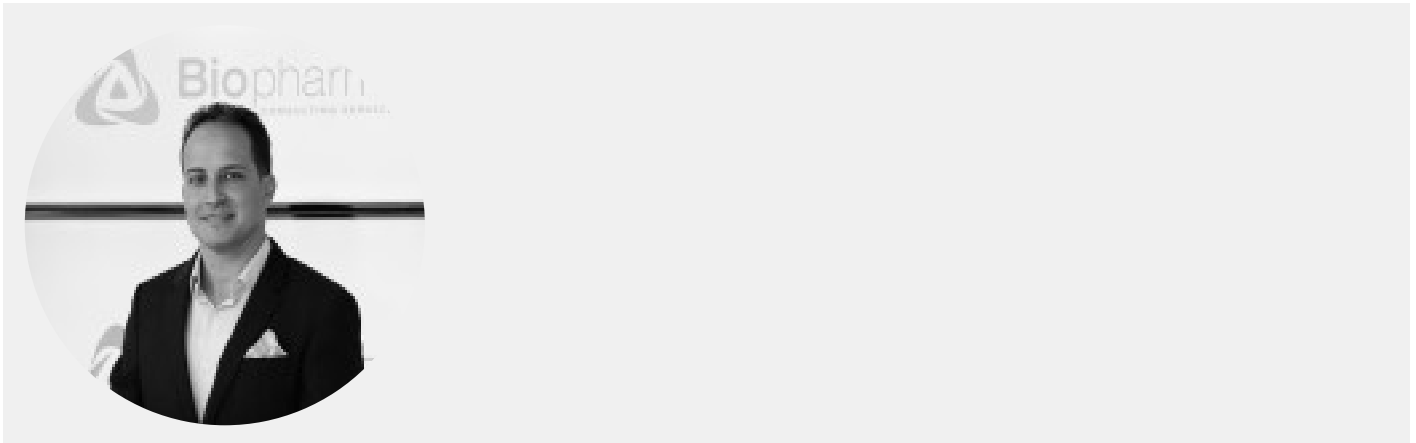


Interview: John Taboas - President, Biopharma Consulting Services, Puerto Rico



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Tags: [life sciences](#), [Puerto Rico](#), [pharma](#), [pharmaceuticals](#), [FDA](#), [biosimilars](#), [Latin America](#), [manufacturing](#)

John Taboas is the president of Biopharma Consulting Services (BCS), a leader in visual inspection and other validation and engineering services. Here he tells PharmaBoardroom how the company is working to position Puerto Rico as a hub for subject matter experts in visual inspection, with a new training facility and inspection committees, their work offering video recording of media fills and airflow pattern studies, and their plans to expand into Latin America, including Cuba.

How has BCS dealt with dynamic changes in Puerto Rico's life sciences market, and how can you stay competitive?

It is no secret that Puerto Rico's life sciences market has not grown in recent years. Following our strategic plan we identified areas in the industry where there was limited technical and regulatory service expertise, such as the Visual Inspection Processes. Since 2010, we have successfully completed visual inspection projects in the US and Puerto Rico markets. These projects include agencies' regulatory commitments as well as process development and implementation for new facilities. BCS tailors turnkey solutions for any visual inspection necessities (manual, semi-auto, and automated processes).

How are you trying to position Puerto Rico as a hub for visual inspection expertise?

Furthermore, we expanded our services in visual inspection beyond development and implementation. BCS has a Laboratory facility for sample sets “defects” preparation (particle seeding / container defects) for local and external markets. Likewise, in a joint venture with a local firm, we design and manufacture manual devices to ease inspection processes for local and external markets.

In addition, we are looking forward to grouping all local customers who deal with inspection processes into what we call the “Puerto Rico Visual Inspection Committee” which will focus on harmonizing practices and further developing studies. We want to position the island and its professionals as SMEs (Subject Matter Experts) in visual inspection. Also, BCS is working on implementing and becoming a training facility and workforce source for so our clients can rely on our expertise and outsource so we can add value to our service provider/customer relationship.

Secondly, BCS has managed to join with local and external companies to expand our services portfolio. One of these companies is Kyoto America, a Japanese company with more than 30 years in the Japanese pharma, food and beverage and electronics industry. Together, we are providing local manufacturers with top quality packaging and assembly machinery as well as custom applications.

Another service worth mentioning is the video recording of media fills and airflow pattern studies which we are offering in a joint with a local firm named Underlight Pictures.

What is your assessment of BCS’ current strengths and weaknesses, and how would you describe its market positioning and growth factors in 2015?

BCS’ strength resides in our employees. Our workforce is a well-balanced one with a mix of seasoned professionals who have occupied leadership positions in the local pharma industry and young bright professionals driven by high quality standards. Additionally, BCS has been able to strategically define a structured services diversification plan that has been critical to our competitiveness and growth positioning for the past years [and will be in the future]. Last but not least, our service’s quality and customer relationships are our biggest strengths.

What are some of the competitive advantages that BCS offers in validation, engineering and quality systems services?

Our competitive advantage beyond our services diversification as mentioned earlier, is our employees. The mix of seasoned subject matter experts and young bright professionals is a combination which improves our workforce. In order to maintain these advantages, BCS has

managed to benefit them in a way that keeps them committed to BCS. As a matter of fact, our employee retention rate is one of the highest.

What is the importance of BCS within the Puerto Rican life sciences industry, and its geostrategic positioning within the Americas?

The strategic importance of BCS is that through our years of experience on highly regulated environments such as Consent Decrees and of being under the constant oversight of agencies, we have developed the expertise necessary to provide excellent results in implementing and sustaining appropriate Quality Systems. This is important for both, to keep a high standard manufacturing industry on the island and to provide the necessary tools and services for emerging markets such as Latin America, which is the logical path to pursue based given our native language. As a matter of fact, we have associates who worked in South America sites and helped them to achieve FDA approvals for the US market.

What contributions has BCS made as a service provider to ensure the success of life-saving products in the healthcare industry?

The best example of BCS contribution as a service provider is its track record of successfully completing clients' critical projects. This includes new product introductions, regulatory commitments for different agencies and new processes for Pre Approval Inspections (PAI). We know deadlines, we know commitments but above all we achieve them with high quality standards and excellent results.

Are your services based only in Puerto Rico or will you expand elsewhere as well?

We started the company in North Carolina, providing services to the east coast of the US. We are looking to expand to Latin America and potentially the Cuban market.

Many validation and engineering service providers are looking elsewhere, but Latin America presents certain challenges in terms of applying an FDA mindset.

Puerto Rico has two advantages. The first is the language; the logical path to follow is to go to Latin America. These companies want to get into the US market, so they have to meet FDA regulations in which we have the expertise. We can provide them with the necessary tools for such matters. In fact, associates working with us have provided services in South America and have managed to get those facilities FDA-approved for marketing in the US. It has been done and we will continue doing it.

Is it worth the investment for a company to get even just one NDA in terms of a return?

It is worth the investment, particularly for biosimilars. One of our associates helped a South American company with a biosimilar pipeline get an FDA approval. Once they finally market that product in the US, the profits will be substantial.

How do you see the manufacturing industry's role as an engine of economic recovery and development, and what role will BCS play in that?

Being in the industry for a period of time and being able to witness its highs and lows, we have seen the pros and cons of decisions that have brought the industry to its current state. For that reason we can advise new entrepreneurs on where and how to invest on the island. It is worth mentioning that currently we are advising South American manufacturers on establishing manufacturing facilities on the island. Of course, there are areas like labor laws and operating costs (among others) which need to be restructured to provide a fertile environment for such investments.

How would you define BCS' commitment to the Puerto Rican population?

Puerto Rico's future relies on our young, who in my opinion are not being treated as needed and are not being provided with the necessary tools for their development. Our mission statement states that "*BioPharma strives to provide opportunities for growth and enrichment to our employees, business partners and the community in which we operate*"; a grant-based program is being developed for 5th and 6th graders. The purpose of this program is to reward their efforts and motivate them to keep studying mathematics and sciences.

In addition, and in alliance with "Iniciativa Tecnologica del Norte" (INTENOR) this program will bring them closer to an "*Entrepreneurship Experience*." We believe that rewarding our youth efforts while opening their eyes to an entrepreneurial ecosystem will kickstart their aspiration for a brighter future, a brighter society focused on entrepreneurship.

How do you assess the service provider industry's future, both in and beyond Puerto Rico?

A couple of years ago, we identified visual inspection as a sector in which other competitors were not paying attention. BCS has built expertise in that area. We have been working in projects on vision inspection in the US and Puerto Rico, including manual, semi-auto, and automated. We have FDA commitments related to vision inspections, new processes for new facilities that are already PAI-approved.

We have also provided associate services to vision inspection, and BCS is designing and manufacturing tools to make those processes easier. We are obtaining patents with some of them. The company is working with industry players on the island who do vision inspection to create a group called the “Puerto Rico Visual Inspection Committee” in order to harmonize processes and further studies on visual inspection. The intention is to help local professionals from Puerto Rico to branch out internationally. Through the committee they can go from Puerto Rico to the rest of the world. We are also working on being the work source for inspectors and training facilities so the big players can outsource that.

Developing a niche is a good strategy for companies that want to succeed.

Ultimately it relies on strategic management. Each case is different; each provider needs to assess the internal and external factors, look at their strengths and weaknesses and decide on a strategy.

What is your vision for the future of the Puerto Rican life sciences industry and what role will BCS play within that?

Puerto Rican life sciences is a decades-old industry, globally known for its production quality. So, our manufacturing knowledge is one of our advantages. Still, infrastructure costs need to be revised to enhance our attractiveness for external capital investments. Meanwhile, BCS’ services on external markets will be the voice of the quality professionals residing on the island. As mentioned earlier; based on the latter we are advising South American manufacturers on how to establish manufacturing facilities on the island.

What objectives have you set for BCS to grow in the next five years?

BCS has a Business Strategic Plan which constantly monitors all factors (internal as well as external) and design or redesign of our strategy. Exports to emerging markets will be a big player in our future. As a matter of fact, we are currently researching the Cuban market as one of those possibilities. In concrete terms, our strategies are market development for exports and market penetration for the local side.

As a result of globalization, the healthcare and life sciences community became one big community. It is our job to strengthen links and maximize the international collaboration. For that, organizations such as PharmaBoardroom are essential; we should support them in fulfilling their mission while taking advantage of the community of collaboration and communication.

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