

**Interview: Yanira Torrellas â?? President,  
Quality Consulting Group, Puerto Rico**

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*Yanira Torrellas, president of Quality Consulting Group, details how her company helps the industry through remediation and prevention efforts while highlighting the importance of the service provider sector to collectively act in order to promote Puerto Rico to the rest of the world.*

### **What is your perspective on the current state of Puerto Rico's life science industry, and how would you rate its evolution?**

In recent times, some companies have restructured and consolidated their manufacturing operations within the island, others outside the island, and others have decided to establish new manufacturing sites in our island. While the pipelines of major pharmaceutical companies around the world are dwindling, the Puerto Rican facilities of some of these global companies continue adding new products to their manufacturing pipelines. Pharmaceutical, biotech and medical device companies continue innovating their own products to hit other markets. We see that the medical devices industry entering into combination products, and this also allows them to expand their portfolios and increase their competitiveness. In terms of the evolution of life sciences, we are observing that innovation is embedded as an intrinsic aspect within organizational structures, processes, facilities and products of manufacturing operations. The results will reveal the positive effects of innovation on firm performance in manufacturing industries, creating innovative and agile systems and allowing these businesses to improve significantly their supply change.

### **Has Puerto Rico been able to stay at the same pace as rapidly emerging countries in manufacturing like Ireland and Singapore?**

The competitive aspects of Ireland and Singapore are somewhat different from Puerto Rico. Those countries have cost-competitive workforces, but we have the expertise. We have top notch labor force—hard workers, dedicated, committed and intelligent—and that is Puerto Rico's number one asset in the manufacturing sector and continues to be one of the main reasons companies continue operating locally and are drawn to the island. In some manufacturing aspects, they can get different revenues from products but conceptually the industry relies on the knowledge and experience of its people, and with our geographic location and US territory status, Puerto Rico becomes very important. Puerto Rico's life science industry is governed by the FDA, so you can manage products in Ireland and Singapore but cannot necessarily export them to all US territories like this country can. That differentiation allows us to continue being competitive.

We have been exposed to this industry for decades, so we are very used to moving through this culture and mentality. Approximately 25 percent of Puerto Rico's GDP is generated by the pharmaceutical and biotechnology sectors. It is very costly for a region like Latin America to maintain such expertise, as they are not used to manufacturing products to the US as per their regulations. Companies in such regions know how to manufacture, but doing it according to the FDA is markedly different. Puerto Rico has investigators that came from local plants who know and are used to working in manufacturing for years. Those investigators may have higher expectations of our plant execution compared to investigators in other parts of the world. They have probably not been

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exposed to that experience even though the regulations are the same. We know that in this kind of industry there are some practices, while not written down, that are the expectations of the FDA (cGMP). When we are exposed to those kinds of systems, they know very well about those practices which have become current unwritten regulations but are the expectations nonetheless. In that sense, this attention to detail is part of many Puerto Ricans' DNA in terms of expertise.

**You founded Quality Consulting Group in 2002, and the company offers a wide variety of regulatory services to the life science industry. What tends to be your clients' biggest challenge?**

In some cases, our customers are very concerned by their regulatory status. They come to Quality Consulting Group so that we may make several assessments to create a clear summary regarding their regulatory and compliance status. We can thus develop a remediation plan for them so that they can comply with the regulation industry while considering their business needs to ensure a sustainable remediated operation. Capacitation and training are areas where there is a need for knowing among Puerto Ricans. They want to be the top of the top, and this is cultural. They are always looking for capacitation and professional development. In those areas we collaborate well with our clients. For example, in December 2015 we will run a boot camp for PMP certification. Quality Consulting Group also created a human resources certification; we provide training for root cause analysis among other currently trending topics. Quality Consulting Group designs training that consider the actual system of the client so they can apply what they have learned within that training. All our trainings are custom-designed for the client's needs. We consider conceptuality, but we add the specifics of the client's processes. As such, the client is able to identify opportunities of the process and start working on them.

**Is this service unique in Puerto Rico?**

I do believe it is unique. Some clients have said they prefer us because they get out of the training room with half of the work done because they were able to apply their learnings to the necessary task. This is a win-win situation; we deploy and deliver the material, which they understand; and we see its applicability, which is good for them because they maximize the hours of training applying lessons learned doing work that is pending completion.

**When a company gets to the remediation stage, how difficult is it to salvage the situation? Can they recover in a way that still allows them to maintain a good reputation?**

It is indeed crucial to design remediation plans that allow the business to recover and continue on the market. You can remediate in a complex or simple way. There is a bad perception that designing a complex and convoluted systems will be equivalent to compliance. Our principle is to design remediation plans based on specific clients' needs in terms of compliance while considering the business aspect. We need to allow the client to recover from failure and design something that ensures the sustainability and profitability of the organization. Our remediation plan designs will always embed a lean manufacturing approach, which for me is the appropriate balance between the compliance and business need aspect. Lean manufacturing, more than a methodology, for me is a complete change of business: how the supply chain operates, how the directors direct, how the managers manage, how employees go about their daily work. Quality Consulting Group has been supporting several organizations between remediation plants and in some cases we have been asked to remediate what was remediated before in a complex way by other companies.

**Do you help more with remediation or prevention?**

It depends on the mentality and the client's needs. Some clients want to avoid remediation plans because they know the cost implications and the disruptions to the operations that these activities

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may cause. As an intelligent industry we need to move from a reactive to a proactive mode; this way of working is closely related to the maturity of the organization. For some clients, I might see a system that with a gap that may be a potential failure, and I will always contribute to make preventative changes. Today's generation understands that their contribution needs to be preventative, which is critical for their success in their career paths. As the industry moves from manual to automation, many aspects become significantly easier and this is great for the sector as a whole.

### **What makes Quality Consulting Group the partner of choice for the Puerto Rican industry?**

We have talented experts, all of whom were part of the industry for many years and often qualified as plant managers, operations directors, technical services directors and/or QA managers. Our contribution is based on knowledge, education and lots of experience in key positions and this is our difference. We are advising, consulting, and supporting clients on a day-to-day basis. Our contribution is to get our clients' problems resolved as quickly and efficiently as possible.

### **Quality Consulting Group is expanding to Costa Rica. Could you elaborate upon this?**

I am working with the Puerto Rico Trade and Export Company on a project called Expo Partners, a joint effort between the University of Puerto Rico and the Puerto Rico Trade and Export department. As part of the program they provided an intern from the international business school of UPR, and together we developed a plan to export our services. Quality Consulting Group has done several commercial missions to Costa Rica, so as part of that effort we will start our implementation phase in the last quarter of 2015. We already have the whole structure implemented and have contacted potential clients. We will pursue similar avenues in other countries such as Panama, Argentina and Brazil at a later date.

### **What else would you like to achieve?**

I want Quality Consulting Group to be a global company, and we are working towards this and it is completely achievable. It is not to do what others are doing well, but rather to do better than them. Our services need to be excellent, and some of our principles will drive us to become a global company.

We are now developing some infrastructure in our systems to be connected with our subsidiaries. We are currently revamping our system for hiring talent, redesigning our website, and making everything in Spanish and English; as such we need to be ready to take on the international market.

### **What is the potential for the collective service provider industry of Puerto Rico to grow globally?**

I think that there are many local companies that are willing but others might not be interested. There should be a centralized effort from the industrial associations that can make alliances with every industry to create one market from Puerto Rico to the world. That is an opportunity. I am a member of an industrial association and we are working on something similar. Many industries offer the same services; we can form alliances and a structure to catapult all of us out of Puerto Rico and to the rest of the globe. Puerto Rico is in the very beginning of that process. We as Puerto Ricans need to make alliances amongst ourselves. We need to start understanding that if we unite our efforts we can achieve better results. But we need to generate a structure and mechanism in which everyone feels comfortable when going through that structure. Competition exists, so we need to make it legally clear that even though companies can make alliances they will still retain the individuality of their business. This should be a government or association effort. More than being a successful professional, I have a responsibility with my nation. Every time I have the opportunity to make that

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contribution I will be there. It is not about me but about us. We will be stronger if we unite our efforts to go outside Puerto Rico.

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