Limaris Alvarado – Business Operations Director, PharmaLex Puerto Rico

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Limaris Alvarado, business director of PharmaLex Puerto Rico (formerly ECHO Consulting Group), started ECHO Consulting Group to enhance and maintain the education of healthcare industry professionals in Puerto Rico via expert resources with international and regulatory experience. After 17 years, the company is a renowned leader of validation, quality and regulatory compliance services on the island that recently merged with PharmaLex, a global consulting firm providing services across the product lifecycle. She explains how the merger has created new opportunities for expansion, both in terms of service offering and internationalization, and is enhancing the knowledge-base of the company in new technologies.

After a career as a validation specialist at Pfizer and Amgen, you co-founded ECHO Consulting with colleague Walquiria Polanco. What need did you identify that made you decide to start your own company?

Walquiria and I were very fortunate in terms of the assignments we had at those companies as we had the opportunity to work on the approval of new facilities and products. At Wyeth, which is now Pfizer, we had the opportunity to work in the early stage of the validation lifecycle. At Amgen, we were able to work on the approval of products which is at the late stage of the validation lifecycle.

The validation lifecycle links product and process development, the qualification and the maintenance of the commercial manufacturing processes. When I refer to the early stage, we are dealing mainly with process design and that includes working with the qualification of each independent equipment/system and the process characterization (including the definition of parameters). The next steps are to deal with the late-stage which refers to qualifying the process and monitoring it to confirm that it is and remains in control; that is, we get to confirm how the different systems work together to produce a final product.

This exposure allowed us to gain experience working with the entire validation life cycle. At that time, companies in Puerto Rico were starting to use different service providers for validation activities. In order to meet the necessary deadlines that the type of projects we were managing require, we sub-contracted from 10 to 20 resources for each project. We noticed that the contractors did not have the level of expertise, experience, and education that we needed. In order to fill this void, we decided to start our own company in 2002 to provide education and training services to the healthcare industry. Aligned with our motto “teach what we use and use what we teach”, we started also offering Commissioning & Qualification, Validation, Quality and Regulatory Compliance services. Our first project was for the Cardinal Health plant which is now owned by Galephar.

Could you introduce the operations of the company?

At the time we founded the company, we were competing with large engineering, construction and service provider companies. Many of the construction projects were being granted to these large companies. As they had significant resources, the whole project would be contracted to them even if they did not have experts in the validation lifecycle. Naturally, they would then sub-contract resources from companies similar to ours to execute the validation activities. We started to get some of these subcontracts and that helped us to penetrate more into clients.

By 2010, we were granted the management and execution of facilities start-up and product transfer and approval projects for two clients in Puerto Rico that manufacture injectable medications. These projects also gave us the opportunity to qualify new technologies/systems that were emerging (isolation and RABS). Those projects were key in defining the growth of the PharmaLex Puerto Rico. Currently, we have a group of 110 resources that vary depending on the project volume. Even though we have Subject Matter Experts on each stage of the validation life cycle, our resources are recognized for their expertise in the late stage of the validation life cycle.

PharmaLex Puerto Rico is certified by the Puerto Rico College of Engineers to provide continuous education to their members. We are also members of the advisory board of the Parenteral Drug Association Puerto Rico Chapter and collaborate very closely with INDUNIV, a very active organization that advances understanding of the pharmaceutical and bioscience development fields and facilitates collaboration between industry, government and academia.

When we spoke with Ronald Pacheco of VEG, he explained how the consolidation of pharma manufacturing has led to a surplus of service providers and thus created the need for them to differentiate themselves from the competition. What makes PharmaLex Puerto Rico stand out from the dozens of companies in Puerto Rico offering services in Commissioning & Qualification, Validation, Quality and Regulatory Compliance?

Education is what makes us stand out. We make our resources very mindful about the importance of every activity in the process validation lifecycle. For instance, if one of our resources owns the qualification of equipment and notices that there is a request to change a specific part of that equipment, our resource will understand the impact that proposed change will have not only on the equipment but also on any product manufactured or to be manufactured on it.

At PharmaLex Puerto Rico, we make sure that our resources are trained to be aware of the entire process validation lifecycle and the potential impact a proposed process change will have in the final product. Additionally, we encourage them to ask questions when in doubt about any task. We have created a role that oversees different projects and acts as a liaison between a client and our resources. This has been very effective in making our resources capable of identifying and mitigating the risk of any event occurrence that could result in a regulatory issue.

You are the leading provider of educational seminars and technical discussion forums on highly specialized topics using internationally recognized experts. Could you tell us more about the educational aspect of the company? What have been some of the more popular events you have done in recent years?

To give a little background, when Walquiria and I were employees of pharma companies, we were able to take one or two training sessions a year outside of Puerto Rico with internationally recognized expertise who also were very involved in the revision of regulations. We saw an

opportunity in bringing these experts to Puerto Rico and allowing the local industry professionals to have access to them without leaving the island. Companies also saw this service as a very convenient one because it allowed them to save both in travel time and cost when sending their employees. These educational activities were also very beneficial for us as a company since we would keep our own resources educated and up to date with the latest regulatory trends.

Nowadays, we host educational summits on an annual basis. For the past three years, we have turned these events around by also including local industry professionals to present their perspective on the topic discussed by the internationally recognized speakers. This allows the local industry professionals to share their expertise in different specialized topics and also provides the audience with a forum to discuss best practices and learn from each other's experience. This is coordinated in a way that enables a productive discussion without the need to disclose confidential details inherent to each company. Finally, in alignment with our motto (**"teach what we use and use what we teach")**, we offer seminars for our clients on any topic relevant to the healthcare industry and customized to their needs.

Last year, ECHO merged with PharmaLex. How does being part of this global group help you better serve your customers?

In 2018, we merged with Pharmalex and are completing the final activities of the integration process. PharmaLex is a worldwide provider of consulting services in drug development, regulatory affairs, pharmacovigilance and epidemiology, and quality management and compliance. PharmaLex has over 25 offices in 14 countries and combines local expertise with global reach in those areas. By integrating with PharmaLex, the original strengths of ECHO have been greatly enhanced by tapping into the strengths from PharmaLex, and encompassing now the entire Product Lifecycle.

This partnership has been key in accelerating our expansion plans, starting with the US mainland, which is a goal we have had for a while now. We have the benefit that the Pharmalex brand is well known in the US and we are completing the rebranding roll-out in Puerto Rico. So far, we have experienced very positive results since we have started projects in August in the US mainland.

Moreover, since our integration with Pharmalex, we have also participated in projects in other countries including providing support before and during Pre-approval inspections conducted by the FDA.

Getting exposed to new manufacturing modalities (such as gene and cell therapies) and gaining expertise and knowledge on those are also unique opportunities PharmaLex have given us.

How has the merger impacted your organization and operations?

First of all, the merger has accelerated our expansion plans and growth by providing existing clients as well as new clients in new markets and locations a wider array of services (encompassing the entire product lifecycle). It also represents new career opportunities for our associates.

It has allowed us to directly contribute to the business goals by discussing ways to enhance the current structure and operations that would allow sustainable growth. Our office has been working very closely with the US offices in those efforts. As a group, we have had several meetings in which we have agreed on the focal points we should work on to facilitate market penetration. Education and training will be key factors in our business goals. We are also working in sharing our respective expertise so that we all have the best knowledge in the four PharmaLex service lines.

Puerto Rico has an excellent reputation for producing world-class talent in the pharmaceutical manufacturing field. However, companies are competing for this talent. How do you ensure you attract, develop and retain the right talent?

A few years back, we converted many of the long-term independent contractors we had to employees and coupled this initiative with a competitive salary and many benefits which are also accessible to all our regular employees. This was a very effective way of retaining talent.

We also are like a family and our employees feel very engaged with the company; they usually refer to us colleagues for hiring so that means they want them to experience our working environment.

Additionally, since our resources are on the field most of the time, we make sure to keep constant and effective communication with them. For this reason, we created an operations management department. The Operations Manager’s role is to communicate constantly and provide them with the necessary technical and administrative support. Lastly, we organize an annual meeting where we provide educational seminars on subjects relevant to the healthcare industry.

What milestones would you like to reach in the next five years?

I am constantly thinking about the hundred resources that I have under my wing so every strategic move I make considers them. I want to be able to tell them that, in ten years from now, they can continue working with us and eventually retire from our company. This can only be achieved by expanding and looking for new opportunities. I also want to bring new technologies and processes to the island.

Moreover, we would like to support the education of the island's talent. To that effect, we are joining forces with several organizations to educate young professionals and PharmaLex Puerto Rico resources in these new processes and technologies.

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