

Elizabeth Plaza - Founder, ProQuality Network



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ProQuality Network, founded by Elizabeth Plaza, leverages over 30 years of experience in the pharmaceutical industry to support companies in maintaining CGMP compliance and improving quality systems. The company provides third party remediation, quality systems enhancement and simplification, project management and validation services, while integrating cutting-edge technologies like AI to help clients stay ahead of industry challenges. Plaza highlights the growing demand for flexible consulting services and the shift towards outsourcing specific functions. With plans for expansion into Colombia and Spain, she is optimistic about Puerto Rico's continuing role as a key pharmaceutical manufacturing hub under the "America First" agenda, emphasising the island's unique advantages such as competitive incentives, bilingual talent, and an experienced workforce.

Could you share an overview of your extensive experience in the pharmaceutical industry and the problem you aimed to address with ProQuality Network?

My journey in the pharmaceutical industry started at a very young age, with an experience that left a lasting impression. I was a child traveling with my parents through Puerto Rico, passing these enormous pharmaceutical plants, and I remember thinking, "I would love to see one of those from inside someday." That curiosity followed me into my career.

I pursued a degree in pharmaceutical sciences, and during my studies, I had the opportunity to intern at the Pfizer-Vega Baja plant, which turned out to be a pivotal moment. I was hired by them after graduation, starting as a pharmaceutical technologist. My role focused on supporting the transfer of new products into the plant. This experience exposed me to various departments—from R&D to process development and plant operations—giving me both technical expertise, the quality awareness to ensure products approval, and leadership skills that were invaluable for my future.

In 1989, I moved to Johnson & Johnson, where I continued working in new product transfer during what I believe was the period of largest growth for Puerto Rico's pharmaceutical industry. It was an exciting time, with multinational companies setting up operations and Puerto Rico becoming a hub for blockbuster products. I developed strong industry connections that have lasted throughout my career.

However, in 1993, personal circumstances led me to take a different path. I resigned from Johnson & Johnson and bought a retail pharmacy to balance work and family life. Little did I know, that decision was part of a bigger plan. During that period, I began consulting for my former boss, which eventually led to the creation of my first business, PharmaBioServ. It wasn't long before others in the industry sought my expertise, and I soon found myself running one of the first consulting firms dedicated to the pharmaceutical sector in Puerto Rico.

Fast forward to 2020, and after selling my company in 2006, I thought it was time to step down. But as life often goes, things don't always turn out as planned. A good friend reached out needing my expertise, and that was the spark that led to the founding of ProQuality Network in late 2021. What started as helping a friend turned into something much bigger, with calls coming from professionals around the world, from California to Spain and Colombia.

The experience I bring to the table has allowed me to create a network that offers valuable opportunities for professionals in the industry, particularly those seeking to remain active as consultants after early retirement. Now, I focus on helping clients stay competitive and compliant while creating opportunities for talented individuals to contribute to the industry. This phase of my career is truly fulfilling—seeing how my knowledge and experience continue to make a difference, and growing with others along the way.

With ProQuality Network now operating for a few years, could you share an overview of your company's core business and strategy for our global audience?

At ProQuality Network, we primarily focus on providing CGMP support to pharmaceutical manufacturers. This means that we assist companies in ensuring they comply with the rigorous standards that are required for the safe and effective manufacturing of pharmaceutical products, which are enforced globally.

When I launched this company, our first project was a remediation one, which involved helping a client address deficiencies identified by an enforcement agency and others that were identified internally within their operations. Our approach is to offer proactive support, meaning we either help with remediation or, in some cases, assist companies in identifying areas for improvement before any external pressure arises. In addition, we conduct audits and assessments to pinpoint weak areas and guide clients through the process of improving their quality systems. We focus on efficiency and simplifying quality. I always say, quality doesn't need to be cumbersome. Quality should be an integral part of any process, and understanding and knowledge is the enabler to simplification.

Our scope extends beyond remediation. We also specialise in supporting the broader aspects of quality systems, including validation practices, which are vital in the pharmaceutical industry. Validation is key, as everything must be thoroughly tested and periodically reviewed and validation state maintained. Though technology transfers aren't as frequent in Puerto Rico today as they once were when I started in the industry, we still support companies in transferring new technologies into their operations.

An exciting area we are venturing into is AI, which is growing rapidly within the industry. We have a professional on our team, Dr. Angel Benitez, who recently completed a degree in AI from the University of San Diego. He brings valuable expertise, and we have already started integrating AI solutions into our services.

What do you see as the key opportunities and challenges of integrating AI into your clients' manufacturing processes?

AI presents both significant opportunities and challenges for our clients, especially in how to implement it in a compliant manner. In the pharmaceutical world, everything has to adhere to CGMP standards, and the regulatory landscape for AI is still evolving. We are actively collaborating with the FDA to ensure we are at the forefront of compliance in this area. While it is an exciting opportunity, the main challenge lies in developing clear guidelines and regulations around AI integration. But it is something we are very enthusiastic about, and we see a lot of potential for AI

to drive innovation in the industry.

Another crucial challenge is talent. Puerto Rico has long been known for its experienced workforce in the pharmaceutical industry, which is why we are seeing some of our best talent move overseas. However, the increasing complexity of medicines and devices, coupled with the rise of AI, has underscored the need for developing new skills. That is why I am particularly proud to have Dr. Angel on board, helping us stay ahead of the curve by applying AI in ways that will add significant value to our clients.

How is the company adapting and updating its service offerings to meet the evolving needs of the industry, especially as complexity increases and costs rise?

As with any business, we have faced challenges, especially when it comes to price pressures and changing customer procurement strategies. But I believe any company that provides products or services must remain flexible to adapt to these shifts. And that is something we have been successful at doing for over 30 years in this industry.

One of the ways we ensure we stay relevant is by being selective in the clients we work with. We focus on building relationships with customers who understand the true value of the services we offer. If a company can't appreciate the experience and quality we bring to the table, then it is likely not the right fit. Feeling the appreciation for a job well done is our main reward and recognition from our many satisfied customers.

How has the competition and your business evolved and grown over time?

In terms of industry changes, one of the key shifts I have seen is how the consulting and contract work business has evolved. Over time, more companies are turning to external resources for specific projects, rather than bringing on permanent employees. This on-demand approach is something we provide, where we come in for a specific project with a clear beginning and end. It is a more cost-effective solution for clients because they don't have to hire permanent employees and deal with long-term liabilities.

This model of on-demand services has been incredibly successful and continues to grow. Many companies today are focusing their resources on their core capabilities, like manufacturing, and outsourcing other functions such as accounting, procurement, and even certain aspects of their

manufacturing to CMOs (Contract Manufacturing Organizations) or CDMOs (Contract Development and Manufacturing Organizations). This creates opportunities for us to step in and provide the expertise they need for specific projects, without the need for permanent hires.

The industry's growing reliance on outsourcing and flexible service models means that the consulting business, including ours, will continue to thrive. There is a strong market demand for specialised support, and as companies look to streamline operations, services like ours are well-positioned to meet that need. Even when faced with rising complexity and costs, this model remains an attractive and cost-effective option for many businesses.

ProQuality Network has made strides in expanding its presence. What are your short-term ambitions for further expansion?

My goal is to continue expanding my export of services, leveraging growth opportunities in Puerto Rico while maintaining a strong focus on the US market, which currently accounts for 85 percent of my business. To support this expansion, I recently engaged a partner in Colombia, where we are already serving clients, and I am also planning to further develop our presence in Spain. Having worked with clients in Spain for some time, this year marks a strategic step toward formalizing our expansion there. I'm excited about the future and look forward to sharing updates with our partners as these efforts progress.

Looking at the bigger picture, with the new administration in the US and the "America First" agenda, including tariffs and trade policies, how do you see Puerto Rico's role as a US territory in pharmaceutical manufacturing?

I am positive Puerto Rico is well-positioned to continue as a key hub for pharmaceutical manufacturing in the US. Despite some companies downsizing or leaving the island in the past, there are still major companies like Amgen, Lilly, AbbVie, Boston Scientific and CooperVision that view Puerto Rico as essential to their operations. The island offers unique advantages, including competitive incentives, bilingual talent, and a strong foundation in GMP. Additionally, Puerto Rico has outstanding universities that produce top engineers, pharmacists, chemists, and other life sciences professionals. While challenges like energy issues exist globally, Puerto Rico's infrastructure, weather, and cost advantages make it an ideal place for business. Water is the main ingredient in most biopharmaceutical process and the availability of water and its cost here are

highly competitive, which is crucial for manufacturing, and yet it is often overlooked. Despite the challenges, Puerto Rico has everything it needs to remain a vital part of the US pharmaceutical landscape.

What final message would you like to deliver to the international community on behalf of Puerto Rico?

Puerto Rico is the top destination for life science products manufacturing. We have a mature sustainable ecosystem built throughout almost 70 years since industry inception, the skills and understanding of technical and quality requirements, a trained and hardworking workforce, a full year perfect weather, the infrastructure to support demanding industrial needs, and furthermore, the best tax incentives that no other country offers. I enjoy working abroad, but certainly, love working at my island and I am fully committed to continuing helping our industry strengthening its presence and compliance standing at home.

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