

Interview: Daneris Fern  ndez â?? CEO and President, DGF Consulting Group â?? Puerto Rico



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Daneris Fern  ndez, CEO and president of DGF Consulting Group, outlines the firm  s services that help Latin American companies enter Puerto Rico as well as its focus on hospital consulting.

What was the inspiration for your change of direction from Merck to DGF?

My last position in Merck was as vice president for Latin America and, whereas my previous post in Puerto Rico focused mainly on manufacturing and the US market, there was a lot of interaction with the commercial side of the business. Therefore I learnt about different market access strategies, the access opportunities to Latin America and the challenges posed by regulatory and financial arenas. I also discovered that some local and multinational companies were looking to expand into emerging markets for very evident reasons, primarily to increase growth while developed markets were not providing that option. As such, companies were trying to expand into markets which previously they had not really considered.

However, I also learned that there were many local pharmaceutical companies in central and Latin America with a lot of capital which were looking to the US as their target market. So I realized that when we were facing significant challenges after the federal tax benefits were changed, this was a huge opportunity for Puerto Rico. I was head of the Pharmaceutical Industry Association of Puerto Rico (PIA) and I knew that many of the changes that were taking place really positioned other countries in a better spot than Puerto Rico. For example, Singapore offers a reduced tax rate and extended agreements that, unfortunately, we are not in a position to provide to the companies here because of the current economic climate.

So what did you feel compelled to do to make a change?

Five years ago, I knew all these factors would leave a hole in the industry and that we needed to start looking towards other horizons: south or east instead of north. For many years we were only

looking north, but that is no longer a sustainable model. Therefore, when I retired I decided that I was going to help Puerto Rico develop a new pharmaceutical model to make the most of the existing infrastructure, ecosystem and supporting system. To do this, I planned to try to bring companies from central and Latin America to at least look at Puerto Rico as an option to access the US market.

However, the owners of companies looking to establish a US corporation knew nothing about Puerto Rico. When these people make their strategic plans, they look to position their facilities based on the market and the opportunity to put the drugs in that market. They were looking at Puerto Rico as a market, which it is, but more importantly Puerto Rico opens up the door to the US market. In addition, they will get a nice package if they manufacture some of their drugs here because they can benefit from our tax benefits and other incentives. Moreover, it is easier to understand and enter the US market if you are from Latin America if you come through Puerto Rico because we have the same language and similar cultures. Therefore we are promoting Puerto Rico as a gateway to the US.

What do you find are the biggest challenges that companies have when trying to enter the US market?

The first main challenge that my clients face is in relation to compliance. Every country has its own regulatory agency and with its own policies, protocols, procedures and guidelines. Many of them have harmonized their requirements with the FDA and the EMEA in an effort to have every country possess a strong regulatory body. However, many company owners tend to fear the administration and compliance requirements of the US. This may be partially related to a lack of understanding or because they could have some real opportunities. The FDA is perhaps more stringent, but ultimately there is still an opportunity. Ensuring that they meet the compliance requirements for the FDA is one of the opportunities.

The second challenge is that the whole regulatory process is financially cumbersome, particularly if they are doing their bio studies in the US and there is no agreement between the two countries. Moreover, for most of these companies the labor and energy costs of producing the drugs in their country are very low compared to the US.

Thirdly, there are already very well established, big generic companies in the US who pose a challenge for Latin American companies. If these Latin American businesses do not have a known brand, the right access strategy or distribution channels in place, it is very difficult for them to compete and access the big drugstores and shelf space or even to the pharmacies and insurance forms.

Do you find that it is a challenge for your companies to adopt the mentality necessary to take on a market like the US?

That is an area in which I help my clients. Firstly, I have to get them into compliance and ensure that they pass approval inspections for the US and to sustain quality systems while continually supplying to the US. Secondly, they need the right entry strategy; they have to choose the right drug, distribution channel and process. Getting into the US requires testing the waters and requires choosing the right pathway. Considering how many generic companies are now in the US and how many are importing from India and China, the market is quite saturated. Consequently, it is very hard for a small company to compete and survive.

Obviously, change management is one of the things that we work on with our clients because the compliance mindset is a prerequisite. Puerto Rico has evolved from nothing to having a very well positioned, compliant pharmaceutical industry. It took some years to get there, but we started with one of the strongest regulatory agencies in the world. So we learned to become the best the hard

way. Most of the CEOs have the right mindset and they know what is needed so in that sense it is very easy. However, as is the case everywhere, if the CEO is not properly wired, it can be challenging.

How successful was DGF's recent symposium in Brazil?

We are working with a couple of companies looking at building facilities in Puerto Rico. They are still working on the location because they still perceive Puerto Rico as a market but there are some doors which are open which is good. We are now going to Panama and Costa Rica to work with local companies both in the pharma and hospital sector.

How did DGF's consulting services for the hospital sector begin?

In a way, my work in the hospital sector has been my brainchild and started during a personal experience of mine in an emergency room. I observed and identified a number of opportunities to improve hospital processes to serve the patient better and to better utilize their resources, from physicians to nurses to physical spaces, as well as their financial flow. I saw that there was a huge opportunity to apply day-to-day concepts from the pharmaceutical industry to the hospital industry. DGF therefore developed a couple of proprietary products including hospital assessments linked to infection control for hospital acquired infections. We offer a compliance index for hospitals based on observations to provide guidance on how to improve policies, practices and procedures and avoid patients getting infections. That is how it evolved and now we also have a biological waste recycling service which is already used in the top seven hospital systems. We are going to expand into Panama with a pilot scheme in government hospitals and we are going to meet with the Costa Rican Secretary of Health.

With Puerto Rico known as hub for health services, do you think DGF will expand throughout the whole region?

We are accessing the markets as we have the market resources available. Directors will take care of the hospital in terms of the commercial side so we're moving into Mexico, Panama and Costa Rica. Hopefully, we'll be working with those countries very soon. One of the things we normally do when we move into a country is convey the potential of Puerto Rico. So with us being there providing services, there are opportunities for people not just to take a look at Puerto Rico commercially but also to form relationships.

Puerto Rico has a lot of excellent medical centers with high caliber physicians and workforce. Hence, there is a real opportunity to expand Puerto Rico's capabilities through medical tourism. Puerto Rico has real prospects to attract medical tourism and become a Caribbean hub but we have to reach out and let people know how we can help improve their quality of life. We have a lot of work to do to spread the word. For example, the success of the Mexican company Neolpharma, which has recently expanded to Puerto Rico, is important because it will give a strong message to all the Mexican company owners that they can come to Puerto Rico and do business successfully.

Where would you like to see Puerto Rico by 2020?

In 2020 I would like the Puerto Rican cardiovascular and cancer hospitals to be the most renowned Spanish-speaking centers as hubs for central and Latin America. Secondly, I would like to see all the facilities and infrastructure that we have here to do with manufacturing with companies from countries other than just the US. Last but not least, I would like to have the top selling US drugs made in Puerto Rico. Not only do we have to look to South America but we also have to recapture the big pharma market and ensure a sizeable market share. We have to regain the confidence of the big pharma CEOs and offer innovative alternatives to make Puerto Rico very cost effective. We have

to bring back the volume of business we used to have from big pharma; this is a must and I know we can do it.

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