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Ivan Lugo-Montes emphasizes the Puerto Rico Bioscience Cluster (INDUNIV)'s instrumental role in advancing the island's biosciences industry for over 60 years. Driven by innovation, workforce development, and global competitiveness, the Cluster has achieved significant milestones in advanced manufacturing, pharmaceutical cold chain logistics certification, business promotion, and international partnerships. Key initiatives include collaborations with the Biotechnology Innovation Organization (BIO), the Puerto Rico Department of Economic Development and Commerce (DDEC), the Puerto Rico Science Trust, Invest Puerto Rico, and STEM education programs, all advocating for favorable policies and reinforcing a thriving ecosystem that bolsters Puerto Rico's position in the global bioscience landscape. Lugo-Montes explains how the Cluster's diverse leadership and active involvement in national forums highlight Puerto Rico's impact on the global pharmaceutical and biosciences sectors, while its commitment to fostering innovation and retaining talent is essential to the industry's sustainable growth on the island.

Could you provide an overview of the Puerto Rico Bioscience Cluster and its role in advancing the biosciences industry over the past 40 years?

The Puerto Rico Bioscience Cluster, known as INDUNIV, has been active in Puerto Rico for 39 years. Next year, we will be celebrating 40 years as a formal institution, having been established in 1984.

Our cluster comprises a diverse range of industries, including pharmaceuticals, medical devices, agricultural biotechnology, medical research and laboratories, and supply and distribution. This broad definition allows us to foster innovation across multiple sectors and positions Puerto Rico as a significant player in the global biosciences arena.

One of our primary strengths lies in our commitment to advanced STEM education and innovation. We collaborate with universities and form advisory committees that focus on enhancing the competencies of our workforce. This initiative involves developing state-of-the-art laboratories and educational programs that ensure our talent is equipped for the future. By continually assessing the evolving needs of the industry, we strive to prepare our workforce for the next wave of opportunities.

How does the cluster enhance Puerto Rico's global competitiveness and what initiatives have contributed to its growth?

In terms of global competitiveness, the Puerto Rico Bioscience Cluster maintains close ties with the Department of Economic Development, Invest Puerto Rico, and other key industry stakeholders to identify and capitalize on emerging opportunities. One of our latest accomplishments is the establishment of the first certification program for pharmaceutical cold chain logistics, which ensures that companies involved in manufacturing, transportation, and storage adhere to stringent quality standards. In partnership with IATA we provided the CEIV certification to key players such as American Airlines' station in Puerto Rico and several local warehouses, that serve the San Juan International Airport, thereby enhancing our logistical capabilities and bolstering the ecosystem.

Our business development and promotional efforts are equally vital. We assist companies in navigating the local landscape, connecting them with the right individuals and resources to establish operations in Puerto Rico. For 21 years, we have actively participated as the BIO affiliate representing PR in the Bio-International Convention, the largest global event for the bioscience industry. At this past year's event in San Diego, we joined the 40-member delegation from various sectors, including companies and universities at the Puerto Rico Pavilion, to promote the Island potential. We also generate and utilize key statistics, in partnership with Invest Puerto Rico, to highlight the island's advantages. Our involvement in the TECONOMY Report produced by BIO further underscores Puerto Rico's standing, particularly its high location quotient (LQ) in pharmaceuticals, positioning PR as the only Jurisdiction with highly specialized talent in 4 of the 5 Bioscience sectors, demonstrating our significant presence in the global biosciences landscape.

Advocacy is another cornerstone of our work. We collaborate with organizations like PIA and PRMA to ensure that public policies and incentives are favorable for industry growth and to address any inconsistencies that may arise. This proactive approach guarantees that Puerto Rico remains an attractive destination for biosciences companies.

Our board of directors is composed of leaders from across the pharmaceutical, medical device, and bio-agriculture sectors, Universities, the PR Science Trust and the Government of PR, ensuring a broad representation of the ecosystem. Our current president is from Abbvie, the vice president is the president of the University of Puerto Rico, the secretary is from Amgen and the treasurer is president of CIC Group, largest construction company in the Island. This diversity exemplifies our cluster model, encompassing all the elements necessary for innovation and growth. Additionally, we are an active member of the BIO-CSBA (Council of State Bioscience Associations), which connects us with partner organizations across the U.S., such as NJ Bio, MassBio, and BioCom in California. We meet twice a month to share insights, strategies and federal advocacy opportunities further strengthening our position in the biosciences sector.

The ability to produce goods domestically is critical, especially considering the significant drug shortages currently affecting the United States, with over 250 products in short supply. While U.S.-based vendors are preferred, domestic production is often insufficient, leading companies to source from countries like India. This highlights the need for a secure and reliable U.S. supply chain to prevent future shortages during public health emergencies or pandemics.

Supporting this objective, INDUNIV works with the US DoC and other agencies in support of increasing the CDMO's local manufacturing. In addition, the Economic Development Agency (EDA) provides essential grants for infrastructure and workforce development. Additionally, Puerto Rico has established the first office of research and statistics from the U.S. Census Bureau, one of only 33 centers nationwide, allowing us to gather crucial data and insights.

We also engage with a variety of governmental bodies, including the U.S. State Department, US Dept of Commerce and DARPA, the Department of Defense's advanced research agency to align strategies attracting on-shoring and developing breakthrough technologies. . A recent roundtable brought together industry leaders to explore how Puerto Rico can contribute to global bioscience efforts. Dr. Hepburn , the White House Vaccines and Therapeutics Lead, visited Puerto Rico for three days to assess the island's role in future health initiatives. These high-level discussions are essential as we continue to position Puerto Rico within the US National Security and global bioscience landscape.

How does the cluster contribute to the economy, and what are its key strengths and opportunities for growth in the biosciences sector?

The Puerto Rico Bioscience Cluster, or INDUNIV, plays a crucial role in the island's economy, where manufacturing constitutes approximately 46% of the workforce, with a significant 33% of that being dedicated to the pharmaceutical industry. This sector is particularly vital, as it accounts for an impressive 70% of all exports from Puerto Rico. In terms of economic standing, while Puerto Rico boasts the highest per capita economy in Latin America, it remains the lowest in the United States, creating a unique position between two worlds.

Despite the inherent risks of such dependency on pharmaceuticals, the strategic geographical location of Puerto Rico offers substantial advantages, allowing us to efficiently ship products to 120 countries. This capability is bolstered by our multilingual workforce, fluent in Spanish, English, and GMP (Good Manufacturing Practices), which facilitates compliance with the FDA and various international standards, including those set by the European Medicines Agency (EMA) and others across Asia and LATAM. This broad capability is something few countries can match.

Pharmaceuticals not only dominate our exports but also contribute to 74% of Puerto Rico's GDP. We are ranked among the top seven U.S. jurisdictions for employment in pharmaceuticals, underscoring our highly specialized talent pool. A recent study highlighted that Puerto Rico is the only U.S. jurisdiction with expertise in four distinct bioscience areas: pharmaceuticals, medical devices, medical research, and distribution. This positions us uniquely compared to other states that typically specialize in only three.

Our location quotient (LQ) for pharmaceuticals is the highest in the United States, indicating our strong competitive advantage in this field. While growth has been somewhat flat recently, we are actively working to change this trajectory, particularly in medical devices and research, where we are developing niche specializations comparable to leading states like Massachusetts and California.

Furthermore, we have a robust infrastructure that supports workforce development, with numerous universities and research institutions aligned with industry needs. Incentives play a crucial role as well; Puerto Rico offers a variety of government grants, Manufacturing tax exemptions, tax credits and angel funding, placing us among the few states with comprehensive incentives to attract biosciences companies.

What key strategies is the Puerto Rico Bioscience Cluster implementing to enhance its workforce and foster innovation in the biosciences sector?

We recognise the need to evolve with emerging in-silico technologies such as artificial intelligence, machine learning, and 3D printing. We are committed to preparing our workforce for these advancements, ensuring that our regulatory processes adapt accordingly. This proactive approach not only enhances our local capabilities but also strengthens our position as a leader in the global biosciences sector, paving the way for continued growth and innovation.

To position ourselves effectively within the biosciences industry, we are actively pursuing several key strategies in collaboration with the Department of Economic Development and organizations like the Science Trust. A significant initiative is the BioInnovate program, funded by government grants, which aims to develop a 21st-century workforce tailored to the needs of our sector. This involves creating upskilling programs in crucial areas, particularly the regulatory processes involved in pharmaceuticals and in-silico technologies.

One such program currently being developed in partnership with the School of Pharmacy will establish a regulatory center that offers certifications covering everything from product registration to quality control in manufacturing. By equipping employees with these certifications, we aim to drastically reduce the training period for new hires—potentially cutting down training time from one to two months to just two weeks. This streamlined approach allows companies to focus on specific operational needs rather than covering broad regulatory concepts.

Recently, Puerto Rico was designated as one of the 31 EDA Tech Hubs in the USA, which is a significant milestone for us. This designation not only enhances our access to infrastructure and workforce development programs but also reinforces the need for an integrated ecosystem that encourages collaboration among various stakeholders. This ecosystem includes organizations such as INDUNIV, the Molecular Center, The science trust, the University of Puerto Rico's School of Pharmacy, and several biotech firms. We are also working on the Phase II application, in partnership with Science Trust under the NSF Regional Innovation Program to compete for \$160 million USD. This initiative focuses on advancing biotechnology and manufacturing practices, further solidifying our ecosystem commitment to innovation.

Additionally, we are developing the Pharmaceutical Research and Manufacturing Institute of Puerto Rico (PRMI), which aims to integrate the entire pharmaceutical value chain—from discovery and product development to clinical trials, manufacturing, and commercialization. This initiative

supports our focus on precision medicine and leverages cutting-edge technologies like additive manufacturing and 3D printing. For example, the ability to 3D print tablets at pharmacies could revolutionize the way medications are dispensed and tailored to individual patients.

These strategies not only enhance our manufacturing capabilities but also improve the quality of our products and accelerate regulatory approvals. By simplifying the supply chain and fostering distributed manufacturing, we are making strides towards greater national security in our pharmaceutical supply, ensuring that we can address drug shortages more effectively and increase the access to needed medicines.

Ultimately, the combination of our talent pool, robust infrastructure, supportive policies, and innovative technologies positions Puerto Rico as an attractive destination for biosciences companies. We are focused on streamlining processes to make onshoring more feasible and cost-effective, which is crucial for the future growth and sustainability of our industry.

How is Puerto Rico working to retain its talented workforce, especially in the context of the ease with which individuals can relocate to the mainland United States?

Retaining talent in Puerto Rico is indeed complex, especially with the ease of mobility afforded by U.S. citizenship. Our strategy centers on a straightforward yet powerful principle: create jobs, and the workforce will stay and diaspora will return. By fostering a vibrant job market that meets the aspirations of Puerto Rico's skilled professionals, we aim to provide compelling reasons for individuals to build and sustain their careers here, contributing to the island's growth and resilience. Puerto Rico has a strong educational pipeline producing engineers, scientists, biologists, chemists and many other STEM professions. The challenge arises when job opportunities on the island are not available for these professionals, prompting many to seek employment in the States. However, many are willing to return if suitable opportunities arise. For instance, I spent 17 years in the U.S. mainland working for Merck and worked in 30 countries, but returned to the Island when asked to startup one of our newest manufacturing plants. . This sentiment is echoed by others in the diaspora who are eager to reconnect with their roots.

To bolster our local workforce, we are developing specialised programs in cutting-edge fields such as gene and cell therapies, in-silico development , and we are establishing apprenticeship initiatives to provide hands-on training. Importantly, we have a rich pool of talent already on the island, which has never been a concern.

Salary competitiveness is another factor. While wages in Puerto Rico are generally 10 to 20% lower than in the States, the cost of living is comparable. Despite this, the desire among the diaspora to return home remains strong, driven by a sense of community and belonging.

Reports indicate that Puerto Rico is a highly specialized location for talent in pharmaceuticals, medical devices, and medical research. Our resilience in the manufacturing sector is also noteworthy; for example, during Hurricane Maria, many facilities operated throughout the storm, with only brief shutdowns to allow employees to address personal concerns. This resilience is a hallmark of our industry, showcasing Puerto Rico as a model for operational business continuity.

Moreover, our companies invest in infrastructure that includes backup energy solutions, ensuring that they can withstand adverse conditions. Overall, our commitment to nurturing talent and creating opportunities is crucial to retaining the skilled workforce essential for the continued growth of Puerto Rico's biosciences sector.

As you approach the 40th anniversary of INDUNIV, what do you believe is still missing for Puerto Rico's industry, and what would make you feel satisfied moving forward?

As we celebrate our 40 years, I believe what's missing is a stable, long-term vision for Puerto Rico's industrial landscape. While we have a robust pharmaceutical sector, exceptional talent, and excellent infrastructure, the political landscape poses significant challenges. As a true democracy, every four years, we could experience a change in government, that could lead to disruptions in strategies, incentives, and policies. This inconsistency can improve or hinder our ability to maintain a competitive edge.

To ensure sustainable growth, we need to mitigate the effects of political changes by fostering a more stable regulatory and incentive environment. A commitment to continuity and a clear understanding of the industry's importance among policymakers is always crucial. As we have done for the last four decades, working together with the industry, academia and the government, I am very confident that PR Biopharma industry will continue a competitive growth path as a leader in advanced manufacturing.

As we approach the upcoming election, what are your feelings about the potential for continuity in policy and support for the industry?

Indeed, maintaining continuity in public policy, especially regarding industrial development incentives, is crucial for Puerto Rico's ongoing economic stability and global competitiveness. For six decades, these incentives have attracted a diverse range of industries—manufacturing, pharmaceuticals, biotechnology, and more—positioning Puerto Rico as a highly competitive hub. The island's established incentive model not only boosts direct investment but also fosters job creation, innovation, and regional economic growth.

As democratic changes inevitably shift leadership, advocating for policy continuity ensures that these benefits persist, protecting against disruptions that could undermine investor confidence or disrupt industrial progress. Highlighting the success of these policies, along with their role in sustaining economic resilience and international competitiveness, strengthens the argument for maintaining a stable, investment-friendly environment.

Absolutely, Puerto Rico occupies a complex and unique position. Its dual identity as both a Latin American society and a U.S. territory has shaped its culture, governance, and economy in distinctive ways. Being a U.S. territory has offered significant advantages, such as a stable democratic framework and economic ties to one of the world's largest economies. This blend of U.S. influence and Latin American heritage creates a rich, culturally vibrant society, but it also means Puerto Rico navigates the expectations and regulations of the U.S. while preserving its local identity. The island's unique status brings both opportunities and complexities, influencing everything from political discourse and economic policy to everyday life. Making Puerto Rico the bridge between the Americas.

Is there anything else you would like to add, or something I might have missed that is important for our readers to know?

I am highly optimistic about the future of the pharmaceutical and bioscience sectors in Puerto Rico. As one of the world's largest hubs, the island plays a critical role in advancing global health and holds immense growth potential. We encourage companies to consider Puerto Rico for their operations, with confidence that our highly specialized talent, robust infrastructure, resilience, and world-class incentives will support and accelerate your business growth.

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