Three Pilot Plant Roles: Development, Training, and Innovation [1]

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Calificación:

By Roberto Rodriguez, Ph.D., MTM, Executive Director, BDTC More than simply a site for small scale bio-processing, a pilot plant can be an engine of development. Set in the right place at the right time, it can not only optimize current industrial bioprocesses and develop new ones, but also promote the training of a workforce highly skilled in the latest biotechnology techniques. The Bioprocess Training and Development Complex (BTDC) under construction in Mayagüez, Puerto Rico will perform these three roles. The Commonwealth of Puerto Rico has established it as part of an overall development program designed to invest in new biotechnology-oriented assets and educational programs. This new facility will house research laboratories and training areas that will serve both the biotechnology industry and Academia. Construction of the new facility at the Guanajibo Industrial Park is scheduled to be completed this fall. Owned by the Puerto Rico Industry Development Company (PRIDCO), the overall site area is 16,020 square meters. The entire site is being developed to house the new building, its parking spaces, service areas, and passive recreational areas such as a courtyard and landscaped areas. The one-story building is approximately 23,176 square feet with a “U”-shaped footprint separating the research and training functions into two wings. The research wing comprises four laboratories with their support areas: a mammalian cell culture suite, a bio-analytical development suite, a purification development suite, and a microbial culture suite. Support areas include a small raw material warehouse, a mechanical room for clean utilities, a biohazard waste holding room, lab write-up areas, offices for lab scientists, and a small reference library. The main entrance is in the wing dedicated to the administrative offices and training. The wing holds an amphitheater, the offices, a small conference room, a large conference and training room, and a wet lab training room with a 24-

person capacity. This facility is intended for use in training skilled workers for the biotech industry in Puerto Rico. The large conference room and the amphitheater will have multimedia capability. The large conference room will also have capabilities for distance learning, incorporating the necessary computer infrastructure, network connections, and acoustical treatment. The three main roles of the BTDC are development, training, and innovation. The development of bioprocesses on behalf of the Island's biotechnology industry is paramount to the financial success of the BTDC. The biotechnological industry will happily use these facilities to optimize or troubleshoot existing bioprocesses without having to sacrifice large amounts expensive materials or incurring downtime in their own operations. The training of the workforce necessary to operate the expanding biological production in Puerto Rico is of critical importance to both the Commonwealth and the biopharmaceutical industry. A local biotechnological institution reports that it takes them 6–9 months to train a new hire to properly run the plant bioprocesses. Even then, the hands-on time available to trainees is very limited given the high costs associated with large-scale bioprocesses. At the Center, the existing biotechnological institutions will be able to shorten this training time from months to weeks of hands-on training on the whole process. We thus expect these institutions will be motivated to sponsor their new hires to work at the BTDC as trainees. At the same time, the facility will also provide the University of Puerto Rico (UPR) with a place for extensive hands-on training of their already highly skilled biotechnology students There are several institutions already offering bachelor degrees in biotechnology on the Island. UPR offers biotechnological programs at the Mayagüez (UPRM) and the Ponce (UPRP) campuses. The new facilities will give these students the opportunity to innovate under the sponsorship of their program professors and technical advisors. Moreover, the biotechnology professors will be motivated to try new ideas and to take on more students to test them. The ultimate goal of these assets is bridge drug research, development, and clinical trials, and eventually promoting small-scale commercial manufacturing. This dynamic process will enhance Puerto Rico's capabilities to serve the biotechnology industry. The Right Place Puerto Rico is recognized as a world leader in the manufacture of pharmaceuticals. For more than 40 years, this tropical island, a U.S. territory, has been the most lucrative place to manufacture pharmaceuticals. It is home to more than 140 pharmaceutical and medical device plants approved by the Federal Drug Agency (FDA), the European Agency for the Evaluation of Medicinal Products (EMEA), and the Japanese Ministry of Health, Labour, and Welfare (MHLW). In 2006, 14 of the top 20 pharmaceuticals sold in the U.S. were manufactured in Puerto Rico, generating more than $47 billion in sales in the U.S. alone, making the Port of San Juan the seventh busiest container port in the Western Hemisphere. Part of what makes the Island an ideal location for pharmaceutical manufacturing is the benefit the plants derive from a foreign tax structure while still operating within a U.S. jurisdiction. These benefits translate into a solid intellectual property protection and very low corporate taxes, thereby maximizing profits. However, what makes Puerto Rico the most attractive site for drug manufacturing is its workforce. The Island is one of only four U.S. jurisdictions considered as specializing in three bioscience sub-sectors: drugs and pharmaceuticals, medical devices and equipment, and research, according to Growing the Nation's Bioscience Sector: State Bioscience Initiatives 2006, Battelle Technology Partnership Practice, and the UW-Stout Technology Transfer Institute (STTI). In fact, Puerto Rico has the highest location quotient (LQ) in the United States in biopharmaceutical employment, 157 percent higher than the second place area, New Jersey. The Right Time Since recombinant insulin was first developed and commercialized in the early 1980s, biotechnology-derived therapeutic products have been growing in both number and revenues generated. The growth has accelerated in recent years and is expected to continue in the near future. The worldwide market for biotech drugs in 2010 is estimated to be nearly $70 billion, with

an estimated compound annual growth rate of around 10 percent from 2005–2010. The number of biotech drugs is expected to grow from 100 in 2005 to about 150 in 2010, as noted in The Biogeneric Market Outlook: Business Insights, 2005. A closer look at the current research and development (R&D) pipeline shows more than 500 protein and 150 peptide drugs in various stages of development, suggesting that this growth will continue (See Bernard Tulsi, “Bugs Punch the Clock as Next Protein Manufacturers”, Drug Discovery and Development, 2006.) This growth could not be more evident than in Puerto Rico, where Ortho Biologics established the Island’s first bulk and finish biotech plant for the production of Erythropoietin (EPO) in 1982, a plant that is still in operation. Today, the top six biologicals sold in the U.S. are currently produced on the Island. In 2006, these biologics sold over $16 billion in the U.S. alone. Taking into account as well the over $4 billion invested in biotechnology plants in the Island over the past 5 years, this level of investment makes Puerto Rico one of the most ideal locations for biotechnology initiatives in the world. The Bioprocess Training and Development Complex is in the right place at the right time to fulfill its three mandates of biotechnology development, training, and innovation. We hope that by so doing it will not only maintain the Island as the most attractive place for pharmaceutical production anywhere, but also place it front and center for the production of new bio-pharmaceuticals, making the Commonwealth of Puerto Rico a true BioIsland.

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- professors [2]

Content Categories:

- Industry and Entrepreneurs [3]

Links
[1] https://www.cienciapr.org/en/external-news/three-pilot-plant-roles-development-training-and-innovation?language=en [2] https://www.cienciapr.org/en/tags/professors-0?language=en [3] https://www.cienciapr.org/en/categorias-de-contenido/industry-and-entrepreneurs-0?language=en