Considering this tough context, we recently bound a strategic partnership with an American supplier, which now imports on our behalf the research material we need. As a result, we don’t

have anymore to wait for several months before receiving these crucial resources, and we can be as competitive as our most prestigious international competitors.

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