Interview: Salvador Berrios Vides â?? Managing Director & Graciela Aguilar Gil Samaniego â?? Technical & RA Director, Qually â?? Mexico

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The technical & RA director and the managing director of Qually Corporacion explain how authorized third partied act as an extension of the regulative body, Cofepris, helping to assure that generics obtain a certain standard before they are released on the market, that is why the main challenge is to be able to produce a laboratory capable of working on biosimilars and how generic drugs represent the future of Mexican pharma.

Qually Corporacion is a young company, founded in 2000 and one hundred percent Mexican. Graciela, what needs did you identify in the market when creating the business?

In 1993, the Mexican Minister of Health began a program to encourage the use of generics in order to increase the populationâ??s access to treatments. Initially there were many products on the market without the required bioequivalence study; as the legislation did not required it, the quality, efficacy and security could not be assured. Over the years, this has changed with numerous guidelines regulating the market. The government did not have the financial means to work on this process alone, and sought the help of private companies, such as ours, to help in this process. In 2005 Cofepris insisted that products must have a bioequivalence study, but most companies ignored this rule, continuing as if nothing had changed. A deadline was set in 2010 for companies to follow this rule and in that time, around 30 third party laboratories were created. Before 2010 there were approximately 15,000 drug products registered, after 2010 there were around 10,000 products remaining. With it being compulsory for all generics to have a bioequivalence study, companies now had to carefully select which products they released to the market.

Cofepris has a commission named *ComisiÃ³n de Control AnalÃtico y AmpliaciÃ³n de Cobertura* (CCAYAC) responsible for authorized third party in Mexico. Every two years we have to renew our authorization with this body and we are highly regulated by Cofepris, acting in partnership with them.

Salvador, you were appointed managing director of Qually Corporacion nine months ago. What have been your key priorities?

My priority has been finding new business with new companies and countries. We need to expand our services outside of Mexico, looking to the rest of Latin America, and our intention is to open another office building, potentially in Brazil or Argentina. We have also started implementing new services, such as sterility tests, technology that we ordered from Shanghai, and we have the ambition to open a business office in this city as well, which produces numerous APIs, to help encourage a trade relationship with China.

We are very interested in developing biosimilar technology, a market that presents new challenges for the regulatory bodies. We are looking to open a new business office in Guadalajara, Mexico, dedicated to this area, which we hope to be up and running by December 2015.

The health ministry of Chile has recognized our bioequivalence studies, as the country does not have the infrastructure to produce authorized third parties, and consequently they select some from outside countries, many of which come from Mexico.

We are waiting for recognition from the Brazilian Health Surveillance Agency (ANVISA); numerous large companies, such as Actavis in Canada, Synthon in the Netherlands, and MSD in the USA have approved us.

Graciela and Salvador, What are the most important services that you offer?

The most important service we offer is laboratory testing, a sector in which we have always worked in and which allows us to fund new business areas. After 2010 the generics market shrunk, with the requirement to conduct a bioequivalence study being compulsory. One of the advantages that Qually Corporacion has is that we offer other services. Indeed, one of the most promising is in R&D, where we have a large commercial infrastructure, with business in Brazil, Colombia and Guatemala. Within the next few years we expect to increase significantly our work in this area. We have also have been selected to transfer a biotech product, produced in the USA, to Mexico. This will be the first biotechnological vaccine in the country.

Another important area is oncology. Within the next two years most oncological products will go off patent and patients expect to have affordable products available as soon as possible. Alongside hormonals and biosimilars, these kind of medicines represent the future for therapeutic drugs in Mexico, where we are moving beyond antibiotics and anti-inflammatories, the most common products in the country, to more high potency medicines. During the next five years there will be a lot of competition from companies trying to register their products in Mexico and Qually is the outsourcing solution for this kind of business.

Graciela and Salvador, What are some of the main challenges you face as a company?

The main challenge we face as a company is to be able to produce a laboratory capable of working on biosimilars. These products are different to other drugs, requiring more experience and new specialized equipment. Around the world biosimilars are increasingly being produced and if we want

to sell such a product in Mexico, an outsourcing company like Qually Corporacion must conduct analytical work, following the same bioequivalence model but with new technology and new infrastructure. We participate in numerous conferences on biosimilars, in Europe and the USA, in order to be up to date with the new tendencies and how other countries are reacting to the challenges faced in this area.

Salvador, As Qually Corporacion do you have a five-year vision?

We have invested in a new administration system where all our operations will soon be stored in the cloud and I hope that by December 20 of 2015 we will have finished our transfer to this new system. Within the next two years we expect to have the first certified biosimilar products by Qually, our pilot plant for R&D in Guadalajara should be fully functioning and we should have an office outside of Mexico, most probably in South America.

Graciela and Salvador, Do you have a final message for our readers?

It is important that the authorized third parties do not feel pressurized by the pharmaceutical industry: we have the drug products of the future in our hands and we need to ensure that all are of proven efficacy, safety and quality to be fully authorized by the Ministry of Health. We act as referees in selecting which drugs meet the standards and we must conduct our activity with the confidence of all stakeholders. The quality of a product is not our responsibility; our task is to make a precise analysis of the samples and our client can then decide to make the required changes, or remove their product from the market. At the end of the day, we all have the same ambition, to deliver high quality products for the Mexican citizen.

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