Interview: Consuelo Albarrán – CEO, DEFI Latina Healthcare, Mexico



"Although the Mexican biotech market is still maturing, we undoubtedly notice a strong trend in bringing to the market an increasing number of therapies targeting diseases with a developing national prevalence, such as diabetes, cardiovascular diseases and cancer - and most of these therapies are biotech treatments."

03.11.2016

Tags: Mexico, DEFI Latina, Biotech, ATP, Healthcare, Pharma, Pharmaceuticals

Consuelo Albarrán, co-founder and CEO of DEFI Latina Healthcare, showcases the increasing added value brought by this leading Cofepris-authorized third party (ATP) to the pharmaceutical industry, the recent expansion of the company's capacity into the biotech field, and its readiness to increase collaboration with both pharma companies and Cofepris to further strengthen Mexico's healthcare eco-system.

DEFI Latina has been steadily developing and consolidating its leadership position as the partner of choice of both the healthcare industry and Cofepris. In this sense, you notably received in January 2016 the certification to review biotech treatments' approval dossiers on behalf of Cofepris. To what extent does this certification stand as an important milestone for DEFI?

I have always been looking at expanding DEFI Latina's capacity into other product areas of the regulatory scenario, and, in this regard, we were particularly interested in the opportunity of diversifying our operations into biotech treatments' approval. I am particularly glad to announce we were among the very first ATPs to receive this biotech certification from Cofepris, which perfectly showcases how DEFI continues to remain at the forefront of the industry year after year.

There is no doubt that biotech products represent the future of the pharmaceutical industry. Although the demand for allopathic and medtech review continue thriving, we have experienced a

significant growth in the demand for reviewing biotech products and, currently, this segment is our fastest growing area.

Although the Mexican biotech market is still maturing, we undoubtedly notice a strong trend in bringing to the market an increasing number of therapies targeting diseases with a developing national prevalence, such as diabetes, cardiovascular diseases and cancer – and most of these therapies are biotech treatments. As a result, increasing our footprint in the biotech area undoubtedly is one of my strategic priorities moving forward.

Merck, Sandoz, Pfizer, Hetero and Probiomed for example told us that they want to launch several biotech treatments over the next four years, while receiving market approval is one of the most critical steps for these companies. In addition, biotech treatments stand as very complex products, while Cofepris has been tremendously heightening regulatory requirements since the release of the NOM-257. How have you been adapting your organization capacity to ensure you can cope with this new responsibility?

[Featured_in]

First, receiving Cofepris certification implied following an intensive medical and technical training during more than three months. It is true that most ATPs have only just started to really adapt their infrastructure to conduct such new certification, and there is a deep industry need for new certified experts in order to meet the current and future demand for drug approvals, especially in the biotech area. Nevertheless, DEFI has already certified doctors and chemists for biotech dossier review, allowing us to fully cope with this increasing biotech demand for the moment.

In addition, we are further developing our biotech capacity by training additional staff as experts, despite the significant resources required. We have also embarked and are about to complete an 18-month ISO 9000 certification program implemented companywide to ensure the highest quality standards.

DEFI has been able to establish itself as one of the industry leaders thanks to the expertise of its teams, and the quality of our human resources is something we will never compromise. Our policy is to hire top graduates and train them until we are sure that they will be ready to succeed Cofepris’ exam for a given certification. As a matter of fact, we boast one of the highest success rates at Cofepris exams among the entire industry.

How would you assess Mexico’s capacity to carry out bioequivalence studies for biotech drugs?

Despite the fact that conducting these trials supposes a new challenge for Mexican CROs, there are already some local companies that have the Cofepris certification for that. This is an ongoing and evolving relationship between Cofepris and ATPs conducting such trials to ensure biotech studies comply with the international guidelines. Cofepris has been actively involved in advancing towards international convergence in terms of regulation through organizing conferences to ensure that the Mexican regulation complies with international guidelines.

How is the pharmaceutical industry supporting the operations of ATPs such as DEFI?

The industry is becoming more and more involved in the improvement of ATPs’ processes. As an example, Roche organized two weeks ago an important event that aimed at homogenizing criteria for dossier reviewing, gathering ATP companies, Cofepris and international experts.. Industry recognizes the added value and the positive impact ATPs have been bringing since we started our operations five years ago, and they are increasingly engaging and collaborating with us. Nevertheless, greater outcomes could be reached by further enhancing this collaborative approach, and all stakeholders of the healthcare value chain have to further intensify their efforts in this regard.

In an industry where cost-containment pressure already stands as a daily reality, companies are looking for service providers that allow them to operate more rapidly, more efficiently while maintaining a remarkable level of quality to avoid any delay. How can you ensure DEFI Latina remains ahead of its customers’ expectations?

First of all, DEFI Latina is one of the longest standing and best positioned ATPs within the industry, and we received some of the best reviews and annual evaluations ever awarded by Cofepris.

[related_story]

In my opinion, one of best opportunities to further improve our processes will pass by the increasing openness of our clients to truly consider us their partners, while actually we already operate as an extension of their own regulatory department. In the meantime, we also stand as an extension of Cofepris’ approval capacity. In this regard, operating at the junction between Mexico’s regulatory agency and the industry also poses a relative challenge, as both of them display different and sometimes contradictory interests. As a company, it is then really important to be aware of where are the limits in our collaboration, as preserving our credibility absolutely is

paramount.

As expert in the pre-approval of treatments, one of our main challenges has been to foster a continuous change in the way our clients have been traditionally approaching market approval methodology. As the legal framework in which we operate is getting stricter, our clients increasingly understand the value of our expertise and embrace our working methodology, which is the best way to receive faster drug approvals.

As CEO of the company, what will be your main priorities to nurture the future growth of the company over the next three years?

DEFI Latina employs over 35 employees and I expect our personnel will grow over the upcoming years, both in terms of certified employees and revenues. Looking at our customer basis, we grew from 32 clients two years ago to more than 45 in 2016, comprising both international and local companies. Based on existing new contracts, I expect to start working with eight new clients by the end of 2016.

I want to maintain our specialization in treatment approvals and enlarge our footprint in biotech drugs' approvals, while we may consider other regulatory areas such as pharmacovigilance. DEFI Latina was one of the first ATPs to receive the four Cofepris certifications and we will ensure to be among the first companies to get awarded any new certification that may be released by Cofepris in the upcoming years.

In addition, I expect ATPs to play a more important role within the health eco-system over the upcoming years, especially given the current economic context and the recently announced health budget cuts. If Cofepris wants to further increase its high standards in the context of scarcity of public resources, it will have to leverage the resources and the expertise of private companies such as DEFI Latina – and we are already ready to fulfill this heightened fundamental mission.

See more interviews