Jorge Luis Rodriguez – CEO, PACIV, Puerto Rico

The country has transformed itself and we have a better value proposition than before. We are the underdog. My message is simple: adversity has made Puerto Rico stronger

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Jorge Luis Rodriguez, CEO of PACIV, a Puerto Rican provider of industrial automation solutions for the life science's industry, reveals the three key performance indicators that make the island a global powerhouse for pharma manufacturing. Moreover, he explains the company's unique one-stop-shop approach and how Puerto Rico has managed to overcome natural and political disasters.

Jorge, prior to founding PACIV, you worked in the industrial automation, instrumentation, and regulatory compliance field for global life science companies in the United States and Puerto Rico. Which needs did you identify that prompted you to start your own process automation company?

I started in the pharmaceutical industry 27 years ago. When I moved to Puerto Rico, I started working with Eli Lilly and then J&J in automation. I started in 1991 and, the very next year, the FDA regulations for computers and systems came out. At the time, I was an automation engineer and all of a sudden, the computers changed automation.

On the other hand, the discipline of validation was very standard in the industry, dealing with process, facilities and equipment. This became the first discipline that they did not put into the validation department and gave it to the automation engineers, so my job became 50/50. Still, all of it has to follow the system development life cycle and the standards of the regulation.

As we put technology into the system in a computerized way, we gained expertise in its compliance regulations. I was part of the very first computer regulation guidance in the industry for Eli Lilly. They put together all the automation engineers and we created guidelines on how to perform the computerize system validations for automation, at the time there were no industry standards like there is now with GAMP5. It might sound very technical, but it was really an important development for the industry.

After finishing my MBA, I moved to J&J to become an automation leader, thinking I wanted the management part of the job as well, but I hated it. I am a bit of a nerd; I love programming and did not enjoy the management side at all. As a client, I realized the service was very fragmented. It simply was not efficient enough, which presented a good business opportunity. Whoever did the validation part would have no clue in the other disciplines, and so on. PACIV was founded to provide integrated turnkey services in the three disciplines: control systems, instrumentation and validation for the life sciences industry. PACIV stands for Process Automation Controls Instrument Validation. The three services are required in any particular automation project within the life sciences industry to provide a solution, and no service provider was able to offer all three under one roof.

What differentiates PACIV in that context?

PACIV is probably one of the few in the world that is able to provide all of that for a single industry. If you look at the map of system integrators for industrial automation, you will find a fragmented group of suppliers, mostly based by geographical regions. PACIV is ranked 37 in the top 400. In Puerto Rico, there are ten system integrators, but only a few local ones for life sciences. What we did very successfully was serving one industry across its geographical regions, because their systems and the regulations are standardized. They look for consistency of interpretation. Today, 30 percent of our revenue comes from Puerto Rico, 30 percent from Ireland and 40 percent from the United States.

The beginning was certainly a challenge. When I started PACIV we had dial-up internet, so the world was not connected. The only way these corporations can be consistent is through standardization, they try to replicate the processes. Plus, we were doing three weeks work in just over two days and they loved it. PACIV became an agent of knowledge transfer. We established an office in Indianapolis in 2003 because there was no competition and large companies like Roche needed our services, we put 30 engineers in seven months and continued hiring. Then we

established an office in the UK for GSK, Lilly, Pfizer and our engineers were trained for each particular company. We then moved the UK office to Ireland because we found a bigger concentration in Cork. We are growing organically. The next step should be Singapore. That is the strategy and once you are a business partner of these companies, it becomes easier, since they require your knowledge and service; especially to bring with you that knowledge transfer and replicable solutions.

While Puerto Rico remains a pharma manufacturing powerhouse, the island has not seen major green field investments for more than a decade. Is this a constraint on growth or does its present opportunities for revamping and upgrading aging infrastructure?

Puerto Rico probably has the best opportunity to grow. We have not seen major greenfield investments, but the conditions are in place. For example, the Financial Oversight Board is an incredibly powerful tool that any jurisdiction would love to have. We have the Puerto Rico Oversight, Management, and Economic Stability Act's (PROMESA) article five to facilitate infrastructure plans. Article five says that the law will ensure that strategic projects for Puerto Rico can be fast-tracked to cause significant impact on the economic development of the island. What we are trying to get the Board to sit down with the industry. I dedicated five years to introduce an entrepreneurial mentality to the industry so we can articulate our value proposition. From 2003 to 2007, no other place in the world had the industrial activity in biopharma that we had, and there is a reason for that. Eli Lilly had the second largest biotech site in the world here, Amgen has its largest installed based manufacturing facility outside of the US in Puerto Rico. The world has gotten more competitive, but few have the skillset to set up a new facility within budget, in a relatively short period of time and correctly, in compliance, the first time.

Besides article 5 of the PROMESA Act, how do you assess Puerto Rico's ability to attract life sciences investment?

Do you know the three things that make any jurisdiction competitive? First, the conversion cost, which is how much it cost me to produce the medicines. Second is market reliability, which measures orders placed and the response to the delivery dates. The third one has to do with the regulatory findings, compliance. Those are the main three KPIs that executives are interested in, and Puerto Rico excels in all of them; it speaks to our competitiveness. Any life science company

trying to manufacture looks into those aspects. The differentiating strategy for Puerto Rico cannot be about cost or taxes, we differentiate by those three performance indexes that prove how we are better than other destinations.

Did we have a crisis? Yes. But the country has transformed itself and we have a better value proposition than before. We are the underdog. My message is simple: adversity has made Puerto Rico stronger. Facing challenges has made us look to our strengths and play on them. The hurricane was a good example of the island's resiliency. The national media warned about shortages, but they never came. The title should have been "look how strong they are". The situation was very dire, it looked like a war zone and we continued producing all the medicines that we were supposed to. The big issue has been communicating all of this. It is a challenge for the companies, individually, to communicate these success stories. It is for the island's government and its local companies to do so. Another example came when they ended Section 936 of the Internal Revenue Code, which gave Puerto Rico a special tax advantage. We had to reinvent ourselves again. That is where PACIV can serve a purpose, telling the story of the resiliency and strength of the island. The only professionals at the world-class stage, excluding artists, that are well regarded and have a global stage are the biopharma sector professionals in Puerto Rico. We must use that influence.

As the CEO of PACIV, how did you convince the industry to continue trusting Puerto Rico?

It was not hard because we have a great reputation in the industry, the doors are always open for us. The connections between the resources and assets of the country are way better positioned than before. In terms of automation engineers, there is an incredible amount of talent here. The universities are accredited, and we work hand in hand with them to address the needs of the industry. The US Department of Education (ED) created a whole curriculum to make industrial automation an official degree at the college level because they realized that automation is a critical element of manufacturing. We are helping the local university in Puerto Rico with the creation of their own automation curriculum, so the engineers fit the requirements right away. We created five or six courses that need to be embedded into the teaching plan. We are trying to make the industry attractive.

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