# Interview – Pepe Rodríguez-Pérez, President, Business Excellence Consulting, Puerto Rico



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*Pepe Rodríguez-Pérez, president of Business Excellence Consulting, tell us how he helps companies in Spain and Latin America enter the US market through Puerto Rico. He explains why he is cautious about Puerto Rico's manufacturing growth potential.*

**What are the factors which have led to the decline of the industry over the past five years in terms of the number of businesses present in Puerto Rico?**

Around 80 percent of the problem is related to the government's decision in 1996 to request that Congress eliminate Section 936 of the Federal Tax Code. I think that the impact of the withdrawal of the reform began manifesting itself not immediately but rather four or five years ago. After the elimination of this section took complete effect in 2006, many companies with a big blockbuster model closed their plants once their patents expired.

I was in Singapore in 2012 when the government announced that they were investing five billion Singaporean dollars in a medical device cluster and even brought over the Nobel Prize winner for cardiology from Sweden to a local university. I do not think that the Puerto Rican government can invest that kind of money in the industry but I think that the request to eliminate 936 was suicidal. At the time, there was no plan B in place and politicians were just trying to sway public opinion in favor of one of the three statehood arguments. I think that was the source of the problem and we are still feeling the repercussions of that decision today.

**Some other consultants have made similar comments but have also said that it's not too late to get the industry back on track. Do you agree with that statement?**

It is very difficult because in addition to the economic situation in Puerto Rico I do not know if there are investors willing to fund this type of project. The reality is that we have all the necessary components to be successful, particularly as we are part of the US which attracts many companies that want to bring medical products to the US market. However, the current political and economic situation is affecting many companies because of increased tax rates. This is also affecting my business because even though my income from outside the island is increasing, I am still bringing that money to the island and paying taxes. So I could decide to leave the island and go to another state such as Florida and I would save money. This is an important part of the equation and I think that the hope of getting the industry back on track is being killed by the crisis we are facing right now.

**Nevertheless, in the last two and a half years alone six new life sciences companies have come and invested a significant amount of money in Puerto Rico including CooperVision, Lilly and Neolpharma. Does that mean that people still value Puerto Rico in terms of what can be offered in manufacturing?**

It is possible. I think that many companies value the talent here in Puerto Rico very highly, for example, CooperVision. Nonetheless, this does not compensate for the closing of plants by companies like Merck and Pfizer. It could certainly be worse but in terms of the local situation I fear that, among other things, the increase in taxes may diminish our ability to maintain or grow the industry here. Our only real advantage is the quality of our talent and services because we are not cheaper in terms of labor, utilities or manufacturing costs.

**What is the biggest challenge for your clients in terms of regulatory or compliance issues?**

In terms of regulatory compliance, local companies are in very good shape as we have some of the toughest FDA regulations here and the local inspectors are among the best in the FDA. I continuously hear that the FDA is damaging local companies because it is too strict but I do not believe that is true at all. The problem with the FDA is not that they are very tough here but rather that they should be consistent elsewhere and apply the same rules and raise the bar outside of Puerto Rico.

However, in order to maintain their local operations, I think that some companies are trying to cut corners in order to save money. But we cannot compromise on quality because this is our only true

competitive advantage. As I say to my clients, even if we weren't to pay our employees, our products would still not be as competitive as those of, say, the Dominican Republic. The average monthly salary there is $200 which is equivalent to about ten percent of a Puerto Rican salary.

**In terms of your international strategy, what factors make you stand out in your ability to help your clients across the globe?**

Having a shared language with Spain and Latin America makes us unique and is a critical factor because there are no communication problems. They are using us as support for the FDA inspections and I have some clients who hire us just to be there for the FDA visit to help them pass the pre-approval inspections. But our main distinguishing factor is our expertise. Half of my one hundred associates have come from companies like Pfizer. Almost all of them have been directors or managers and have at least 20 to 25 years of experience.

**Is it a challenge for companies in either Spain or Latin America to adopt an FDA mindset required to get a product into the US market?**

Here in Puerto Rico, we have had an FDA mindset for many years but that is not always the case in countries outside the US such as Spain. Unfortunately, transferring that mindset to others cannot be achieved in just a couple of hours and that is something that we are struggling with. I go to Spain every other month and on my next trip I will be delivering conferences in Madrid and Barcelona about the FDA and cultural mindsets you need to adhere to. In fact, it can sometimes be difficult for us to explain this is something we live and breathe! An example I often use is of a time when I was at the checkout in Walgreens with my medicine and there was a mistake on the date I wrote on my check. As such, I crossed the date out and put 'wrong date' as I would do if I were on the manufacturing site. The pharmacist looked at me as if I was crazy. But the truth is that it was a subconscious act because if there is a mistake at work, I automatically correct it. When that becomes automatic then you know you have the right mindset and I try to transmit that message to the people I work with outside the US.

**The US is already such a large and saturated market; with all that competition, is it really worthwhile for these Spanish or Latin American companies to go to all that effort to get a single product into the market?**

Absolutely; for example in Spain they have a fixed price for medicines so you pay more for peanuts than you do for Acetaminophen. It is crazy because a lot of the fixed prices set by the government are in fact lower than the manufacturing prices. Many companies therefore have to produce hundreds of different products to achieve some benefits. On the other hand, just getting one

generic drug into the US market could earn them several million dollars which would be the equivalent of a blockbuster in Spain. Hence, it is worthwhile for them to attempt to break into the market with perhaps initially one product that could pave the way for more in the future.

**One of the value-added services you offer is training courses and seminars. To what extent are you helping clients here in Puerto Rico through that aspect of the business?**

We have an extraordinary example with one of the top medical product companies. My first book was on CAPA (Corrective and Preventative Action) and that was actually our most popular course. A few years ago we provided this training to a local plant of a big company, and during a corporate audit, their auditors noticed a significant improvement in terms of the CAPA system and the local site said that was because of our training sessions. As a result, we now have a global contract with the company and are bringing this certification worldwide, to countries such as Singapore, Brazil, Belgium and France, UK, and Mexico, among others. So we are very happy that our work has become the CAPA standard for this big company

**Looking ahead to the future, what are your expectations in terms of growing this business?**

I am pretty sure that the business will continue to grow because of our expertise and people. The pool of local talent is the most important asset that we have on the island. In addition, we have more business outside of Puerto Rico every year. We have a new audit division which started two years ago with a contract to perform supply and audit for a German company and now I have four full-time auditors going to India, China and Latin America every other month. Finally, as I mentioned we also have the IACET accredited trainings which we are providing worldwide.

**What would you like the legacy of Business Excellence Consulting to be?**

The spirit of the company is to have passion in everything we do and a passion for quality in particular. I think that in many years from now, the pharmaceutical industry in Puerto Rico will be remembered not just because of the high concentration of plants in the 1980s and 1990s but mainly for the quality of the local people who are at the top of international companies.

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