Interview: Elizabeth Plaza – Founder & Chairwoman of the Board, Pharma-Bio Serv – Puerto Rico



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Prevention versus remediation is the name of the game in regulatory and compliance issues for pharmaceutical manufacturers; the cost of non-compliance is much higher than investing proactively in compliance. Elizabeth Plaza, founder and chairwoman of the board of Puerto Rican-based regulatory and compliance consultancy Pharma-Bio Serv, discusses how her company helps manufacturers ensure the best practices and controls to stay competitive in the industry.

What was the basis for establishing Pharma-Bio Serv?

I founded Pharma-Bio Serv in 1993, having witnessed an opportunity to create a consulting company based on my experiences in the previous two companies for which I worked. In the 1990s and early 2000s, the industry was growing around the world, and with the concentration of companies in Puerto Rico there was still a strong pipeline of new products being transferred to the country.

At that time, there was not much competition in the consulting services space. As a pharmacist by profession, I was debating between continuing my career in that area and starting a consulting business. The opportunities in manufacturing were so huge at the time that founding a company was the best option, and Pharma-Bio Serv has expanded exponentially ever since. In 1995, J&J offered me to manage an important project that provided exposure to many important people within the company. This project also offered the opportunity for us to demonstrate our capacity.

The project was significant and allowed me to create the first employment opportunities within the company.

How has the company evolved since that time?

Companies like Pharma-Bio Serv that understand those regulations are a need for this industry. We have been expanding our services to meet our industry customers' needs from Technology transfer to Process validation, to Quality Systems and Regulatory Compliance and to Management of projects from engineering through Commissioning and Qualification.

In 1999, we received our first international opportunity in Italy, where I spent two years supporting an important customer. Moreover, because of the need for technical training in the industry, particularly since regulations and industry practices change over time, to stay on top of those changes we also started a division in 2002 called Pharma Serv Academy to educate and train our customers. I have also been involved extensively with the boards and committees of associations such as PRMA and PIA. Pharma-Bio Serv has been ranked the top regulatory compliance and validation company in Puerto Rico by Caribbean Business since 2003. In 2004 we created a social responsibility program for children. In 2006, I acquired a small company in Pennsylvania, which now serves as our US base. Pharma-Bio Serv went public that year too, and we were named a Top 20 Employer in Puerto Rico.

Towards the end of the 2000s, fewer products in companies' pipelines were being released, and many mergers and acquisitions took place. How has that impacted Puerto Rico and Pharma-Bio Serv?

It has impacted Puerto Rico as in any other country. At this time, Ireland was starting to replicate and improve upon the Puerto Rican manufacturing model with new incentives. As the industry grew there, I realized that our services could be utilized there. I opened an office in Ireland in 2008, when we also built Scienza Labs, a testing laboratory facility for microbiology for customers who need additional testing capacity, or who are looking to outsource their laboratory operation and focus on the manufacturing core business. In 2009, we expanded this facility to analytical chemistry. Over the years, we have continued integrating new divisions and services here and abroad. In 2009, we received the Exporter of the Year award from the federal government as our sales were evenly split between Puerto Rico and internationally.

In 2011, Pharma-Bio Serv expanded to Spain, where the pharmaceutical industry is very important and there is a natural connection culturally and linguistically. We believed that Spanish companies could benefit from Pharma-Bio Serv in terms of qualifying to export their products to the US and

take advantage of our knowledge and understanding of FDA regulations. Today, Pharma-Bio Serv's Irish office reports to Spain.

Additionally, Pharma-Bio Serv opened an office in Los Angeles in 2013 and we have just registered a subsidiary in Sao Paulo, where we already have some business with multinational as well as native companies. We are also focusing heavily on Latin American countries such as Panama and Costa Rica, and we have done business with the Dominican Republic and Curacao, too. We have identified Latin America as a region that will benefit greatly from our experience and background in FDA regulations. More recently, we also established a calibration division, Metrologix.

How has the industry's generally dwindling R&D pipeline and major consolidation impacted manufacturing and does it pose any risks?

Regulations have evolved to help the industry and we must perceive them as a benefit. The industry needs to be aware of their importance for producing top quality products. This extends beyond the FDA; Puerto Rico receives visits from regulatory agencies worldwide, each with a different approach but ultimately all looking to ensure that companies have quality systems that protect the consumer.

Changes to regulations require companies to invest and while the industry may perceive that as a challenge in terms of cost, adapting to those changes ultimately brings savings and allows companies to be more competitive. When companies manufacture products with the best possible quality, the risks are lower and thus the cost associated with non-compliance is reduced. In fact I usually say that the cost of non-compliance is much higher than the cost of compliance. The cost of non-compliance for some companies, such as warning letters, recalls, or changes to stock price, may never be recovered compared to investing in improving equipment or facilities. Pharma-Bio Serv works with companies in terms of prevention over remediation, although we do help with the latter as well. We help companies not only maintain robust quality systems, but we ensure that their processes are validated to today's standards. We also work with our customers to ensure that their manufacturing processes are controlled and optimized in addition to our other services like technology transfer, laboratory services and calibration.

What are the main points in which Puerto Rico demonstrates solid KPIs that could be a lesson for companies in other countries to learn from?

Puerto Rico has decades of experience. I grew up with GMP in my DNA! This is true for everyone in the industry, so it comes naturally. When I visit other countries and I speak about regulation requirements, I realize how much we can contribute from that experience. Regulations are a

learning process that Puerto Rico has already undergone. That knowledge for manufacturing is our major asset and competitive advantage. The Puerto Rican pharmaceutical, biotech and medical device industry professionals are well-versed in what it takes to produce quality products.

Furthermore, regulators are important for our ecosystem. The FDA office in San Juan, which works alongside the industry, collaborates to share FDA's expectations with the industry. This is also a competitive advantage because the FDA has had a constant presence in Puerto Rico. They know the industry and vice versa, and we can work together transparently.

Secondly, the Puerto Rican government recognizes that pharmaceutical manufacturers bring employment and development opportunities to our people. Thus the government has provided many different types of incentives to retain and bring new companies to the island. Even after 936 loss, PR provides very attractive incentives for the industry. Finally, Puerto Rico has developed a very strong ecosystem to support this industry, of which we are part. Every necessary component that might be part of what any company needs for competitiveness is easily accessible here. That makes Puerto Rico a very strong place to come, establish operations and be successful for many years.

What would be an example in which Pharma-Bio Serv exemplifies those traits?

I am currently working with a Florida-based pharmaceutical company, to establish their first finish product manufacturing operation Puerto Rico. I met them when two years ago when they were about to have a new product approved and did not have a place to manufacture by themselves. We spoke about Puerto Rico and its advantages and I invited them to consider Puerto Rico as an alternative to establish a manufacturing facility. We are currently working on the construction of this facility which will be located in the North corridor of the island. Pharma-Bio Serv has assembled a turnkey program for them with local suppliers. We have provided them local project management, designers, engineers and construction companies. Pharma-Bio Serv will establish and validate their systems, and we are selecting the best talent for the company management. Because of all the experience we have developed over the years, we can speak to CEO's looking to establish or expand a manufacturing operation. Pharma-Bio Serv can easily help companies understand that Puerto Rico is the best place to manufacture because we have it all.

What has been the key to success of Pharma-Bio Serv?

It is all about the quality of the people in the company. Pharma-Bio Serv has a vast amount of knowledge, as we all come from the industry. Furthermore, in the service business the customer is always first and we are very clear about that. We have no limits when we work for a customer. Our

expansion and adding of additional services is a consequence of our customers identifying areas where they need additional help. As such, this process has been very natural.

How do you want to expand your presence in the future?

As the industry changes, we need to adapt to stay competitive. That is why we are looking at Latin America now. We constantly study what is happening around the world, and I see part of our growth to continue from that region. But I also see many opportunities with SMEs that were not initially our focus. The majority of the industry in Puerto Rico consists of multinationals, which mostly have their systems established. I see opportunities with smaller companies, who do not necessarily have that internal knowledge. More recently, we have realized that SMEs are truly in need of companies like ours that can assess their regulatory needs and help them resolve those issues. Furthermore, many more emerging countries want to do business in the US now. Because we know FDA regulations well, it would be very prudent for companies to use Pharma-Bio Serv to accelerate the process of marketing their products in the US.

What else does the international life sciences community need to know about Puerto Rico?

Puerto Rico may be a small island, but it has the best ecosystem, incentives and talents to make any pharmaceutical company succeed and be competitive. I would love to replicate the model we are currently implementing for our customer to many other companies looking to grow safely. Puerto Rico has so many advantages to offer and fewer risks; it is the right choice!

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