Interview: Claudia Soto – General Manager, PAREXEL Mexico

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Claudio Soto, general manager of PAREXEL Mexico, discusses how the clinical research process required to receive approval for a new clinical protocol in Mexico is fairly straightforward compared to other countries in Latin America. She also addresses the government´s increasing awareness of the importance of their role in helping to fuel the overall economy, as well as how

Mexico can serve as the door to the Latin American market, with many potential clients showing interest in having a presence in the country.

IMSS and Cofepris reached a cooperation agreement to increase the participation of beneficiaries with chronic diseases in the research protocols of drugs. Do you believe such cooperation provides an opportunity for the CRO industry?

This is a great opportunity for pharmaceutical and CRO companies, and for the patients belonging to such institutions in Mexico – as this agreement enables them to receive new alternative treatments for chronic diseases. A high number of people with chronic diseases stand to benefit from receiving an alternative treatment entering into the clinical research protocols.

What advantages does Mexico have as a clinical research environment when compared to competitors in the region?

The clinical research process required to receive approval for a new clinical protocol in Mexico is fairly straightforward compared to other countries in Latin America. Mexico’s advantages include a

substantial patient population in a number of therapeutic areas. There are many qualified trial investigators and facilities suitable for clinical research.

In terms of infrastructure, how would you evaluate the level of infrastructure and human resources in the country?

Hospitals in Mexico are ranked from level one to three. From a clinical research point of view, if we would like to work with a specific hospital, site or principal investigator, PAREXEL will visit the potential site to assess whether the specific facility meets the needs of the study. The principal investigator must be a medical doctor qualified to run such a study.

According to M. Arriola, nearly 37 percent of clinical research studies realized in Mexico are Phase three clinical trials, the objective of which is the final confirmation of safety and efficacy of new drugs. At what stages of clinical research is Mexico competitive and why?

Mexico is capable of participating in the four phases of any study. At PAREXEL, we also work on all phases. The main interest of a sponsor is to have the authorization from Mexico's Ministry of Health (MoH) to have new molecules approved for sale on the national market. This is why the market is so important for sponsors.

The latest figures we have are that global investment in clinical trials is USD 70 billion and only USD 200 million are invested in Mexico. What is holding Mexico back from receiving more sponsors?

There are multiple factors restraining the growth of our industry. One such factor is , delays in the authorization of drugs from the MoH. There have been instances when protocols were not ready to be run in Mexico because they were lacking the required approval. As an industry, we need to be competitive. Sponsors are always looking to start with the fastest country. The sooner a study can begin, the more patients can be included. Additionally, the Mexican government underwent major changes two years ago, which caused disruption within the MoH, as well as other institutions and hospitals.

We heard from Eric Alvarez, managing director of Janssen de Mexico, that the government´s attitude to the sector is starting to change. He sees a growing understanding that conducting more studies can be the best investment in the country´s future. Do you see such a change in mind-set occurring?

We are witnessing a change in mentality in the sector. Last year, the MoH implemented a strategy to increase cooperation with the pharmaceutical industry and CROs improving timelines as part of the regulatory approval process. Following this initiative, we have seen improvements in timelines and the authorities have became aware of the importance of our role in helping to boost the overall economy.

Why do you believe the government is now starting to take more of an interest in the sector?

PAREXEL, as part of the alliance of CROs in Mexico, as well as the pharmaceutical industry through AMIIF (Mexican Association of Pharmaceutical Investigation Industries), makes a concerted effort to work with the authorities. We have discussed with them the impact delays were having on clinical research timelines and the importance of the MoH in this process. As a wider industry, the CROs and pharmaceutical companies have worked together to establish a channel of communication with the government.

PAREXEL is the only biopharmaceutical services provider offering a comprehensive global network of expertise, clinical resources, and technology within a single company. Globally, PAREXEL is strong in oncology, cardiovascular and metabolic, CNS, and infectious diseases; what are the most important areas for the business in Mexico?

In Mexico, we are focusing on metabolic disorders, such as diabetes. In Mexico, we are focusing on metabolic disorders, such as diabetes. We are participating in various studies in the rheumatology field. We have also been participating in infectology studies for HIV. We receive a lot of satisfaction when drugs under investigation have a positive impact on the patient.

PAREXEL was involved in bringing some of the first biosimilars to Europe, and also worked on 95% of the top 200 biopharma products. How does this experience color your outlook on Mexico´s biosimilar efforts? What is your outlook on biotechnology development in Mexico?

PAREXEL’s strong presence in Europe is very important. As many of our clients are investing in biotechnology, we see this as a large focus for the future of the clinical research industry.

Josef H. von Rickenbach, Chairman and Chief Executive Officer of PAREXEL, said in 2006 at the time of the opening of the Mexico office, that the county was “one of the most important Latin American centers for medical device companies planning to conduct domestic and global clinical research programs.” How does Mexico fit into a global

clinical trial strategy?

Mexico can serve as the entry to the Latin American market. Most potential clients are interested and able to use the country as a means to expand into the rest of the region, including such countries as Chile, Argentina, Brazil, Colombia and Peru. From a business point of view, Mexico opens the door to start such an activity, as it hosts a large population that can participate in clinical research studies. As such, many clients ask for Mexico to be included in their work.

The geographic location of Mexico is also a considerable advantage. We are very close to the US, Central America, and other countries in Latin America.

What would you like to see PAREXEL Mexico achieve in the next five years?

Within five years, we'd like to see PAREXEL Mexico seeing strong results from successful clinical research studies, including those for biotechnological drugs. This is an emerging market and we are ready to begin working on these studies.

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