Interview: Carlos Pérez Munguía – CEO at NYCE, Mexico



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Carlos Pérez Muguía, CEO at NYCE, showcases the increasing added value brought by this leading Cofepris' authorized third party (ATP) to the healthcare industry, the future objectives of the company to enter into the biotech field, and its readiness to continue helping Cofepris in other areas to further strengthen Mexico's healthcare eco-system.

Could you please introduce to our international readers the key operations of NYCE as well as the company's milestones during the last five years?

NYCE was founded in 1994 and it currently has more than 330 employees. Our operations are focused on the standardization, certification, verification and training of products and services for different industries. Therefore, we are recognized as a certification body by the Mexican government and we are heavily investing in expanding our operations within the region. We started our activities in the electrical and electronic products but we rapidly diversified our business portfolio onto different industries such as healthcare.

NYCE has more than 20 years of experience positioned as one of the leading companies in certifying and verifying products of different industries. How strategically important is the healthcare and life sciences industry within your entire business?

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We identified the business opportunity in the national healthcare and life sciences industry when Cofepris created the figure of Authorized Third Parties (ATPs) in 2011 with the aim of leveraging on

private companies the operations in the registration of new drugs and medical devices. Indeed, the government does not have enough financial resources to do such tasks by themselves and, therefore, they need the ATPs figure to enlarge the Mexican market access to innovative and high quality health solutions.

There was a necessity and we already had a longstanding expertise in the verification industry backed up with a very strong quality system during more than 22 years of operations. In 2011 we undertook the strategic decision to enter this area and we managed to have the infrastructure and the capabilities needed to compete and operate as an ATP in less than three months. Currently, NYCE is able to register, modify, and extend dossiers for both pharmaceutical and medical devices solutions.

In terms of mix of revenues per business line, electronic, electric, telecommunication and energy efficiency certifications have always been our main contributors, representing around 55 percent of our total income. The healthcare business line represents approximately eight percent of our total business but we expect to substantially grow the size of such line in the next five years.

NYCE is positioned as an ATP for pharmaceutical and medical devices companies. What is your footprint in each one of the industries you serve?

Our mix of revenues of pharmaceutical versus medical devices has varied throughout the last three years, hand in hand with the performance of each industry. In fact, 80 percent of our operations in the healthcare industry in 2011 came from medical devices dossiers; however, we managed to turn it around and currently 60 percent of our revenues come from pharmaceutical dossiers.

Such transition has been a consequence of the regulation changes carried out by Cofepris during the last five years. We have been able to successfully adapt our clients' portfolio to the latest industry trends strengthening our footprint in the pharmaceutical sector attending to different events leaded by pharmaceutical associations such as Canifarma. I would like to reinforce that it has not been an easy task considering the fact that Cofepris also decided to increase the number of ATPs in the market from 11 players in 2012 to nearly 21 in 2014.

Are you considering obtaining any other certification from Cofepris to act as an ATP in other business areas such as biotech?

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It is a fact that the current national healthcare interests are more focused on chronic rather than infectious illnesses; and such health issues can only be properly targeted through biotech or

biosimilar drugs. This is a big challenge for us and we are already investing in building up the capabilities needed to get the certification by Cofepris to act as an ATP for such biomedical medicines. We expect to obtain the certification to review biotech dossiers by the first semester of 2017.

NYCE stands as a bridge between Cofepris and the industry, which both have different priorities. How do you manage the pressure of both sides in order to meet their needs ensuring the quality as well as minimizing lead times?

We have more than 22 years of experience in the certification and validation industry and we fully understand the interests of both sides. Referring to the healthcare industry, we contracted a third party before entering such market in order to assess the level of service that we were able to offer; I am proud to confirm that we obtained a score of 97 percent of satisfaction. Indeed, we have designed a scorecard, containing specific metric to ensure that we are able to meet our service level, in reviewing and ruling a dossier in less than 20 working days.

In addition, Cofepris has recently reviewed all our processes as well as facilities and we have obtained outstanding results positioning NYCE as one of the leading ATPs within the industry in terms of quality and servicing (we were graded highly reliable by COFEPRIS).

How do you manage to obtain such level of quality?

Quality must be reattributed and, therefore, the salaries of our employees are higher than the average of the industry to ensure that we attract and retain the best talents.

Nevertheless, there has been a trend of reducing the final prices of the service during the last two years as a consequence of the increasing number of ATPs in the industry. We have had to adapt our pricing to such trend enhancing our efficiency ratios to ensure that we are fully able to remain competitive both in terms of prices and margins.

In this sense, we are investing in developing an IT system that will allow our customers to send us all the information online. We will be able to implement such operational improvement once we get the ISO 27000 certification by the beginning of next year.

Sanchez y Tepoz and many of the companies that we have met have highlighted how ATPs have been playing a crucial role in enhancing the Mexican healthcare ecosystem. How are you partnering with Cofepris in order to continue improving the Mexican regulatory system?

In 2011 we supported Cofepris by training their professionals, free of charge, in the implementation of quality systems in the healthcare industry. We consider ourselves as an extension arm of Coferpris' operations and we enjoy a symbiotic relationship with them.

We are currently discussing with Cofepris in different angles because there are other areas such as manufacturing certification where the ATPs' model does not exist and in which NYCE could help the government based on our integrated expertise in other industries. We consider that there are a lot of opportunities, both for Cofepris and for us, and I would like to develop them based on a win-win relationship.

NYCE has international presence in Colombia, China and Hong Kong. The ATPs model is quite unique and it is a fact that several countries across the region are looking into such model in order to implement it in their healthcare regulatory system. What are your conclusions on that and how do you perceive such circumstance as an opportunity to continue driving the internationalization process of the company within the region?

Even though it is true that the entire region is interested in ATPs' business model to enhance their local regulation and market access to high quality and innovative health solutions, each country has its own regulation body with its specific rules and standards.

There is a challenge in such international business opportunity and Cofepris is already doing some agreements with some other national regulator bodies from other countries in order to extrapolate the same process carried out in Mexico for registration, to other nations such as Chile and Colombia.

We are currently in the process of assessing if the authorities in other countries will release the figure of ATPs and we are targeting to promote such model in Colombia and Central America in the mid-term.

What is your main competitive advantage that makes NYCE the partner of choice considering the fact that cost, lead times and quality are critical for the industry?

The fact that NYCE is an atypical ATP with its broad portfolio of solutions targeted to several industries has certainly played an important role in our performance. We are able to offer an integrated solution to our customers in different areas such as quality management systems, electrical and electronic products.

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

As aforementioned, one of my main objectives is to increase our footprint in the healthcare industry. Indeed, we estimate that NYCE has around seven percent of the market share and we expect to increase that figure in the next three years. We will increase our capabilities and infrastructure leveraging our performance on our competitive advantage of being able to offer integrated solutions to our customers.

In addition, I will be fully focused on maintaining our equation of success based on improving our efficiency by reducing costs but maintaining the quality in order to offer the best service level to our clients.

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