

Interview: Luisa Gutierrez - CEO, Medisi, Mexico



"We are a company that helps the medical devices business community to get the registration of its products done correctly and efficiently."

22.03.2017

Tags: [Mexico](#), [Medisi](#), [Medtech](#), [Regulation](#), [Registration](#), [Market Access](#), [Investment](#)

Luisa Gutierrez, CEO at Medisi, explains the importance of helping get fast registration for high quality medtech products registrations and explains Medisi's integral solutions for both the regulation and distribution of medical devices.

Ms. Gutierrez you have quite an unusual professional profile. What triggered you to start your entrepreneurial journey with Medisi in 2012?

I started my professional career working as an interpreter with an international legal approach and during this stage I had the opportunity to enter into the healthcare and life sciences regulatory world, and more specifically medical devices regulatory affairs. Afterwards, I got hired by a leading medical devices distributor to lead its regulatory affairs department and took intensive training courses about medical device regulation.

It is well-known that Mexican regulation is mostly tailored to pharmaceuticals rather than medical devices and, consequently, there was an inherent challenge when interpreting such regulation for medtech. I took advantage of my interpretation skills to disrupt the way the registration for medical devices was done and I had outstanding results in getting such registrations done better and faster.

I identified the opportunity and I decided to turn such best practices into a business when I had the opportunity to acquire Medisi back in 2012. Medisi was founded in 1980 and I had already enjoyed a good relationship with the founders for a long time. Thus, I acquired the company and reshaped

its strategy, focusing on Medisi's operations in medtech regulation services to implement my knowledge as well as the best practices in the company.

Could you please introduce our international audience to the main activities and operations of Medisi?

We are a company that helps the medical devices business community to get the registration of its products done correctly and efficiently. Our concrete services vary according to our clients' portfolio needs.

Most of our clients are international SMEs that are looking to expand their business in Mexico and such players also need a company based in the country to hold its product registries; indeed, as opposed to other countries in Latin America, in Mexico companies cannot own a Mexican registration if the company is not fiscally based in the country. In this sense, Medisi also acts as a registration hub for these clients.

Medisi offers an extensive spectrum of services such as registration projects, registration holder, and distribution search. As a consequence, we are able to offer an end-to-end and integral solution from the registration to the distribution of the products.

[Featured_in]

In addition, we are also starting to enlarge our product portfolio offering into other areas within the regulation arena such as quality assurance for international maquilas *[manufacturing operations where factories import certain material and equipment on a duty-free and tariff-free basis for assembly, processing, or manufacturing and then export the assembled, processed and/or manufactured products, sometimes back to the raw materials' country of origin e.d.]* since they need the national GMP to produce in Mexico.

What have been the main accomplishments of Medisi since 2012?

Medisi has positioned itself as a highly reliable partner for the international and national medical devices business community to get effectively and efficiently its products registrations.

Your results talk for themselves with an annual growth rate of 250 percent since 2012, an average of 65 projects per month, a 100 percent rate of success, and an increase of personnel up to 25 in 2016, all against the backdrop of an increasing number of competitors. What has been your strategy to ensure such success?

Our strategy is based on two major pillars: solid expertise and deep understanding of our clients' needs. This combo ensures that Medisi is fully capable of tailoring a methodology to each of its clients. Currently, my biggest challenge is to encompass such growth with a growing team of professionals that will ensure the same level of quality in our services.

What are the most demanded services within the comprehensive portfolio of Medisi?

The most demanded service is medical device registration since both companies that are willing to enter Mexico as well as players that already established in Mexico, either distributors or medtech companies, need this service. We name this service "Holder" and it positions Medisi as an outsourced regulatory affairs department for such companies. Nevertheless, we have another service called "Holder Premium" that offers an integral solution to those clients that request us to lead their business development in Mexico and we support such service with our leading partners such as UPS and I2medi.

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

[related_story]

It has certainly been a challenge and a "learning by doing" process until we finally defined the right profile of people that Medisi we were looking for. One of my main commitments as CEO of the company is to replicate my passion in each one of the members of the team. Medisi's profile is young people with prior professional experience and passion in understanding regulatory affairs; in this sense, we provide a strong and intense training program that maintains our team at the forefront of the regulatory changes. Furthermore, we strongly involve our teams in their projects bringing them to the meetings with our clients since the beginning; such connection with the projects is crucial to succeed in our job.

One of your main objectives as CEO of Medisi is to drive the internationalization of the company. Indeed, Medisi already has some business presence elsewhere Latin America. Could you expand on the advancements in the internationalization process of the company?

We currently have operations in Brazil and Colombia through different partners. Our operations in Brazil have been quite successful so far and I foresee promising growth coming from our activities

in this market. Indeed, it is important to consider that both Brazil and Mexico are the two biggest economies within the region and, consequently, international companies choose one country or the other to start their business in Latin America. In this sense, I expect that in the next two years we will have a person fully dedicated in getting registrations from Brazil to Mexico and the other way around in order to help companies to enter both markets. My main goal is to position Medisi as the leading regulatory services provider within Latin America.

In addition, I strongly believe that the fact that Cofepris aspires to be the standard of quality within the region will be a lever to continue driving the internationalization process of Medisi within Latin America.

Medisi has partnerships with other companies such as UPS and I2medi in order to support as well as to enlarge the reach of its operations. Could you tell to our international readers what is your partnership strategy?

Medisi has several strategic partnerships with other leading companies to continue offering to its clients what they may need after the dossier such as distribution services.

Nonetheless, Medisi has the expertise that I gained when I worked for a leading national distributor and the know-how of regulatory affairs, which is its business arena. Hence, such common understanding with our partners permits a perfect and agile symbiosis that ensures outstanding outcomes with our different collaborations putting always the clients at the center of our strategy.

How are you promoting your high added value proposal within the national and international healthcare and life sciences business community?

We assist different national and international conferences and congresses such as Hospitalar and Medica where we meet current and potential clients. However, I am proud to confirm that we have enjoyed word of mouth promotion from our own clients, which is a great certification of the high quality of our services.

What are the key competitive advantages that make Medisi the partner of choice for the industry?

Our main differentiator is that Medisi's operations fully comply with the highest international standards while providing strong local knowledge. In addition, we fully understand the impact that any delays in our activities can generate to our clients' and partners' operations, therefore urgency is part of our culture and we ensure efficiency and effectiveness. I would like to highlight that Medisi is fully capable to offer an integral solution to its clients and maintaining the highest level of

quality has been certainly crucial in our success.

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 the consolidation of Medisi's unique branding for all Latin America. Secondly, one of my objectives is to help more international companies to get established in Mexico for manufacturing objectives in order to strengthen their positioning both in national public tenders as well as to use Mexico as a gateway to serve the rest of the region. Finally, I want to develop my team of high quality professionals to support the accomplishment of the aforementioned objectives.

[See more interviews](#)