

Interview: Consuelo Albarran Ampudia – CEO, DefiLatina Healthcare – Mexico

The CEO of DefiLatina Healthcare reveals how a reliance on social security has seen the public health system struggle to meet the demands placed upon it, how her company's vision is to partner with the regulatory authorities, helping to increase the country's access to medicines and why they were voted among the most trusted authorized third parties.



Can you tell our readers about your idea behind the establishing of DefiLatina Healthcare? What needs were identified in the market when creating the company?

We were founded in 2011 to act as an extension of the regulatory authority, Cofepris. Our vision is to help our government, and health ministry, to deliver medicines, that are safer and more effective for the benefit of the Mexican citizen.

The Mexican population is aging and consequently we are seeing an increase in chronic diseases. People now require new types of medication that is efficient, secure and affordable. In [Mexico](#), the use of private health insurance is not common practice; instead people have traditionally relied on social security, a public health system financed through onerous taxes in order to meet the demands.

In 2010 Cofepris realised that there were between eight and ten thousand products that had not been approved, many of them generics. Mikel Arriola, the visionary commissioner of Cofepris and his staff, saw an opportunity to take the review of technical and medical information on the dossiers submitted for approval from Cofepris out of government hands and invited the private sector to play this role. Reviewing dossiers is a delicate and time consuming job done, page by page almost like the work of an artist. It is not something that can be processed in bulk by a machine. In 2011 Cofepris invited companies interested in becoming authorized third parties, to go through the application process and an extensive audit. Our company's team of two passed the exams and three short years later we have grown to 24 professionals, including three doctors and 19 chemists who have earned the highest grades in certification exams.

Authorized third parties were introduced by Cofepris in order to speed up the registration and renewal process for drugs and medical devices. Could you explain to us how the system works, how it can help drug and medical device manufacturers to register their products?

The pharma industry is constantly seeking new registrations, renewals and or amendments to existing dossiers. Initially there were only four authorized third parties, now there are 19. In terms of productivity, 285 drugs were approved by Cofepris in 2013 through the review of third parties, and 656 in 2014, an increase of 141 percent. In medical devices it went from 577 in 2013 to 1050 in 2014, an increase of 82 percent. We have an excellent working relationship with Cofepris, and we are seeing considerable improvements. Before third parties, a dossier could take three years to be approved; now, working with the private sector, it takes around three months. Time is money, and especially for the pharma industry. With the help of third parties, foreign companies that want to enter the Mexican market can register their products and start selling in a very short period of time.

What are some of the main challenges you face as a company and how do you overcome them?

Our main challenge is working with our clients who have great knowledge and experience in regulatory issues. Although they sometimes push to keep working in the old ways it is our job to train them and make sure they understand the benefits of the new system. Given the strict legal framework in which we operate, clients can feel

overburdened with information requirements but they need to understand that our objective is to ensure that the dossier is complete and easily understandable for anyone who reads it which will allow for a faster and more accurate approval.

Why is DefiLatina the partner of choice? What is the added-value you offer to clients?

Cofepris keeps a strict eye on all third parties auditing and supervising us to make sure we are trustworthy and accurate on our evaluations. DefiLatina has been rated among the best third parties by Cofepris based on the number of dossiers submitted, the very few and not critical preventions issued for our dossiers and the evaluation by Cofepris staff. In the end it all comes down to results and we have never had a dossier rejected. We can prove our efficiency with more than 200 approved medications.

At DefiLatina we try to be creative with clients. We do not charge for services that many other companies do, such as initial consultations. In order for us to take on a project we want to feel confident that we will be able to deliver what we promised.

We also take security very seriously. Our office is surveyed by fourteen CCTV cameras, doors are electronically locked and the computers that our chemists use do not have any USB sockets. All our clients are protected with NDAs, and therefore we go out of the way to ensure that their industrial secrets are never leaked.

We like to keep our clients in the loop through detailed weekly reports specifying the week's findings. This way our clients can see our progress with their projects and work with us to expedite the approval process.

As a company, you attach a great deal of importance to the training of your staff. Could you say more about this focus and why it is an important part of your business model?

Our team is our main asset. We run a very tight ship and that is why we have paced our growth, taking on average five to seven new chemists per year. Our policy is to hire recent graduates, offer them a position at DefiLatina and then train them for a whole year after which we decide who is ready to pass the Cofepris exam. As of today all of those selected have been successful.

We like to consider ourselves a boutique company, carefully selecting our clients and offering a very personalized service. We look to grow at a steady, efficient and sustainable pace.

What is your three to five year vision for the future of your company?

I see continuous controlled growth with our company expanding into other areas of the regulatory scenario such as biotech and pharma vigilance. The government infrastructure cannot keep growing indefinitely and sooner or later much of the work they do will have to be delegated to the private sector. I feel DefiLatina has a great future and hope that it will stand strong for many years to come.

What is it that motivates you every day?

The fact that I started DefiLatina from scratch. I was an employee for a number of years, and being an owner is more challenging but also more rewarding. Every new registration that is approved through our company makes me feel very happy because we are helping bring quality medicines and medical devices to the Mexican market.

I love to feel that I am accomplishing something and take great pride on passing the knowledge I have acquired along so many years on to new generations.