

Ivan Lugo - Executive Director, INDUNIV, Puerto Rico



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Ivan Lugo, executive director at Puerto Rico's Industry University Research Center, Inc. (INDUNIV) with over 40 years of global pharmaceutical expertise, explains how his not-for-profit organization promotes Puerto Rico's competitiveness in science and technology by facilitating collaboration between industry, government and academia. He also highlights how the island aims to enhance its position as a global biologics hub for the life sciences industry by growing the footprint of international companies their and fostering local start-ups.

What is your general assessment of Puerto Rico's life sciences and pharmaceutical industry status today?

Looking at the industry from a global perspective, a trend towards biotechnology manufacturing can be spotted and this is no different in Puerto Rico. Now that we have overcome most of the damages of Hurricane Maria, we need to put together Puerto Rico's new value proposition, which ensures the continuous growth of the life sciences industry on the island. Overall, I am quite positive - as there are many reasons why companies should choose to expand development and manufacturing operations to Puerto Rico. Nevertheless, in the past, we have not been effective enough in promoting and communicating the opportunities our island has to offer to the life sciences businesses.

Puerto Rico has more than 60 years of experience in highly regulated biopharmaceutical manufacturing and all areas of life science and it is exporting medical products to more than 85 countries around the world. Currently, our island is producing eight of the 15 bestselling biological pharma products and ten of the 20 largest pharmaceutical companies do have a manufacturing presence on the island. Additionally, six of the top ten medical devices companies worldwide are producing in Puerto Rico.

Overall, the island ranks among the top seven states in the biosciences field with 70 medical device and 46 biopharmaceutical FDA-compliant plants, as well as 10 agricultural-bio operation sites. No other manufacturing hub in the world has such a high density on a rather small territory. Only Puerto Rico and New Jersey have highly specialized employment in four specific areas of biotechnology, which includes biopharmaceuticals, medical devices, agricultural biologicals and medical research/labs. For Puerto Rico, this sector makes up more than 60 percent of all our exports. However, internationally Puerto Rico's manufacturing capabilities in this industry are not well known.

What do you highlight when communicating the value proposition of Puerto Rico?

All our manufacturing sites are not only FDA-approved but fulfil the standards of every other regulatory agency worldwide as well. Additionally, Puerto Rico has high-quality human capital, providing a huge pool of talent for companies in the life sciences industry. The highly qualified human resources, research institutions and proximity to headquarters research enabled the development of the first global approval of a product with a continuous manufacturing full process. This ensures that Puerto Rico remains one of the key hubs for new technology platforms development and new products launches.

Our island has a legacy of manufacturing and has some of the fastest launched for the best-selling pharmaceutical products in the world, which does not happen without having a strong and well-educated workforce.

Puerto Rico is in the on-going process of moving beyond being a manufacturing hub only. Are the right incentives in place to attract investment in the R&D sector here in Puerto Rico?

With such a strong life science ecosystem, Puerto Rico wants to grow and attract startup companies to our bioscience hub. I am confident that we have the right incentives in place. Particularly, the government offers a tax credit in the amount of 50 percent for eligible investments and operational cost made in research and development on the island. Big pharma companies see the value Puerto Rico offers for research and innovation – for instance, one major biotech company, has a 60.000 square feet product development facility.

Nevertheless, incentives for attracting R&D are worthless without having the right human capital, supply chain and infrastructure. Puerto Rico stands out in this regard as we have great universities, renowned for engineering, biological, chemical and physical sciences and math. Moreover, significant investments in building a biotechnology infrastructure have been made recently. For start-ups, a new 14,307 m² Molecular Sciences Complex and a new Comprehensive Cancer Center with the Medical Sciences campus with multiple laboratories and clinical research units has been built. It serves as a translational research centre park for emerging biotech start-ups for the development of new drug products and treatment. The complex offers the right infrastructure for incubation with state-of-the-art analytics and laboratories space.

Are there any success stories related to biotechnology you would like to highlight?

One of the success stories is the homegrown start-up MBQ Pharma, which will soon test an immune therapy product in phase one clinical trials. The company has emerged of the University of Puerto Rico Medical Sciences Campus pharmacy school and is working with the Molecular Center and already has received funding from PRIDCO. INDUNIV is also helping to set up more laboratories for biologics and gene and cell therapy, as part of the process of moving towards personalized medicines. We are collaborating in the development of an advanced controls system laboratory for the factory 4 concept and catalyzing the development of a PhD program in Biopharmaceutical Engineering Sciences and developing strategies for the application of the blockchain in the life sciences.

One of the most relevant achievements that impact the future of pharmaceutical technology was the world's first FDA product approval on a full continuous manufacturing process here in Puerto Rico by Janssen. This shows that Puerto Rico is not only an expert in launching products but has also significant expertise in technological innovation and research.

What are the biggest challenges that the industry and your members face today?

Despite the negative headlines after Hurricane Maria, most of the pharmaceutical production was up and running within two weeks, with many companies even continuing to manufacture during the category 5 hurricane. Hence, there is a big misconception that there were supply issues or stockouts in Puerto Rico. This was not the case and our facilities worked closely with the FDA to ensure all plants were able to return to their regular business schedule as fast as possible. The overall response of the industry has been great, with companies supporting the local ecosystem, supplying gas and ice and even flying in cash to pay wages of employees. One of the lessons learned is to have strong business continuity plans and redundant utilities, which allow fast recovery. Significant investments are being done by the companies and government to be better positioned for future catastrophic events. The industry is more resilient than before, and pharma companies are here to stay, which is shown by their dedication to their employees and supporting their surrounding communities and our educational institutions. It is now our job to communicate this message.

How do you promote Puerto Rico's capabilities externally?

INDUNIV was founded in 1984 as a nonprofit organization representing industry, government and the academic sector. As the life sciences cluster, we advance the understanding of the pharmaceutical and bioscience development fields and develop strategies and road maps to support public policy and advocates its implementation. Together with academia and government, we are enhancing Puerto Rico's competitiveness and making it more attractive for the development and manufacturing activities. Moreover, we are also communicating this message to the world, for example branding the island at the annual BIO international convention, at which we have been participating for the past 15 years. Here we will have a pavilion and the leading stakeholders of the Puerto Rican private, academic and political ecosystem working together to promote the island and its biotechnology capabilities.

How will Puerto Rico's life sciences industry look like when we will come back for our next report in five years?

We will see an increase in our development and manufacturing capacities with the rise in immune therapies as well as gene and cell therapies. There are already some companies in this field with an interest in setting up their facilities in Puerto Rico, so this sector will definitely grow. In addition, our

local services companies in the areas of engineering, design, construction, commissioning, validations, clinical research, health IT and regulatory will continue to grow and export there services to the world and we have built and started-up some of the most sophisticated facilities in the world. Moreover, I hope that there will be more molecules developed on the island, as many smaller companies and start-ups seeing Puerto Rico as an attractive destination for research and innovation. Our goal is to be a leading platform destination for start-ups in the life sciences field.

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