

Interview: Cecilia Calderón - Founder & General Director, Vigpharma, Mexico



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Cecilia Calderón, general director at Vigpharma, highlights how the national pharmacovigilance and technovigilance regulations have been evolving during the last five years as well as showcasing the added value of Vigpharma to help both public and private institutions keep pace with such dynamism.

Ms. Calderón, you have more than 13 years of experience in leading pharmaceutical companies. What triggered you to found your own company in 2014?

Even though the first pharmacovigilance law in Mexico was implemented in 2005, the regulation in such field started to become very strict in 2013 and there was a lack of knowledge in the compliance area. Therefore, I identified an opportunity to support the industry to enhance its pharmacovigilance and technovigilance compliance in their operations.

In addition, we are working with different Associations to support the Mexican healthcare authorities to enhance the national landscape in both the pharmacovigilance and technovigilance areas.

What have been the biggest accomplishments of Vigpharma since we last met you in 2015?

We started our operations back in 2014 and we have enjoyed promising growth rates since the beginning; indeed, we already signed our first contract the very first day of Vigpharma, it was a great opening!

I am proud to confirm that we have expanded our clients' portfolio based on our great results and the word-of-mouth of our clients. Thus, Vigpharma has an interesting customers' portfolio that embraces nearly all the leading pharmaceutical players in Mexico; furthermore, it is important to highlight that the majority of such clients are requesting complete or integral solution meaning that Vigpharma is fully in charge of their pharmacovigilance management. In addition, we have had the opportunity to collaborate (through our contributions in several Associations) with Cofepris to update the national pharmacovigilance regulation, which will be published in February or March of 2017.

To conclude, our biggest achievement has been to gain the confidence from the public and private sector in Mexico, and remain a reliable partner for the industry.

What has been your strategy to ensure the success of Vigpharma considering that Mexico is a quite a dynamic and challenging market from the regulatory standpoint?

We have always anticipated the changes that are taking place in the industry and the fact that Vigpharma is closely collaborating with different organizations of the Pharmaceutical field as recognized Associations and the national authorities, which has helped us to be successful in this sense. Vigpharma fully understands Cofepris' requests and we therefore help our clients to be part of such common knowledge; it obviously needs to go hand in hand with excellent work in each of our services.

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Vigpharma has a broad portfolio sorted out in two major divisions: pharmacovigilance and technovigilance. Could you expand on what type of solutions is Vigpharma offering in each one of them?

In both areas we provide either an integral solution, which means the entire management of the unit, or modular services. Our commercial approach is to offer a fully integrated solution to our clients; however, we normally start our commercial collaborations with smaller services. Vigpharma is positioned as an extension arm of its customers' regulatory departments through managing their entire pharmacovigilance or technovigilance units.

What is your breakdown of revenues per division?

Pharmacovigilance is currently our main contributor representing around 90 percent of our total revenues; nevertheless, we are aiming to enjoy a more balanced mix in the near future because of the changing regulations and increasing need for technovigilance services in Mexico.

The reason why pharmacovigilance concentrates the majority of our business is that it has become drastically stricter in the last four years demanding stronger levels of security and safety in the medicines that are in the market. However, according to Cofepris, technovigilance is going to be the new focus of the national regulators as the pharmacovigilance landscape is already well controlled.

Vigpharma ensures that the products of the pharma, biotech and orphan medicines companies are doing what they are supposed to do. What is your footprint in each one of the markets?

The pharmacovigilance regulation for the biotech, orphan, and allopathic segments does not vary at all. Nonetheless, allopathic players represent roughly 75 percent of our total clients' portfolio since it is the largest segment in Mexico.

Human capital is one of the most important assets in your operations since your employees are the ones that are certainly the ones bringing high quality and reliable results to your clients. How is Vigpharma attracting, retaining and developing its professionals maintain such quality in its operations?

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It is certainly a challenge and we have developed a very rigorous human resources plan in the company. In terms of attraction, it is a fact that both pharmacovigilance and technovigilance areas are still in their inception but there is a lot of development yet to come there; and, considering that we offer our employees the opportunity to be enrolled in such landscape since the beginning, it is an great opportunity for their professional profile. Even though we assume that our clients will move onto other professional step in the future, we highly invest in their development trough training courses and so forth. In addition, we also strongly empower our teams since the very beginning giving them full responsibility about the projects that they are leading.

Vigpharma runs partnerships with other public and private institutions such as AMEPRES, CANIFARMA and Cofepris in order to enlarge the reach of its operations. Could you explain your partnership strategy to our international audience?

We are closely collaborating with them to position Vigpharma as the specialist in the field. We separate our relationship with such institutions from our commercial purposes in order to avoid any conflict of interests that may arise. Our partnership strategy with them aims to create a constructive association that will enhance the national pharmacovigilance and technovigilance landscapes in Mexico.

How is Mexico positioned within the regional pharmacovigilance and technovigilance landscape?

Mexico is leading the development of both the pharmacovigilance and technovigilance within the region and it is a reality that many of our neighboring national regulators are using Mexico as an example of what should be done in their respective countries. I would like to highlight the excellent role that Cofepris has played in this sense putting Mexico in the regulatory spotlight within all Latin America.

One of your main objectives as founder and CEO of Vigpharma is to drive the internationalization of the company. What have been the advancements in the internationalization process of the company?

We are currently 100 percent focus on developing our business in Mexico but we will be able to help our clients in pharmacovigilance and technovigilance subjects in other countries within the region if they need it. In this sense, the fact that Cofepris aspires to be the standard of quality in the region meeting with the requirements set by leading regulators such as EMA and FDA, has been very beneficial for us; we strongly consider such trend as a potential lever to drive our internationalization in the mid future.

What is the key competitive advantage that makes Vigpharma the partner of choice for the industry?

Our positioning within the market is certainly a key competitive advantage that differentiates us from any of our existing competitors. As we are fully aware about that, we invest a lot in building up such collaboration with Cofepris and other institutions and remain at the forefront of pharmacovigilance and technovigilance subjects in Mexico.

What are the key objectives that you would like to achieve in the upcoming three years?

The main priority on my agenda is to ensure that Vigpharma will maintain such leading positioning in both the technovigilance and pharmacovigilance areas. Secondly, one of my objectives is to continue developing our strong non-business relationship with associations and institutions within

the industry such as Cofepris. Finally, I want to grow my team of high quality professionals to support the accomplishment of the aforementioned objectives.

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