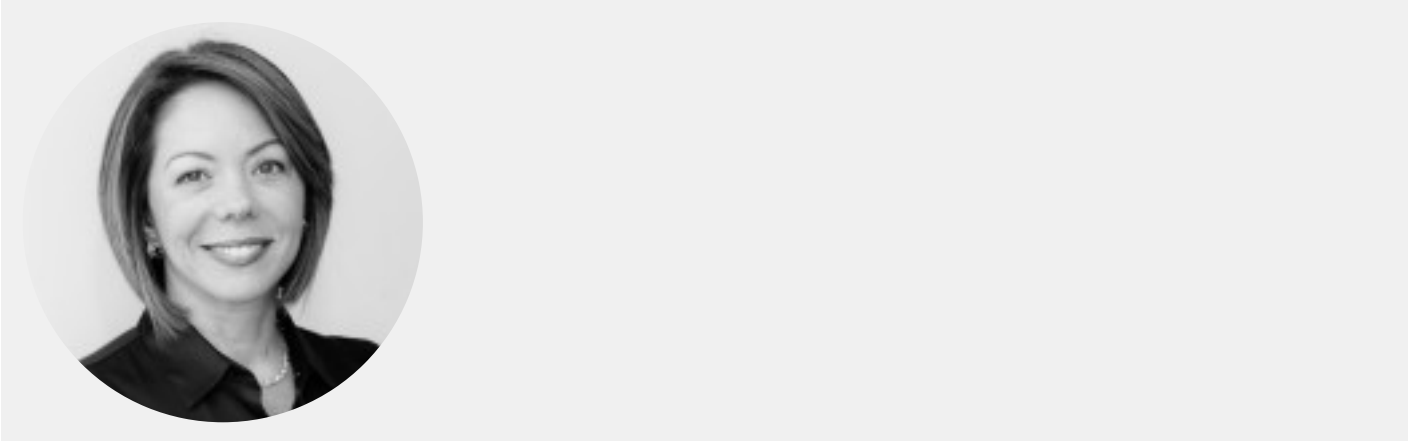
Interview: Verónica Cruz, PhD – Executive Vice President & COO, ReComS, Puerto Rico



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Verónica Cruz, PhD, executive vice president and COO of Puerto Rican consultancy ReComS Group, discusses the need to bring investments in the life science industry back to Puerto Rico while focusing on the country's manufacturing strengths as a competitive advantage.

What are the main challenges which ReComS is facing?

Today in Puerto Rico, there is substantial unemployment and great talent just sitting idle looking for an opportunity to contribute. Many leaders have a commitment to turn things around and use our knowledge to attract new investors to make use of that idle capacity. However, consultancy is a lot more competitive than it used to be and you have to be very cost-competitive to get contracts. We are partnering with other local consulting firms, and this is a nuance that I feel is unique to Puerto Rico. I have certain knowledge related to compliance and quality strategies through my many years in leadership roles in the pharmaceutical industry, so these companies will reach out to me for that type of consulting. On the other hand, they have more facilities and manpower than us, so we will also leverage their talent.

In terms of remaining competitive, what can Puerto Rico learn from Ireland and Singapore which have emerged as stars in the manufacturing industry?

If you want different results, you cannot continue doing the same things the same way. When Puerto Rico's industry took off, it was very labor-intensive and we took advantage of that through the tax and legal infrastructure with Section 936. It was very convenient for Puerto Rico and created a job boom because the more people that a company hired, the higher the tax incentives were. Ireland and Singapore began in the following generation of pharmaceutical development which was less labor-intensive and more automation-driven. In comparison, we have not moved quickly enough to reach that technological level. The challenge we face is that retro-fitting halts production is more difficult than building from the ground up. Furthermore, although we were producing the majority of the products on the island for the US and globally, when patents started to expire those volumes dropped. As an example, when the legacy product of a client in one of my former companies became generic, the production volumes dropped from around 300 batches a month to between 10 and 15.

What is your assessment of that situation in terms of what Puerto Rico should be looking to do in the future?

Puerto Rico cannot remain static; we need to think three steps ahead and ask ourselves what we have to do differently. I think the products we still manufacture are tremendous opportunities that we need to protect but we cannot rely on them alone.

One of the great Puerto Rican success stories is MOVA Pharmaceutical Corporation, which engaged in both contract manufacturing and R&D. The vision of the founder, Joaquín Viso, was to have a locally developed products in Puerto Rico; we succeeded in developing an NDA for Levothyroxine which is a grandfather product used for treating thyroids. However, it is a very complex product with around eleven different dosages and many of its manufacturers had several recalls because of stability issues. As such, the FDA announced that every company had to submit an NDA for Levothyroxine and those who did not would have to pull their product from the market. MOVA was the one of the first to submit its NDA and we had all 33 item codes approved in the first round. The FDA was very enthusiastic, but unfortunately we have had no similar successes. For some reason, Puerto Rico has not succeeded in bringing as much R&D work here as we would like to.

Do you think that has the capacity to change or is it more of a pipe dream?

The energy and the knowledge are already there, so we just need to tap into them; with current government initiatives and the creation of the San Juan Technology Corridor, I am hopeful it could happen. However, R&D is very different to manufacturing and while Singapore has a strong pipeline of scientists, we have a strong pipeline of manufacturers. That is starting to change as

academia is engaging in more scientific development and healthcare projects. Ultimately, R&D has to begin in academia because we cannot import scientists in a sustainable manner.

However, I strongly believe that Puerto Rico needs to think about what it really wants to do. Just because Ireland is really successful in R&D, is that a reason to try and compete with them in that area? We have a tremendous footprint here of idle capacity and globally approved sites; we ought to put that to work and bring in other kinds of products. Puerto Rico's monetary system as part of a US jurisdiction is an advantage and is the quality of the products manufactured locally. There is no reason why we cannot start building other skills in the long-term, but in the meantime Puerto Rico should be exploiting its fortes rather than trying to be good at what someone else is already great at.

What tends to be the biggest challenge you face when meeting your clients' needs?

There is a diversity of needs and some are driven by a lack of knowledge of new regulations, others by financial constraints. One of the challenges with the latter is that speed to market is pushed over to the consultant in terms of meeting expedited timelines and we do not have staff ready to go but rather a network of contacts who help us when available. Another issue is that companies are investing less and less in prevention which means that they are relying on remediation which is a lot more costly.

However, in terms of opportunities a niche that I have experienced is having the knowledge to help companies that are unable to import resources quickly enough for the technology they are bringing in. In fact, one of my biggest clients right now is a medical device company which has a drug coated device and they have no experience with drugs. I am helping them implement the applicable drug GMP's through procedures, standards etc.

What would you say makes ReComS the partner of choice for the industry?

First and foremost, we are a local, minority-certified business with a long-standing history of being trustworthy, reliable and cost-competitive. From the financial perspective, when you use a minority company you have added financial incentives. In addition, our staff has a very critical eye and we voluntarily give our clients recommendations that can go beyond the original scope of work. For example, I carried out a five-day assessment for one of my clients and provided a 25-page report including their requests and everything else that I saw. This is how we function and it is valued by our customers; sometimes they think they know what the problem is when, in fact, it may just be a symptom of a bigger issue. Finally, for me, partnering with companies to create long-term relationships outweighs the financial aspect and that has made ReComS Group a partner of choice.

What have you found to be the biggest challenge joining this company?

First of all, as Osvaldo's expertise is in the regulatory and legal arena, I was responsible for shaping the consultancy area. ReComS stands on the very strong principle of having a meaningful partnership with our clients. We have been running the entire calibration program for one of our biggest clients, Medtronic, for several years; they trust us completely to run the calibration of standards and certain instrumentation for all their Puerto Rican plants. Therefore, one of the main challenges involved starting up the compliance consultancy division, in the same spirit, was strategizing on where to focus so as to avoid biting off more than we could chew. It has been a very rewarding process so far and there have been many invitations to do presentations in industry forums and speak at conferences in the US which have resulted in consulting opportunities. However, although there is not much work here, I am trying to focus my work primarily in Puerto Rico.

After many years working in the J&J, how did you find the transition from a large multinational to a smaller, regulatory consulting firm?

When I retired from J&J, I was based in Fort Washington, PA and most people anticipated that I would remain there, particularly as many Puerto Rican professionals are leaving for better opportunities elsewhere. However, although I grew up in New York, my house and family were always in Puerto Rico. The driving factor to return to Puerto Rico was to do whatever I could to support the local industry. I am one of the endless examples of Puerto Rican talent that has been able to grow with the organizations I have been with such as Pfizer, Bristol-Myers Squibb and Johnson and Johnson.

In the 1980s, the general managers and senior leaders of companies in Puerto Rico were primarily American expatriates. In the 1990s, this underwent a shift and local talent was starting to be exported to take on leadership roles. There is a strong focus on the pharmaceutical industry in professional education here and one of the great assets we have is the consortium between industry and academia. I personally participated in shaping various industrial chemistry programs alongside other science and engineering programs which are targeted to the industry so it only makes sense that I come and give back.

What drove you to ReComS in particular?

The President and Founder of ReComS Group, Osvaldo Carlo, is a friend of mine and he invited me to join him. As such, when I decided to retire it was an easy decision. As part of my work with J&J, I had also been a client of ReComS and I had always been very pleased with the service they

offered.

What would you like to achieve in the future?

Looking back ten years from now, I want ReComS Group to have supported the current initiative in Puerto Rico by helping through publicity or engaging with investors to return to the island. In terms of expansion, we are currently focused on the island but we see an opportunity to strengthen our links with Latin America because we have the advantage of being culturally aligned, sharing the language and having the US knowledge to which Latin America wants access. For me, the talent we have here is a natural link between Latin America and the US which we can exploit to bring more manufacturers to Puerto Rico.

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