

**CRITICAL SUCCESS FACTORS FOR PUERTO  
RICO'S BIOTECHNOLOGY INDUSTRY:  
THE BIOPHARMACEUTICAL SECTOR CASE**

by

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## **ABSTRACT**

With dropping sales of pharmaceuticals due to patent expirations of pharma blockbusters and the development of knowledge based economies around the world, there has been a growing interest from Puerto Rico for biotechnology's next batch of wonder drugs. Puerto Rico's expertise in the pharmaceutical industry manufacturing and the current presence of several biotechnology firms on the island has stimulated the island to bet on the biotechnology industry to achieve high value added economic growth. Facing competition from economies around the world, Puerto Rico needs to determine the critical factors that will drive the island's success in biotechnology. Several biopharmaceutical companies located in Puerto Rico participated in this study in order to identify success factors for Puerto Rico, its weaknesses and strengths. Tax rates and the availability of engineers and science professionals are among the main reasons biotechnology companies have established operations on the island. These are also some of the identified factors that are necessary for the success of this specific sector.

## RESUMEN

Debido a la caída de ventas de productos farmacéuticos por la expiración de patentes y el desarrollo de economías basadas en conocimiento alrededor del mundo, existe un creciente interés por parte de Puerto Rico en la próxima generación de drogas. La experiencia de la isla en la industria de manufactura farmacéutica y la presencia de varias compañías biotecnológicas en la isla ha estimulado a que Puerto Rico apueste a la biotecnología para alcanzar un crecimiento económico de alto valor añadido. Enfrentando competidores a nivel mundial, Puerto Rico está en la necesidad de determinar cuáles son los factores que lo llevarán a ser exitoso en el campo de la biotecnología. Varias compañías biofarmacéuticas localizadas en Puerto Rico participaron en este estudio para identificar los factores para el éxito de Puerto Rico, sus fortalezas y sus debilidades. Entre las razones más mencionadas como factores para el éxito de este sector en específico se encuentran el ofrecimiento de bajos impuestos y la disponibilidad de ingenieros y científicos. Estos fueron también mencionados como las razones principales que influyeron en el establecimiento de estas compañías en Puerto Rico.

To my family who has always supported my goals, to my husband and forever friend who always believes in me, to my friend Ivelisse who always encouraged me to finalize this chapter and begin a new one in my life, and most importantly, to God ,who is always at my side.

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## **List of Abbreviations**

A*STAR	Agency for Science, Technology and Research
BIO	Biotechnology Industry Organization
GDP	Gross Domestic Product
IPO	Initial Public Offering
NAFTA	North America Free Trade Agreement
NAICS	North America Industry Classification System
PRIDCO	Puerto Rico Industrial Company
R&D	Research and Development
SME	Small and Medium Enterprises

## List of Definitions

- Biotechnology** A collection of technologies that capitalize on the attributes of cells, such as their manufacturing capabilities, and place biological molecules, such as DNA and proteins, to work for us. (Biotechnology Industry Organization, 2009)
- Biopharmaceuticals** A pharmaceutical drug produced using biotechnology. Usually consists of proteins and/or nucleic acids mostly produce by genetic engineering. (Walsh, 2003)
- Blockbuster drug** A drug generating more than \$1 billion of revenue per year for its owner. (Renneberg & Demain, 2008)
- Clinical trials** Clinical investigation for the evaluation of a treatment. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. (Shein-Chung Chow, 2004)

Clusters	Geographic concentrations of interconnected companies, specialized suppliers, service providers, firms in related industries, and associated institutions in particular fields that compete, but also cooperate. (Porter, 1998)
Continuous manufacturing	A manufacturing strategy that produces a part via a <i>just in time</i> production approach, and calls for ongoing examination and improvement efforts which ultimately require integration of all elements of the production system. The goal is an optimally balanced production line with little waste, the lowest possible cost, as well as on time, and defect-free production. (Cheng, Podolsk, & Jarvis, 1996)
Critical Success Factors (CSF)	Limited number of characteristics, conditions, or variables that have a direct and serious impact on the effectiveness, efficiency, and viability of an organization, program, or project. Activities associated with CSF must be performed at the highest possible level of excellence to achieve the intended overall objectives. (Collis, Montgomery, & Goold, 1999)  (Justice & Jamieson, 2006)

Hispanics Biostatistics	Study of statistics applied to biological areas as the analysis of biological and medical data of Hispanics. (Belle & Fisher, 2004)
Pharmacogenomics	Is the science that examines the inherited variations in genes that dictate drug response and explores the ways these variations can be used to predict whether a patient will have a good response to a drug, a bad response to a drug, or no response at all. (Biotechnology Industry Organization, 2009)
Process optimization	The discipline of adjusting a process so as to optimize some specified set of parameters without violating some constraints. The most common goals are minimizing cost, maximizing throughput, and/or efficiency. (Castillo, 2007)
Stem cells	Cells that can give rise to a diverse range of specialized cell types. They can be derived from two sources: the inner cell mass from a blastocyst or the primordial germ cells (eggs and sperm) of an older embryo. (Biotechnology Industry Organization, 2009)

## Thesis Outline and Structure

The structure of this thesis study is organized in five chapters. The information is presented as follows:

- Chapter 1 includes an introduction to the research topic, the justification for selecting the specific area of research of study, the expected contributions of the study and the objectives to be accomplished.
- Chapter 2 presents the relevant literature about the research topic being studied. The literature focuses mainly on key findings from topic-related surveys, academic research studies, journals from different disciplines, economic studies performed by governments, and their respective development plans. This chapter is mainly divided by locations, giving emphasis sections to the Biotechnology Industry in United States, Canada, Europe, Asia and Pacific, Latin America, and Puerto Rico.
- Chapter 3 explains the methodology used in the study which includes an overview of the population and how it was identified and selected and the description of the questionnaire used.
- Chapter 4 presents the results of the study and its discussion. It presents the population profile, the company profile and the results related to Critical Success Factors for Puerto Rico. The results are illustrated with the aid of tables and figures. A discussion of results follows.

- Chapter 5 presents the study conclusions based on the study objectives, and gives recommendations and suggestions for future work.

# 1 INTRODUCTION

The economy during next decade is expected to be ruled by science and technology. Because of this, local governments are directing their efforts to nourish the appropriate conditions to develop technologic centers advanced enough to attract new investment in their jurisdiction. With knowledge as the major focus to develop local economies around the world, currently, biosciences are recognized globally as a key driver of modern economic progress (Battelle, 2008). Total United States (US) general employment in Biosciences reached 1.3 million in 2006, up from 1.2 million in 2004. The total employment impact of the bioscience sector is 7.5 million jobs when direct, indirect and induced jobs are taken into account (Battelle, 2008). As presented in the 2008 State Bioscience Initiatives Report by Battelle, this total employment comes from four sectors: (1) Agricultural Feedstock and Chemicals, (2) Drugs and Pharmaceuticals, (3) Medical Devices and Equipment (4) Testing and Medical Laboratories. Of these, 24% of employment in 2006 came from the Drugs and Pharmaceutical Sector. This sector is defined as one that produces commercially available medicinal and diagnostic substances and that is generally characterized by large multinational firms heavily engaged in research and development activities to bring drugs to the market. Moreover, this sector has the highest US average annual wages per employee, which is around \$86,892. Battelle's report indicates that Puerto Rico has specialization in all subsectors except agricultural feedstock and chemicals and that it is vast and specialized in the drug and pharmaceutical sector meaning that more than 5% of Puerto Rico's national employment is in this sector and that Puerto Rico has a high concentration of employment in

this area. California and New Jersey are the largest states in the subsector and together account for 73% of US subsector employment. Puerto Rico is in third place (Battelle, 2008). One of the latest topics in Puerto Rico's economy has been biosciences, specifically the Biotechnology Industry sub-sector on the island. Biotechnology is defined by the Biotechnology Industry Organization (BIO) as the use of cellular and biomolecular processes to solve problems or make useful products. Biotechnology is a collection of technologies that capitalize on the attributes of cells, such as their manufacturing capabilities, and place biological molecules, such as DNA and proteins, to work for us (Biotechnology Industry Organization, 2009).

The Biotechnology industry employs hundreds of thousands of people in the world and, in 2007, generated global revenues of \$84.8 billions. The United States contribution to these global revenues was \$65.2 billions (Ernst & Young Global, 2008). These revenues have been rising year after year and with them the countries race to position themselves as leaders in the industry. Countries such as Singapore, Sweden and Finland are some of the countries in the race as well as US states like California, Massachusetts, and Arizona. The Global Biotechnology Industry has strengthened throughout the years and recently it has been evident with mergers and acquisitions of biotechnology businesses by big pharmaceutical companies (Ernst & Young Global, 2008). Pharmaceutical companies face patent expiration of blockbuster products and are looking for biotechnology innovation and cutting edge technologies. Being part of this biotechnological revolution represents a potentially great injection to the Puerto Rican economy.

In recent years, many Biotechnology Industries have established operations and/or undergone expansion projects of their operations on the island. Amgen, Eli Lilly, Abbott, Johnson & Johnson, and Becton Dickinson are some of the companies that have invested millions of dollars that will benefit Puerto Rico with new employment creation. Most of Puerto Rico's biotechnology related employment comes from the manufacturing sector.

Many countries, like Singapore and states as Arizona, Massachusetts, and Puerto Rico are building strategic plans with different kinds of incentives and projects to attract new investment from this billion dollar industry and become a leader in the bioscience industry.

## **1.1 Justification**

In the literature review no formal study was found that identifies what could be called the Biotechnology Industry's "wish list", which can create the necessary conditions that would lead to the establishment of new operations in Puerto Rico. No Critical Success Factors have been identified for Puerto Rico's case either.

The Manufacturing Industrial sector employs approximately 10% of the Puerto Rican labor force, being Puerto Rican government being the principal employer accounting for about 30% of employment (Puerto Rico Planning Board, 2009). Biotechnology related companies are among the leading United States and foreign companies with manufacturing operations in Puerto Rico. The Biotechnology Sector in Puerto Rico is represented by several companies, which include the second largest biotechnology company by market capitalization, Amgen. During 2006, Amgen announced over \$1 billion investment in the island to meet rising global demand for the company's products. Currently, Puerto Rico

manufactures over 60% of Amgen products (Lockwood, 2009). Ortho Biologics LLC, from Johnson & Johnson operates on the island since 1991; which benefits the island with the experience of more than 15 years in the biotechnology area (Caribbean Bussiness, 1991). During 2006 Eli Lilly inaugurated a new biotechnology manufacturing facility as part of a \$1.2 million investment in Puerto Rico (Pharmaceutical Industry Association of Puerto Rico, 2006). The Recent opened Beckton Dickinson manufacturing plant is part of a \$42 million capital investment on the island (Beckton Dickinson, 2005).

The presence and investments of numerous biotechnology companies provides access to different ways of doing business and this access can lead Puerto Rico to create a “wish list” of the factors the biotechnology industry seeks when deciding where to establish new operations or to make an expansion of existing facilities. As the biotechnology industry grows, the number of world locations that looks for biotechnology investments also grow to jump start economic development. Locations such as Singapore, Ireland, Arizona, New Jersey, Canada, and Australia are trying to develop new economic and non economic incentives to attract these investment opportunities. They are also trying to access the “wish lists” of promising companies in order to accommodate local business environments to Biotechnology companies’ needs. In order to maintain and improve local competitiveness, Puerto Rico can take advantage of a formal study that could identify success factors to attract biotechnology investment to the island.

## **1.2 Expected Contributions**

This thesis project was intended to be a contribution to government, private entities and society. A “wish list” of factors that the Biotechnology Industry seeks, when deciding where to locate, was created. At the same time, strengths and weaknesses of Puerto Rico, in order to improve economic and non economic proposals to Biotechnology Industry, were determined. The study tried to serve Puerto Rico’s best interest and contribute to economic decisions and resource allocations by the government.

Educated government decisions can benefit private entities and society in general. These decisions can lead to a better place to establish operations and an overall win – win situation.

These educated decisions then can lead to the establishment of stable company operations that can benefit society via larger employment rates and higher wages leading to a higher standard of living for people on the island.

## **1.3 Objectives**

The main objective of this study was to identify the factors that Puerto Rico needs to emphasize in order to stimulate the development of the Biotechnology Industry on the island. The specific objectives were:

1. Identify the main reasons that motivated existing biotechnology companies in Puerto Rico to establish operations on the island.
2. Identify Puerto Rico’s main strengths that can positively affect the decision of companies to view the island as a location for biotechnology operations.

3. Identify Puerto Rico's main deficiencies when it is considered as a possible location for biotechnology operations of a company.
4. Identify the Critical Success Factors for the Biotechnology Industry in Puerto Rico.
5. Identify the perception of general managers and top executives of biotechnology industry established in Puerto Rico.

## 2 THEORETICAL BACKGROUND AND LITERATURE REVIEW

With the global “boom” of knowledge-based economies there has been an increased interest from countries towards policy making, high-end education and incentives to foster innovation. It is important for countries to be in a place of strong fundamentals underpinning economic growth and development. (Couchman, McLaughlin, & Charles, 2008) The Global Competitiveness Report is a contribution to enhance the key factors determining economic growth and to explain why some countries are more successful than others in raising income levels and opportunities for their populations. The Global Competitiveness Report also identifies the several factors that are needed to have lasting prosperity and constant economic growth. One of the twelve pillars of the Report, which are the several components that help determine competitiveness, is Innovation. Also, the Report describes countries to be in three different developmental stages: factor driven economy, efficiency driven economy and innovation driven economy. The Global Competitiveness Report have identified Puerto Rico at stage three which is innovation driven. In countries at the innovation driven stage, companies must compete through innovation and business sophistication (World Economic Forum, 2009).

A recent study identified a growing interest in policy making and academic circles, both correlated with two major initiatives. The first, policies on knowledge production and exploitation between universities, business and government which consists of policy measures that focus in technologic transfer and knowledge transfer and commercialization.

These policies call for the cooperation and integration of government, academia and private entities. The second focus is on policies that are directed toward the establishment of local innovation systems often called innovation corridors, science cities and science corridors, among other common names. Clusters concepts and policy guidelines have been adopted by several policy makers in order to foster the creation of these localized innovation sites (Couchman, McLaughlin, & Charles, 2008). The different policies and strategies of government seek to guess correctly the critical factors that are necessary to ensure their success.

## **2.1 United States Biotechnology Industry**

The biotechnology industry has grown rapidly in recent years and makes a significant contribution to US economy. The industry has doubled its size from 1993 to 1999 and directly employed 150,800 workers. The biotechnology industry employed more workers than toys and sporting goods and even dairy products. An employment multiplier of 2.9 was determined when the indirect and induced impact of the industry was considered, which means that each job directly created in the industry creates a total of 2.9 jobs. Similarly, while biotechnology companies directly produce \$20.2 billion in revenues and \$14.8 billion in personal income, the multipliers were identified as 2.3 and 2.0, respectively (Ernst & Young, 2000). By 2007, the biotechnology industry accounted for 195,500 direct employees and reported revenues of \$68.4 billion (Ernst & Young Global, 2008).

This rapid growth has convinced regional and state governments to grab a piece of the economic advantages' pie that represents the biotechnology industry. Almost all states have implemented policies to support their own biotech industries. Although policies and incentives differ from state to state, some common characteristics are: (1) A recognition by the government that biotechnology is central to state economic development and an understanding the important role of the government (2) High powered coordinating bodies that facilitate networking and collaboration between industry, academia and government (3) Support to life sciences research , (4) Aggressive courting of biotech companies to locate or expand in state and, (5) State funding for new biotech start-ups (Battelle, 2008). Some of the most commonly used policies by the states are the following: (1) Tax incentives as carryover of net operation losses for purposes of tax deduction and sale of unused operating losses to other tax payers; (2) Biotech strategic planning as identifying niches, cluster creation guidance, among others; (3) Appointments of state biotech specialists to deal with industry needs; (4) Allocation of tobacco settlement funds for biotech (5) Allocation of state funds for biotechnology industry needs; and (6) Construction of research parks and incubators. (Zhang and Patel, 2005)

States and regions that want a biodrive in their economy need to work to provide the factors necessary for biotechnology industry development. But, which ones are these factors? The key success factors for biosciences industry growth that Battelle's study highlights are: (1) Engaged research institutions with active leadership, (2) Intense networking across sectors and industry, (3) Available risk capital covering all stages of the business cycle, (4) Discretionary federal or other R&D funding support, (5) Access to specialized facilities and

equipment, (6) Stable and supportive business, tax and regulatory policies, (7) Patience and long term perspective (Battelle, 2008).

### 2.1.1 Massachusetts

The State of Massachusetts academic research expenditures were \$1.12 billion in 2006. There were \$7 billion in venture capital from 2002 to 2008. The largest single investment sector was human biotechnology with 40 percent of all venture capital. (Battelle, 2008) In 2008, biotechnology accounted for 18 percent of the state venture capital investment, 27 percent of its R&D spending, one sixth of its public companies and approximately 10 percent of its market capitalization. Some of the factors that made the state a leader in the biotechnology industry have been the entrepreneurship of scientists, the presence of world renowned universities, and world class research. When a group of biotech executives were asked why they chose to locate in the state; the top reasons were proximity to universities and access to research scientists. Despite all this, the share of total US biotechnology jobs in Massachusetts has declined slightly in the past years. Massachusetts has always been attractive for research but, it is not as attractive when it is being considered for development and manufacturing. This doesn't offer the state the possibility to enjoy from the benefits that arise from downstream employment like taxes and indirect employment. In the study commissioned by the Massachusetts Biotechnology Council and the Boston Consulting group, more than 60 CEOs and senior executives in biotech companies, pharmaceutical research organizations, universities, hospitals and government were interviewed. The executives expressed that one of the reasons for not choosing

Massachusetts as a location for manufacturing is the perceived unpredictability of the local regulatory and permitting environment. When a company decides to establish a manufacturing facility, it is essential for them to have no delays because it represents a delay in its time to market. Massachusetts needs to institutionalize the responsiveness and coordination needed to establish manufacturing operations. The executives also mention that doing clinical trials in Massachusetts hospitals is too costly and too slow. In order to overcome the challenges in the biotechnology industry the study calls on the governor and legislature to become a catalyst for biotechnology industry, improve the business climate, plan the next generation of biotech development and work to speed up the permitting process for new biotech facilities and to invest in strong science education among other things. The study also calls for the cooperation of industry and academic leaders to organize a clear leadership group focused on the success of the life sciences cluster, to improve networking and collaboration between industry and academia, to work together to address common interest and to make a commitment to activate public outreach programs, so that the community is educated about the benefits of biotechnology in order to have public support. (The Massachusetts Biotechnology Council, The Boston Consulting Group, 2002)

### 2.1.2 California

California and New Jersey combine to make up more than one quarter of national pharmaceutical employment. The state of California is large and specialized in the pharmaceutical subsector (Battelle, 2008). California's employment exceeded 10 percent of the 2006 national employment in drugs and pharmaceuticals; medical devices and

equipment; and research, testing, and medical laboratories. Academic research expenditures in the biosciences grew at 41 percent over 5 years with an approximate total expenditure of \$4 billion in 2006.

Being the place where the recombinant DNA technique was discovered, and later on the birthplace of Genentech, the first biotechnology company and the largest biotechnology company by market capitalization, today California is recognized as a hub for world Biotechnology Industry (Biotechnology Industry Organization). With the highest number of initial public offerings (IPO's), the largest market capitalization and the largest product pipeline, California is the current leader in Biotechnology Industry.

Even when there were no states or local policies that directly caused the start of biotechnology industry in the 70's, some factors can be identified as critical for the past and current success of the biotechnology industry in California. These factors are the state's entrepreneurial tradition and its strength in biological research. The state was one of the earliest to identify the potential of the industry. Being conscious of the possible success of this industry the government had an early start in policy making and conducted studies to analyze different policy options. The state encourages industry and university cooperative research and provides matching funds programs between industry and government to allow University of California researchers and R&D companies to jointly conduct commercialized research. The state government also sponsors biomedical research (Zhang and Patel, 2005). To encourage business formation and technology transfer, California constructed and planned several research parks or incubators that either are dedicated to biotechnology or included it as a major component. Even though private venture capital funds are available for

biotech start ups, the state continues to boost access to venture capital. The strength of bioresearch in California was and still is crucial to the success of the biotechnology industry. A highly educated workforce is also needed for the success of the biotechnology industry, and the state of California has developed several programs in higher education in order to strengthen these factors. California is also involved in biotechnology workforce development. They foster labor training and education in community colleges requiring them to contribute to economic growth through continuous workforce development. (Zhang and Patel, 2005)

One of California's latest attempts to promote biotechnology was decided by voters in 2004 when a 59% vote rate was given in favor of Stem Cell Research in California. This success attracted a great deal of money for research, along with over the top researchers from all over the world interested in stem cell research. (Zhang and Patel, 2005)

California does have an innovation and entrepreneurship culture, strong research capacity, along with world renowned universities, a high quality labor pool, and a tradition of venture capital investment, but when talking about California's disadvantages, the most prominent are the high cost of living and doing business. The high cost of living drives away talent and the high cost of doing business may force firms to move manufacturing and marketing operations to lower cost regions. Policymakers are weighting the cost of creating new businesses against the cost of keeping some business from relocating to other locations. They are focusing their policies mostly in the formation of new biotech business and the commercialization of research discoveries. The Public Policy Institute of California recommends policy makers to prioritize policies to support biotech research, technology

transfer and accommodation of biotech manufacturing. They are conscious though, that cost pressures may eventually prevail and force firms to move manufacturing and marketing operations elsewhere (Zhang and Patel, 2005).

In 2001, the National Technology Agency of Finland conducted a study in order to identify and compare critical success factors in biopharmaceutical industry between Finnish and California Business. The Critical Success Factors were categorized under two main groups: internal and external success factors. Internal factors were defined as those that a company may affect themselves such as human resources, products, networking and company climate. The external factors are the ones independent from company activities and often dependent of geographical location like clusters, infrastructure and national policies (Rautiainen, 2001).

Human resources factors look for qualities such as commitment, entrepreneurship, teamwork and management skills in addition to the necessary educational level. The California Industry supported more strongly the need of entrepreneurship and management skills. Four general factors about products were identified that are believed to affect company performance. These factors are the number of products in the pipeline, strong technology platform with the presence of quality products, market with unmet needs and early marketing. California businesses identify strong platforms with quality products in the pipeline as valuable. The emphasis on unmet needs was more valued in Finland than California. The study suggests that gaining global visibility is easier when an unmet need is targeted. Partnering with big pharma is often thought to be beneficial to biopharmaceutical companies in the sense of gaining resources. Investors view deals between biotech and large

pharma as a validation of company product or technology credibility. California relies more in private sector validation and finances while in Finland a startup company relies on public funding for a longer period of time. Company climate was not fully supported by interviewees (Rautiainen, 2001).

A biopharmaceutical company seeks also alliances with academia, big pharma and foreign partners. Networking was proven to be a success factor by both, Finnish and California interviewees. Proximity of research institutions is definitely a critical success factor. California's networking with academia was given more importance than it was in Finland.

Clustering external factor was considered critical by the California Industry. Californians saw the advantages of being situated on a cluster area as labor pooling and knowledge spillovers were viewed as critical factors, but not so much the advantage of having access to nearby specialized services. California's experts argue that labor pool is critical to gain access to talents, to expertise variety, and an easier recruitment processes. California is an area with a high concentration of Biotech firms, universities and research installations which gives them access to information about competitors' plans, development in production technologies and new proceedings from academia. The study suggests this could be the reason why California values more knowledge spillovers than Finland does. Specialized services were not seen important by either Finland or California. It seems that, as long as the service provider was one day away by mail and time differences did not make contacting too difficult, the service provider does not have to be located in the cluster area (Rautiainen, 2001). In terms of location, survey studies tend to find that taxes have little

effect but some authors argue tax may be a factor at certain stages of the location decisions, such as the location decision of manufacturing (Zhang & Patel, 2005).

To attract people into a company, a reputation for quality of life in a certain area is critical. A high cost of living is believed to be one factor that affects the ability to attract new professionals to move to California. Experts do support quality of life as a key success factor for biopharmaceutical company success. The good infrastructure, high quality of life and good water and electricity services in Finland may be reasons for Finnish experts not to consider this factor as critical (Rautiainen, 2001).

The study of Californian and Finnish biopharmaceutical businesses identified some national policy topics. These were government funding of basic research, the government support for startups, and tax deductions. Overall, national policy was identified as important for both, Finland and California companies. The Finnish experts supported the significance of government funds and support for startups stronger than California. Tax reductions were not supported as a success factor by either of the experts. The study suggests that either tax reduction plays a less important role or was not mentioned because they do not exist in the areas (Rautiainen, 2001).

Overall the key success factors identified in the study for the California biopharmaceutical companies are: (1) Educated human resources along with management skills and entrepreneurship (2) Strong platform with quality products (3) Networking with academia and big pharmas (4) Clustering that stimulates and facilitates labor pools and knowledge spillovers and (6) Infrastructure of the community (i.e. Quality of life) (Rautiainen, 2001).

## **2.2 Canada Biotechnology Industry**

The biotechnology industry currently accounts for 6.4% of their GDP. Canada recognizes the importance of the government to the success of knowledge industries. Some of the nation's issues the Canadian government recognizes that need attention are to maintain a science-based regulatory regime that enables discovery, commercialization and market introduction of biotechnology products and processes, ensure adequate intellectual property protection, and facilitate access to capital for emerging firms (BioteCanada, 2009).

Some elements like funding, human resources, networking, infrastructure, national policies, and industry clusters, among others, are reported in literature to be needed in order to develop a technology based economy. On the other hand a study was conducted to determine the specific factors necessary for the development of the Biotechnology Industry in Canada. The Biotechnology companies that participated in the study gave a high priority to knowledge assets, which can be explained by the industry R&D intensity. Intellectual property protection, followed by the availability of scientific databases, was the top ranked knowledge assets. Scientific databases are important for innovation, while adequate intellectual property regulations protect the innovation created by the scientific database and help recoup product development costs and make a profit. Employee education was ranked third in knowledge assets and it reflects the necessity for qualified personnel. Use of resources ranked highly as a success factor. Maintaining the product pipeline and new R&D projects were the top two priorities when allocating resources. External environment was the third ranked success factor. An entrepreneurial environment and government support were the top two ranked external environmental elements. When segregating early stage company

from late stage companies, the former are more dependent on external factors than the latter. These could be related to the fact that early stage companies have minimal product related revenues and are more affected by the financial and economic climate. Funding was ranked number four as a critical success factor. One of the main reasons for it could be that, as the company becomes self sustaining, it assigns a lesser priority to funding (Vanderbylt & Kobelak, 2007).

### **2.3 Europe Biotechnology Industry**

At the European level, a common legislation framework for biotechnology was decided in 1990, but only a few countries slowly implemented it. Around 1995, as USA was the home of over 1,000 biotech companies, European countries had only a few. Shortcomings were identified in providing capital and in training scientists as biotech managers. In order to best achieve the efficiency of R&D, most governments came to the conclusion that creating clusters was the best way to do so. Each nation was trying to foster biotechnology industry development in their country. A team of researchers from various European countries sought to assess the effectiveness of nation innovation policy on fourteen countries in the development of biotechnology. They agreed on the following conclusions: Political instruments for allocating funding are crucial, a competitive knowledge base has to be set up and renewed in order to be successful, effective technology transfer instruments are critical, and different approaches must be well coordinated to target all aspects of the innovation system. The most important outcome was the fact that biotechnology is now taken seriously by industry, finance, and government willing to cooperate in the best possible way to develop

this important sector further into maturity and making it fully competitive (Zechendorf, 2004).

In 2004, European and US biotechnology industries, both, had around the same number of companies, but the US sector employed nearly twice as many people, spent three times as much on R&D, had twice the number of employees involved in R&D activities, raised over twice as much money from venture capital, and had access to 10 times as much debt finance. It also earned twice as much revenue than its European counterpart (The European Association for Bioindustries, 2006). Investments in research and development, education and training, and new managerial approaches, are recognized by the European commission as factors of key importance in meeting the challenges posed by life sciences and biotechnology. One of Europe's main strengths is its science base; centers of scientific excellence in specific technologies exist and are at the core of regional clusters of biotechnology development. However, it must be recognized that total European investment in R&D is lagging behind the United States. Moreover, Europe suffers from fragmentation of public research support, and a low effort in interregional cooperation in R&D this happens among companies and institutions from different regions of several States (European Commission, 2002).

More recently, Europe's Biotechnology Industry has shown a growing strength, especially through recent acquisitions of European companies. This is evident from the growth of products approvals. In 2007, the European biotechnology industry employed 81,947 workers and accounted for € 13.3 billion in revenues in 2007 (Ernst & Young Global, 2008).

### 2.3.1 United Kingdom

The United Kingdom has benefited from a strong chemical and pharmaceutical industry with an excellent science base, becoming the European leader in the race to biotechnology industry success (Ernst & Young Global, 2008). In the way to become Europe's biotechnology leader, the British government has identified ten critical success factors for biotechnology cluster development. These factors are: (1) A strong science base (2) Entrepreneurial culture (3) Growing company base (4) Ability to attract key staff (5) Financing availability (6) Premises and infrastructure (7) Business support services and large companies in related industries (8) Skilled workforce (9) Effective networks and (10) Supportive policy environment.

In the way to obtain and sustain the leadership position it has today, the UK's government had to work to overcome the separation between industry and academia. This was necessary in order to foster technology transfer. The government launched the Biological Science Research Council to enhance industrial competitiveness and help the biotechnology industry take advantage of developing markets in the UK and overseas. The government also helps small and medium enterprises (SMEs) to enhance their manufacturing potential as they recognized the production bottleneck as an obstacle for biotech industry growth. They also focus in clustering of biotech firms and research institutes. Once a cluster reached a critical number of firms and people, knowledge exchange happens easily, networks form, infrastructure adapts, business supports service expansion, and technological convergences lead to new innovation. Even though United Kingdom has become the leader in biotech business in Europe because of their assertive policy measures and from an early stage, it still

has some problems. Some of the more significant ones are the lack of interest among young people to make a career in life sciences, the brain draining of educated and specialized personnel to USA, the shortfalls expected during the consolidation phase (which has started) and, the differences in the patent protection and legal systems between EU and USA, among others (Zechendorf, 2004).

### 2.3.2 Ireland

Ireland has become an attractive location for multinational biopharmaceutical companies. This island is now recognized among the top 25 global locations for biotechnology. (Ernst & Young Global, 2008) The development of a knowledge based economy and the sustainability of recent achievements are now some of the key challenges and opportunities facing Ireland. However, back in 1999 Ireland was not perceived as an international center for biotechnology. Behind Greece, it had the lowest level of government supported R&D. Irish biotechnology graduates were leaving the country, and science students were not educated as entrepreneurs (Kate Johnston, 2005).

Ireland understood the need to benefit from biotechnology, because these science advantages could aid pharmaceutical and chemical industries, food and drink industries and agriculture. The Irish government took measures, such as: (1) The development of quality R&D program, (2) Additional focus on commercialization of research output, (3) Developing programs and funds in order to foster indigenous activity, (4) Communication strategies to increase public awareness and participation, (5) The establishment of public institutions as the Science Foundation Ireland in order to enhance, develop and promote research and (6)

The establishment of a coordinated strategy between main support agencies on the island(Kate Johnston, 2005).

In general, the Irish government's strategy had focused mostly on building an industrial profile and in developing world class bio researchers. More recently, attention has been directed toward developing Ireland's emerging indigenous biotech sector.

In order to set the investment priorities and the weight to be assigned to the various programs, the government took into consideration the key strengths and weaknesses of Ireland's economy when unfolding their National Development Plan. Some of their strengths are: (1) The macroeconomic stability reflected in a very low debt and general government surpluses (2) Ireland's high quality educational system at all levels (3) A taxation and regulatory regime generally conducive to productive investment and (4) Ireland's membership in the European Union, which gives them access to a single market of 494 million people, among other strengths. Some of Ireland's weaknesses identified in the report were: (1) The significant infrastructural deficit (2) Rising cost at levels higher than global competitors and (3) The underdevelopment in science, technology and innovation at business and academic levels, among other weaknesses.

Finally, Ireland National Development Plan has "Enterprise, Science and Innovation" as one of Ireland's five investment priorities and the Science, Technology and Innovation Program was established. This priority is looking primarily to (1) fully implement the Strategy for Science, Technology and Innovation by the year 2013 in order to achieve a transformational change in the quality and quantity of research and enhancing the contribution of research to economic and social development and increasing the numbers

with advanced qualifications, (2) to improve the capacity of indigenous industry to compete in the domestic and global marketplace, and (3) to continue to attract Foreign Investment and grow indigenous industry along with other objectives(Ireland Government, 2007).

Increasing competition between regions is increasing pressure for improvements in efficiency, quality and productivity, and a growing need to innovate. Public funding for Research and Development has risen rapidly in recent years but Ireland's performance in Research and Development is still behind that of leading countries. The Strategy for Science, Technology and Innovation provides for the continued development of a world class research system looking to double the number of Ph.D. graduates over its lifespan and also has implications for the curriculum and teacher training improvements to stimulate science interest among students. The strategy is to foster active recruitment of top level researchers from home and overseas, and to grow Ireland's stock of quality researchers. Science Foundation Ireland was established under the Industrial Development Act of 2003 and it aims to help build research of globally recognized excellence and nationally significant importance in areas as biotechnology. The Centers for Science, Engineering and Technology programs operated by the Science Foundation Ireland, is looking to build a world class research system with the physical and human resources necessary. Programs have been developed to fund scientists who will build collaborative efforts that develop internationally competitive research clusters allied to the industry.

The strategy works to ensure that the investment in research is turned into commercial value at the greatest extent possible. They look to transform R&D activity into

enterprise getting more firms involved in doing R&D, stimulate collaboration between industry and education institutions and to realize the commercial potential of Ireland's research community.

This competition to innovate has been complemented by other investments in important sectors such as economic infrastructure and human capital. Their national development plan then assigns infrastructure the highest priority and budget including areas like transportation, communications, energy, waste disposal, and energy among others. The energy sector is vital and it is characterized by rapid growth, high dependency on imported fuels and environmental obligations. Ireland will focus on increasing the efficiency of energy use in order to reduce energy demand and to bring forward promising renewable energy technology (Ireland Government, 2007).

## **2.4 Asia and Pacific Biotechnology Industry**

Regulation plays an important role in biotechnology development. Lax regulations can place patient's lives at risk but too strong ones can slow down product approvals and raise the costs of product development, which will be paid finally by customers. Several recent and well publicized incidents in Asia showcase the importance of strong regulations in these countries. China, for example, had product safety scandals that gained global attention. India's National Biotechnology Development Strategy specifies and promotes the need of a transparent and clear regulatory authority. A stifling regulatory system has caused Japan to lag behind other Biotechnology economies in the world. Another key problem for Japan is the drug reimbursement pricing system that provides few commercial incentives to drug

companies. Even with the presence of these hurdles, the revenues of publicly traded companies grew by 21% in 2007 and research and development expenditures grew by 22% (Ernst & Young Global, 2008). In order to be competitive, biotechnology sector in the region is in need of a solid regulatory frame, strong intellectual property protection and strong support for startups.

#### 2.4.1 India

India is the only economy in this study that is considered by the World Economic Forum as a factor driven economy, and even given this fact and persistence of the hard times for world economy, India has continued to improve on its competitiveness fundamentals (World Economic Forum, 2009). In 2007, India approved its National Biotechnology Development Strategy. India is recognizing the importance of the biotechnology sector in its economy and the need for nurturing it. One of the most important points in this strategy is the creation of a National Biotechnology Regulatory Authority. This strategy awards 30% of the Department of Biotechnology's budget to biotechnology industry related Public-Private partnerships programs in order to promote innovation, technology and product development (The Department of Biotechnology, India Government, 2007). In India, attracting scientific talent has become a challenge (Ernst & Young Global, 2008). In order to obtain scientific talent and human capital from other areas, some of the initiatives included in the National Strategy are: Improving and expanding Ph.D. and post Ph.D. programs, to enhance the quality of undergraduate and graduate education, improving knowledge and skills of teachers, generating the appropriate infrastructure and making it accessible to students (along

with materials and chemicals needed), life science fellowships and reengineering university curriculums to stimulate innovation and creativity. The Indian government offers fellowships and R&D support to scientists of Indian roots to return to India and pursue research of national priorities, getting back good talent that was located overseas.

In order to protect Intellectual Property, India's government has drafted a bill scheduled to be taken to the Indian Parliament in 2008, related to protection, utilization and regulation of intellectual property.

The cluster concept once again is recognized and thought to be important for the development of an economy. India is planning around four major clusters: Agri-Food Technology Cluster, Health Science Biotechnology Cluster, Animal Science and Biotechnology Cluster, and Marine Science and Technology Cluster. Along with the cluster concept, we can refer to parks and incubators. Biotech Parks and incubators have been established around India's co-locating research, entrepreneurship and infrastructure in order to promote innovation (The Department of Biotechnology, India Government, 2007).

#### 2.4.2 Singapore

Singapore has been an early investor in their way to compete in the biotech sector globally and has had considerable success attracting foreign big companies to establish operations. In 2007, a US based biotech company, Codexis opened in Singapore its first Asia research facility, and the US major biotech company Genentech announced plans to establish a manufacturing facility there (Ernst & Young Global, 2008).

Despite the considerable amount of available funding in Singapore, they still have a challenging funding environment due to the lack of a strong public market that could provide a reasonable exit for local venture capitalists (Ernst & Young Global, 2008). Singapore continues to attract investment funds on a large scale despite its relative high-cost operating environment. The United States is the major foreign investor, accounting for 63% of new commitments to the manufacturing sector. To maintain its competitive position, the government is promoting higher value-added activities in the manufacturing and services sector (US Department of State: Bureau of East Asian and Pacific Affairs, 2009).

Singapore ranked third from 144 economies in the 2009 Global Competitiveness Report. The country's institutions are ranked as the best in the world. Singapore also has world class infrastructure with quality roads, ports and air transport facilities (World Economic Forum, 2009). This has been a factor that influences biotechnology companies to select Singapore to establish their operations. Singapore's legal system supports stem cell research, animal research and clinical trials, it has good regulatory policies, and its access to Asian Pacific disease population, are some key factors that attracted Biotechnology Companies to establish themselves in this country. Other factors considered important are their high standard of living, democratic society, liberal laws, efficient administration, safety, and relatively low tax regimes (Maralitharan, Agricola, & Chandler, 2006).

Some of Singapore's identified weaknesses are: their poor track record in research and patents, their weak university and industry collaboration, the high R&D operation cost, the lack of local scientists and of skilled workforce (Maralitharan, Agricola, & Chandler, 2006).

Although Singapore was able to attract many world class researchers, it is vital that the growing Singapore biotechnology sector enrich the local talent for the future. The Agency for Science, Technology and Research (A\*STAR) has developed many scholarships that seek to nurture 1,000 local Ph.D. graduates (Singapore Agency for Science, Technology and Research, 2009).

The Singapore Economic Development Bank (EDB) is the leading government agency responsible for planning and executing strategies to enhance Singapore's position as a global business center and grow the Singapore economy (Singapore Economic Development Board, 2009). A\*STAR has as mission to foster world class scientific research and talent (Singapore Agency for Science, Technology and Research, 2009).

In 2003 a biomedical research hub named Biopolis was opened, similar to the concept or research park in US. The Biopolis is located near the National University of Singapore and the National University Hospital. Research from private and public sectors are co-located in the Biopolis. The concept is a one stop shop for excellent science facilities, world class partners and global talent base along with good quality of life location (Singapore Agency for Science, Technology and Research, 2009). In addition of Biopolis, the government set aside land for the Tuas Biomedical Park for pharmaceutical and biologics manufacturing. Tuas Biomedical Park is a plug and play environment where already several biotechnology companies are located (Singapore Agency for Science, Technology and Research, 2009).

Singapore is considered to be driven by innovation and it was ranked eighth in the Innovation Pillar of Competitiveness (World Economic Forum, 2009).

Singapore has successfully leveraged its strengths and its achievements are impressive. However, most of today's internal investments have been for manufacturing active ingredients to re-export. Singapore's challenge for the future will be to develop a homegrown innovative biotechnology industry (Ernst & Young Global, 2008).

## **2.5 Latin America Biotechnology Industry**

Growth of the commercial biotechnology sector in Latin America brings the necessity of addressing some issues related with public perception, regulatory frame work and intellectual property protection, financing mechanisms and workforce development among others. In order to develop a bio driven economy, the governments have to develop and adjust public policy in order to access these needs. It is critical for Latin America to continue with the preparation of the human resources necessary. It is also important to address ethical issues and general public perception about biotechnology. Commitment to public funding of science and technology research and education have to continue and to strengthen (Quezada, 2006).

### **2.5.1 Mexico**

With the approach of patent expiration of most first generation drugs, Mexico has turned to pharmaceutical biotechnology (Ramirez & Quintero, 1999). Mexico's community had many points of view about the genetically manipulated organism issues, until finally the government revoked restrictions on the use, sale, import, export and farming of genetically manipulated organisms and provided coordination of the permitting process (Quezada, 2006).

The San Diego Dialogue program from the University of California conducted an initial study to assess Mexico and Baja California's opportunities to increase competitiveness of the science and technology industries. Trade between US and Mexico in biotechnology and life sciences goods is on the increase. There has also been an increase in higher education degrees related to sciences. However, it should be noted that this gives rise to concerns about the lack of highly skilled labor. Comparisons of global technology regions usually conclude that the low number of patents issued annually in Mexico indicate a lack of availability of inventiveness. Even patents are certainly below expectations; the inefficient Mexico patent system has led some Mexican inventors to file patent application in the US. Given that San Diego has a large concentration of US biotechnology firms along the US-Mexico border, there is an opportunity to work with Mexico's emerging sciences industry (Crossborder group, 2007).

## **2.6 Puerto Rico Biotechnology Industry**

Puerto Rico is recognized as a leader with approximately 40 years of track record as a major center of pharmaceutical manufacturing. During the industrialization period, the main economic strategy for the island was to export manufactured goods to the mainland US. Puerto Rico based its economy in this strategy and became competitive. However, today's economy is very different and the elements that helped Puerto Rico compete are no longer as helpful and relevant. As a territory of the United States, Puerto Rico enjoyed benefits as would any other state, along with exemption on tariffs and duties on goods and services. However, as the US continues to liberalize its trading policy, Puerto Rico's free access to US

markets is becoming less exclusive. Puerto Rico had considerably lower wages than in the States, which presented cost benefits to companies. More recently, however, along with rising living standards rising wages have also resulted. While labor costs are still lower than US, the costs are higher than its Latin American and Asian competitors. Federal incentives and fiscal exemptions were cut back or eliminated. Puerto Rico faces two main challenges today: (1) losing its traditional competitive advantages and, (2) increased competition for the goods and services it exports today. The island is in direct competition with US states and regions and, in addition, faces international competition from countries such as Singapore and Ireland (New Economy Strategies, 2005).

Currently, Puerto Rico is rated large in employment size and specialized in the pharmaceutical sector (Battelle, 2008). The manufacturing of many blockbuster drugs takes place in the island. However, due to patent expirations and few product approvals and transfers, the total sales of drugs totally or partially manufactured in Puerto Rico will drop drastically from 2009 to 2012 (Generans Bioventures, 2007). The pharmaceutical and medical manufacturing employment has been dropping these recent years as presented in figure 2.1 (Puerto Rico Planning Board, 2009).

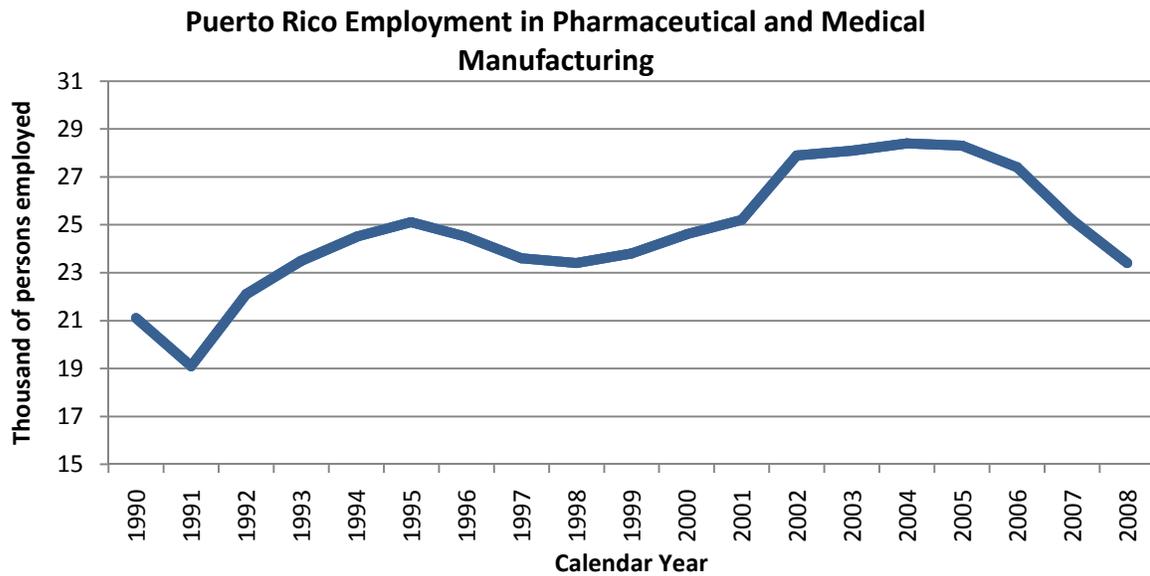


Figure 2.1 Pharmaceutical and medical manufacturing employment  
 Puerto Rico Planning Board. (2009) Number of Employed Persons by Major Industrial Sector

The unemployment rate can act as a barometer for socio-economic well being of a country. Puerto Rico has a high unemployment rate compared to its competitors. This subtracts from the total welfare and does not add value to the economy. Puerto Rico’s unemployment rate could have been expected to be even higher, but many have decided to move to the mainland US because of lack of economic opportunities in the island. This can hurt Puerto Rico’s economy, since this migration continues to exports many of the most talented and creative workers (New Economy Strategies, 2005). Recently, engineer Emilio Rivera from Amgen said that the high concentration of bioscience companies in Puerto Rico provides the island with a power that is not used efficiently in order to attract and retain skilled labor (Collazo, 2009).

Puerto Rico does have a well educated workforce, but it could increase its economic impact in the innovation strategies by taking better advantage of the interaction between

education and technology. The inability to create enough jobs can result in a workforce less educated than it currently is due to the existence of fewer incentives to individuals to make time and financial investments in higher education (New Economy Strategies, 2005).

INDUNIV is a nonprofit organization representing industry, government, and the academic sector that promotes the island's competitiveness in science and technology. They promote the bioscience education through an Education Committee covering the Life Science clusters, which include the pharmaceutical, biotechnology and medical devices sectors. One way in which some states are trying to reach larger number of students is by means of traveling laboratories that essentially bring the lab to middle and high schools, providing the opportunity for students and their teachers to conduct hands-on experiments. Science on Wheels at the University of Puerto Rico at Mayaguez has one of eleven mobile labs in the Nation (Batelle, BIO and Biotechnology Institute, 2009).

Puerto Rico is looking to develop a knowledge base economy in order to move forward and benefit from the biotechnology economic "boom". Several biotechnology industries have major industry developments in the island. Most of these activities have been attracted by the 0% tax offered by the Tax Incentives Act of 1998 to pioneer industries. Under the new economic development act of 2008, the pioneer industry is identified through different factors such as the degree of utilization and integration of research and development activities in Puerto Rico, tax impact for Puerto Rico and uniqueness of activities, among other factors. The pioneer industry has attracted significant investments in biotechnology, medical devices, telecommunications, and information technology and has generated over 3,000 jobs. The new Economic Development Act, in addition of offering 0% to 1% rate

income tax to qualified pioneer industries also offers up to 50% credit on qualified R & D expenses, 10% credit on industrial energy consumption, credits for purchase of locally manufactured products, infrastructure incentives, competitive financing options and training incentives among others (Commonwealth of Puerto Rico, Puerto Rico Industrial Developing Company , 2008). Abbott Biotechnology Limited, Lilly del Caribe (a subsidiary of Eli Lilly and Company) and BD Biosciences (a division of Beckton –Dickinson) opened new facilities in 2007 (Battelle, 2008). Amgen, the second largest biotechnology company by market capitalization, also made a millionaire investment in Puerto Rico. Most biotechnology companies established in the island has made partnerships with universities and/or made significant contributions for science research.

Puerto Rico's academic research and development per capita is higher than its Latin American competitors, but it is still considerably below the US. Identification of federal funding trends can help detect areas that have potential to be successfully developed in a region. Federal R&D funding to Puerto Rico from 1993 to 2003 was directed mostly to life science and Biotech. Agricultural Science is the next most important sector (New Economy Strategies, 2005).

The output of patents invented in a country gives an idea of country innovation capacity. The United States Patents and Trademark Office (USPTO) reports a total of 688 patents invented in Puerto Rico from 1998 to 2008 (United States Patents and Trademark Office, 2008). Maybe it is no far behind its Latin American competitors when population size is taken into consideration, but it lags far behind the big US, European and Asian competitors. During 2001, Puerto Rico had 3.1 patents per million inhabitants, whereas,

Chile has 1 patent per million inhabitants, and Mexico 0.8 patents per million inhabitants. However Ireland had 43.6 patents per million inhabitants and Singapore had 73.6 patents per million inhabitants (New Economy Strategies, 2005).

Investing in biotechnology and life science today is Puerto Rico's best bet for ensuring sustainable, high value added economic growth in the future. With its highly skilled, well educated and bilingual workforce, its modern educational resources, and its existing advantage in pharmaceutical and medical device manufacturing, PR clearly has the necessary assets in place to succeed in these new areas. The key will be whether or not Puerto Rico will be able to create a self sustaining innovative economy, a creative climate and successfully commercialize the resulting products as sealable products (New Economy Strategies, 2005).

In 2005, INDUNIV along with PRIDCO (Puerto Rico Industrial Development Company) which is a government-owned corporation dedicated to promoting Puerto Rico as an investment destination for companies and industries worldwide funded a report on Puerto Rico Life Science Road Map. The report concluded that, in order to overcome a decline in competitiveness, it is necessary to concentrate on two goals: (1) Achieving a world class status and (2) achieving global differentiation. The study also identified five fundamental actions to address ongoing challenges. This fundamental actions are: (1) Create cluster strategies and offices to grant management and innovative funding in order to have appropriate compliance and as a strategy for increasing the flow of dollars in Puerto Rico (2) Make significant investment in basic research teams and facilities (3) Create a future workforce learning resource center (4) Create a Puerto Rico science and technology global network and data portal looking forward to networking with Puerto Ricans who live and

work in top research communities in the US and abroad and also create a one stop data portal to access and leverage our assets. (5) Improve and increase marketing and branding efforts. To address the global competition, they also presented some ideas. These ideas were: (1) Create a physical and innovation zone in order to connect its centers of excellence and leverage proximity of talent and related activities. (2) Expand upon clinical trials and clinical research to create a center that aggregates global interest in trials around the unique genetic base of its population, and (3) Leverage Puerto Rican expertise in high tech manufacturing and brand itself as the place to locate this knowledge intensive industry and “sell” its knowledge to interested market players.

In 2007 the government transferred 80 acres valued at \$200 million to the Puerto Rico Science, Technology and Research Trust to start a “Science City” dedicated to the advancement of knowledge and innovation with laboratory and incubator space(Battelle, 2008) ( Puerto Rico Science Technology and Research Trust, 2009). During 2008, the Bioprocess Development and Training complex was inaugurated. This non – profit institution fosters research interactions between industry and academia to strengthen Puerto Rico’s capabilities in bioprocess development and improvement. Also it provides a venue to conduct training in cutting edge technologies, in biotechnology manufacturing, and bioprocess engineering. Private entities, government and academia also worked together to made the Center for Research and Training in Bioprocess a reality (Industrial Biotechnology Program, UPRM). Several campuses of Universities in Puerto Rico now offer certificates in biotechnology in addition to the Bachelor’s degrees offered by the University of Puerto Rico, Mayagüez Campus.

Puerto Rico is considered to have an innovation driven economy and it is ranked the second most competitive economy in Latin America, but, it is still behind its North America, European and Pacific competitors. As for an overall competitiveness ranking for Puerto Rico, the Global Competitiveness Report identifies Puerto Rico as 42 out of a list of 133 countries. Specifically, it obtained position # 31 in the innovation and sophistication factors with business sophistication pillar ranking # 29 and innovation ranking # 31. Puerto Rico is positioned as # 44 in overall basic requirements, which includes the pillars of institutions, infrastructure, macroeconomic stability, and health and primary education. It is also #33 in overall efficiency enhancing factors which includes higher education and training; goods market efficiency, labor market efficiency, financial market sophistication, technological readiness and market size (World Economic Forum, 2009).

To increase productivity in an innovation – driven economy, an environment that is conducive to innovation activity, support by both the public and private sector is required. Sufficient investment in Research and Development is needed, along with high quality scientific research institutions, extensive collaboration in research between universities, and the adequate protection of intellectual property. It is worth mentioning at this point the US federal regulations pertaining Intellectual Property protection apply in Puerto Rico, and the island does not have the authority to modify these rules when it comes to patent protection.

There is no quick fix that allows Puerto Rico to become a leader in biotechnology and life science. It is necessary to make long term serious commitment to increase the quality and quantity of research and development, and commercialization being performed on the island. The study presented here is intended to be part of such efforts. What is even more

important is the need of a commitment towards taking action (New Economy Strategies, 2005).

## **3 METHODOLOGY**

The design of this study is exploratory in nature due to lack of previous research about critical success factors in Puerto Rico's biotechnology industry. A questionnaire was used to collect the opinion of operation managers, general managers or other personnel involved in high management decision in biotechnology companies. The instrument asked about the key informants' general perception about the state of biotechnology in Puerto Rico and critical success factors they understand influence the most when their company is deciding where to expand or establish new facilities.

### **3.1 Population**

A general manager, plant manager or operation manager from each biopharmaceutical company with operations in Puerto Rico was surveyed for this study. The companies were identified from a list of biotechnology promoted companies supplied by Puerto Rico Industrial Company (PRIDCO) and PRIDCO manufacturing facilities directory using North America Industry Classification System (NAICS). The companies classified under NAICS sector 3254 of pharmaceutical and medical manufacturing were investigated through their websites and through direct phone calls to verify population compliance with the study requirements. The six companies identified as members of the population are: Abbott Biotechnology Limited, Lilly del Caribe (a subsidiary of Eli Lilly and Company), BD Biosciences (a division of Beckton –Dickinson), Amgen Manufacturing Limited, Ortho

Biologics LLC and Bristol Myers Squibb. Because the population was so limited the questionnaire was sent to the general manager, operation manager or plant manager in all biotechnology companies. Four of the six companies returned the questionnaire for a rate of return of 67%.

### **3.2 Questionnaire**

A questionnaire was used as the instrument to acquire the data needed for the study. The researcher called key informants in each biotechnology company to seek their participation. Once they agreed to participate, an email with the questionnaire link and an informed consent letter were emailed (Appendix 1). The questionnaire was administrated electronically through Survey Monkey, web-based survey software, (Appendix 2). For the validation process, the committee members and one industry related expert in the area of study reviewed the questionnaire. The final instrument consisted of twenty four items, including sixteen multiple choice questions, six Likert scale questions, and two open answer questions.

The questionnaire was organized as follows:

- The first part of the questionnaire sought information about the participant's profile like job title, education, experience and their involvement in the company's aimed and expansion of operations decisions.
- The second part of the questionnaire was looking to validate the company's profile with information as operations in Puerto Rico, characteristics of the company's largest operations and business related areas to new location decision process.

- The third part of the questionnaire contained the questions related to success factors. The first objective was to identify the key influential factors in the decision to establish biotechnology operations in the Island. The second objective was to identify what are the critical success and failure factors that Puerto Rico has to attract or discourage investment in biotechnology operations.

## 4 RESULTS AND DISCUSSION

The questionnaire that was administered to general managers, operations manager or someone in a related position in each company had a 67% of population response. Four out of six company executives responded the questionnaire. Questionnaire items were analyzed using descriptive statistics. The responses will be compared to related information of other countries.

These results are presented in three different sections focused in specific areas: Respondents profile, Company profile and Critical Success Factors.

### 4.1 Population Profile

Of the 67 percent (four of six key informants) who answered the questionnaire, two participants indicated that their current job title is General Manager while the other two indicated their job title is operations Manager.

To identify their education, the participants were asked in which areas they had completed their studies. As presented in Figure 4.1, a 50% of respondents indicated that they completed studies in engineering, a 25% completed studies in Biology and 50 % indicated other areas of studies which include pharmaceutical Science and Environmental Health.

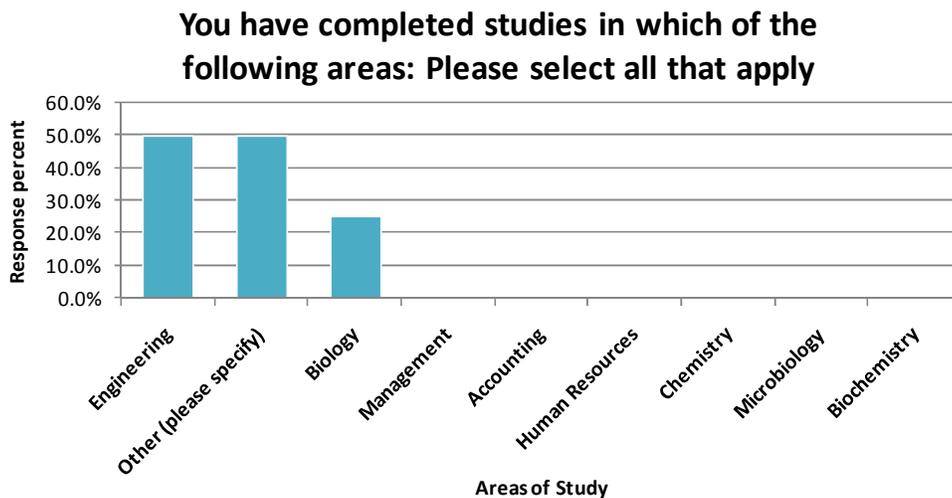


Figure 4.1 Area of respondents

To identify their work experience, the participants were asked in which part of the industry they had gain experience through the years. All the participants indicated they have experience in production, specifically, one hundred percent (100%) in production management, seventy-five percent (75%) in product unit operations, and fifty percent (50%) in production control. Seventy-five percent (75%) of the participants have experience in standards, practice and guides in regulatory compliance, fifty percent (50%) in government regulations, seventy-five percent (75%) in risk management and quality, and seventy-five percent (75%) in quality validations. Other areas of experience mentioned were product development, facilities, accounting, human resources, finance, and marketing and sales. None of the respondents had experience in Research, Product Development: Formulation, Clinical Phase, or Supply Chain Management: Warehouse. Table 4.1 shows all areas of experiences with their respective percentages of response.

<b>In which of the following areas you have work experience? Please select all that apply</b>		
<b>Answer Options</b>	<b>Response Percent</b>	<b>Response Count</b>
Research	0.0%	0
Product Development - Formulation, Clinical Phases,	0.0%	0
Product Development - Technology Transfer	50.0%	2
Product Development Production Scale up and	25.0%	1
Facilities - Design and Construction	50.0%	2
Facilities - Commissioning and qualification as Risk	50.0%	2
Facilities - Controls and Automation	50.0%	2
Information Systems	25.0%	1
Supply Chain Management - Materials Management	50.0%	2
Supply Chain Management - Operational Economics	50.0%	2
Supply Chain Management - Warehouse and	0.0%	0
Production Systems - Production Unit Operations;	75.0%	3
Production Systems - Production Management	100.0%	4
Production Systems - Production Control	50.0%	2
Regulatory Compliance - Government Regulations	50.0%	2
Regulatory Compliance - Standard, Practice and Guides	75.0%	3
Quality Systems - Risk Management and Quality	75.0%	3
Quality Systems - Quality Validations	75.0%	3
Accounting	25.0%	1
Human Resources	25.0%	1
Finance	50.0%	2
Marketing and Sales	25.0%	1
Other (please specify)	0.0%	0

Table 4.1 Work Experience of Respondents

The survey asked the participants if they were members of a committee for making new location decisions or advisory. As shown in Figure 4.2, three participants (75%) of respondents indicated they do participate in a similar committee of this type. The survey also asked the participants if any of their colleagues who participate in a committee is involved in making new location decisions or advisory. Seventy-five percent (75%) of respondents indicated they do have a colleague involved in such committee as shown in Figure 4.3.

**Are you a member of a committee in your company involved in making new location decisions or advisory?**

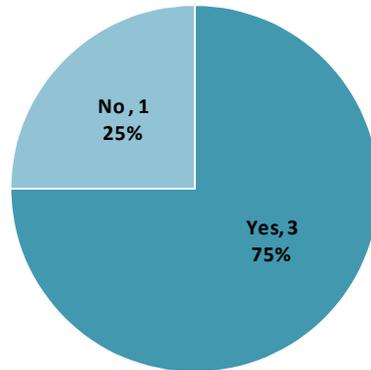


Figure 4.2 Respondents involved in making new location decisions or advisory

**Is a Puerto Rico colleague of yours a member of a committee in your company involved in making new location decisions or advisory?**

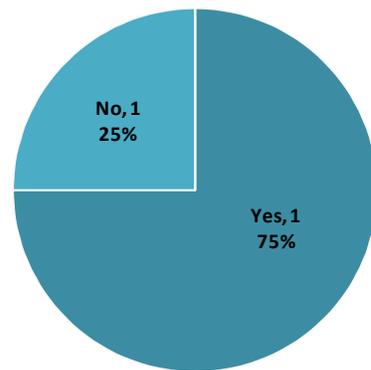


Figure 4.3 Presence of other individuals involved in decision making process

## 4.2 Company Profile

All participant companies were multinationals with manufacturing operations in Puerto Rico. Seventy-five percent (75%) of companies have packaging operations in the island, fifty percent (50%) have process scale up and fifty (50%) have regional and/or global logistics. None of the companies have research and development, and marketing and sales operations in Puerto Rico as presented in Figure 4.4

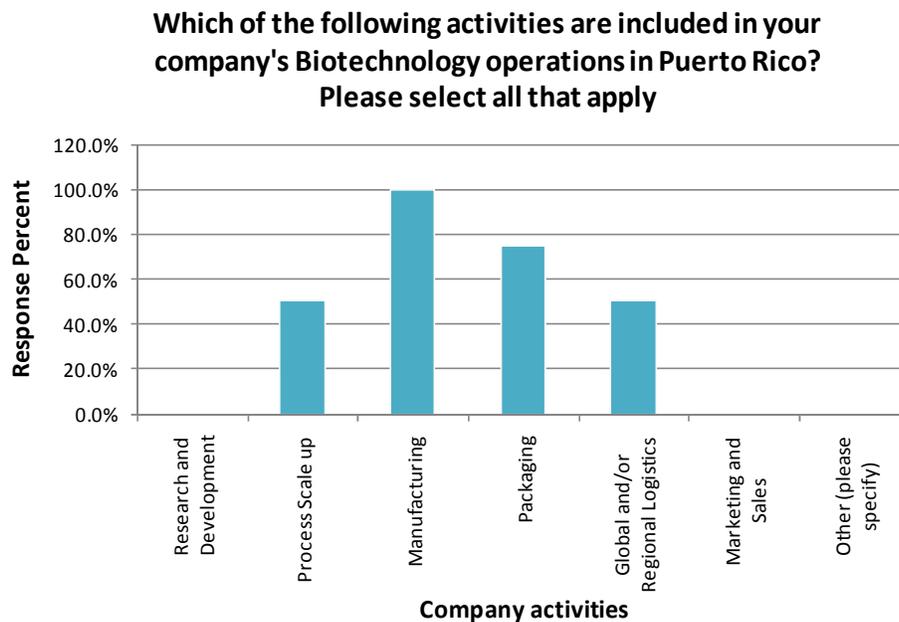


Figure 4.4 Company activities in Puerto Rico operations

The participants were asked which areas of the company are more related to the new location decision process. Top management was the option was most related by the participants with seventy-five percent (75%) of them relating it to the location decision

process. Production, Engineering, Accounting and Finance, all had a fifty percent (50%) of response. Logistics was only mentioned by one participant accounting for a twenty five percent (25%) as presented in Figure 4.5.

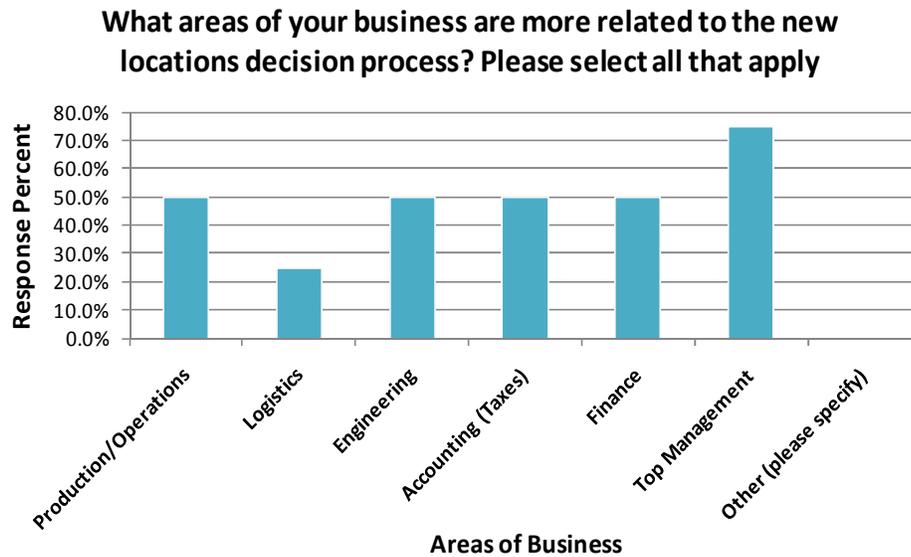


Figure 4.5 Areas of the business more related to the locations decision process

In general the participants identified that their major biotechnology operations are located in relevant and applied research and knowledge zones, and in low tax zones as shown in Figure 4.6.

**Your company's largest biotechnology operations (in general) are located in which of the following regions? Please select all that apply**

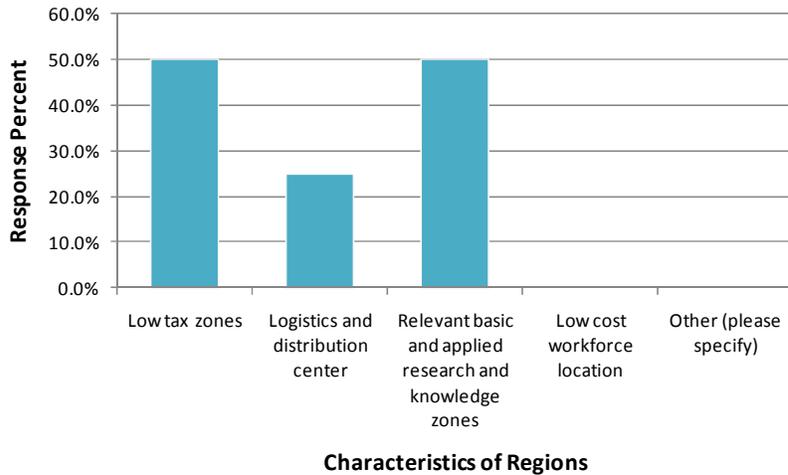


Figure 4.6 Main characteristics of regions where company's largest operations are located

### 4.3 Success Factors

The participants were asked about what factors they believed influenced the most in the company decision to establish operations in Puerto Rico. The high supply of engineers and science related professionals (75%) was the most selected factor by the participants. Tax rates and general educated work force were mention by half of the respondents. Other factors chosen selected were tax incentives, the availability of specialized services, the regulatory and permitting environment, the presence of universities available for collaboration with industry, and the intellectual property laws and policies. (See Figure 4.7)

**What are the factors that you believe influenced the most your company's decision to establish operations in Puerto Rico? Please select no more than 3**

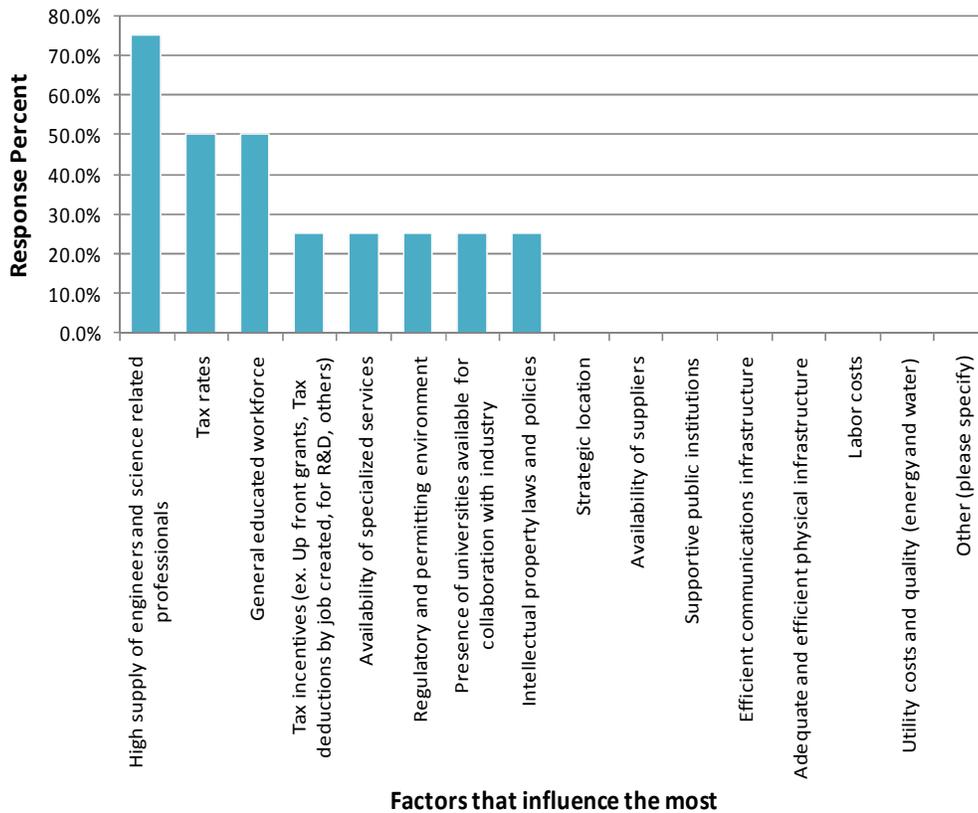


Figure 4.7 Factors that influenced most company decisions to establish operations in Puerto Rico

The participants were asked in the survey if they agreed with some statements about Puerto Rico and/or Biotechnology operations the island. Respondents were given a five point Likert scale (one being strongly disagree ,and five being strongly agree) to indicate how much they agreed with the statement. They did strongly agree that Puerto Rico has qualified engineers and science related professionals, sufficient general educated workforce and universities with special scientific and engineering expertise available for collaboration.

They agreed Puerto Rico has sufficient availability of suppliers and specialized services, strong intellectual property laws and has high grow potential to strengthen biotech cluster. The participants also agreed that the company was offered tax breaks and/or direct government assistant and that the manufacturing facility was established or wanted to be established to facilitate exports to non-US markets. The participants neither agree nor disagree about Puerto Rico government stability. The respondents disagree about Puerto Rico having low labor cost and reasonable water and energy costs. They also disagreed with the statement about PR having a high quality of life. (See Figure 4.8)

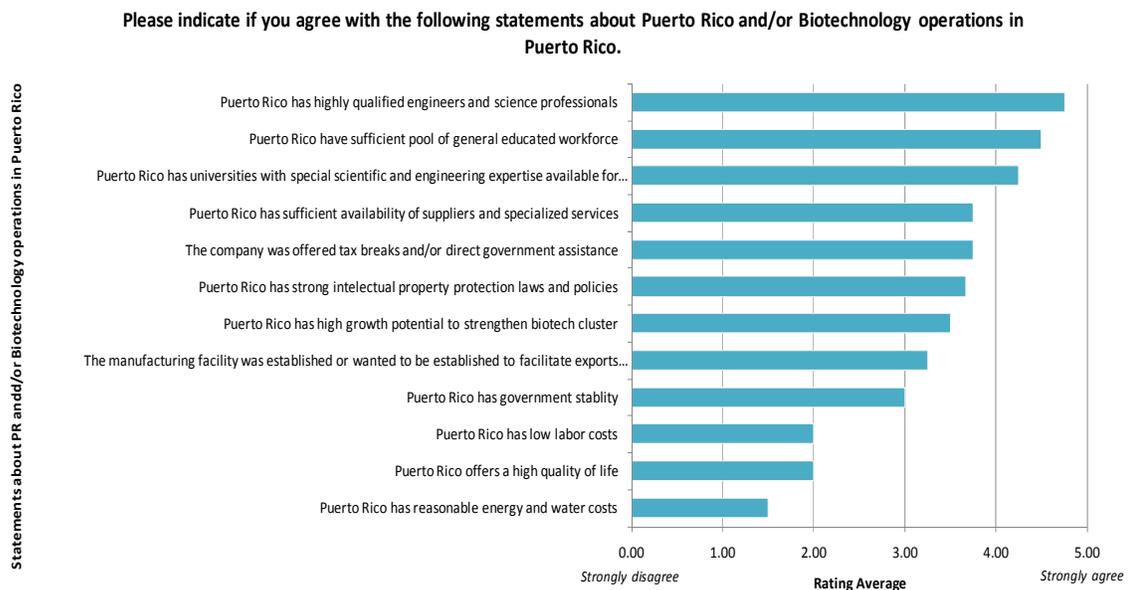


Figure 4.8 Statements about Puerto Rico and/or Biotechnology operations in PR

In order to determine the importance of different factors, the participants were asked to indicate the importance they believe had several factors in the decision making process

when the company considered Puerto Rico as a Biotechnology operation site. Respondents were given a five point Likert scale (one being not important at all, and five being very important) to rate the importance of the different factors. Tax breaks and/or direct government assistance was the factor rated as most important, followed by the availability of educated workforce, and logistics. Government stability, low labor cost, availability of qualified engineers and science related professionals, availability of suppliers and specialized services, low energy and water cost, growth potential of clusters, intellectual property protection regulations, and presence of universities with special scientific and/or engineering expertise available for collaboration with the company, were rated as important factors. The quality of life was rated as neutral and was the factor with the lowest rating average.

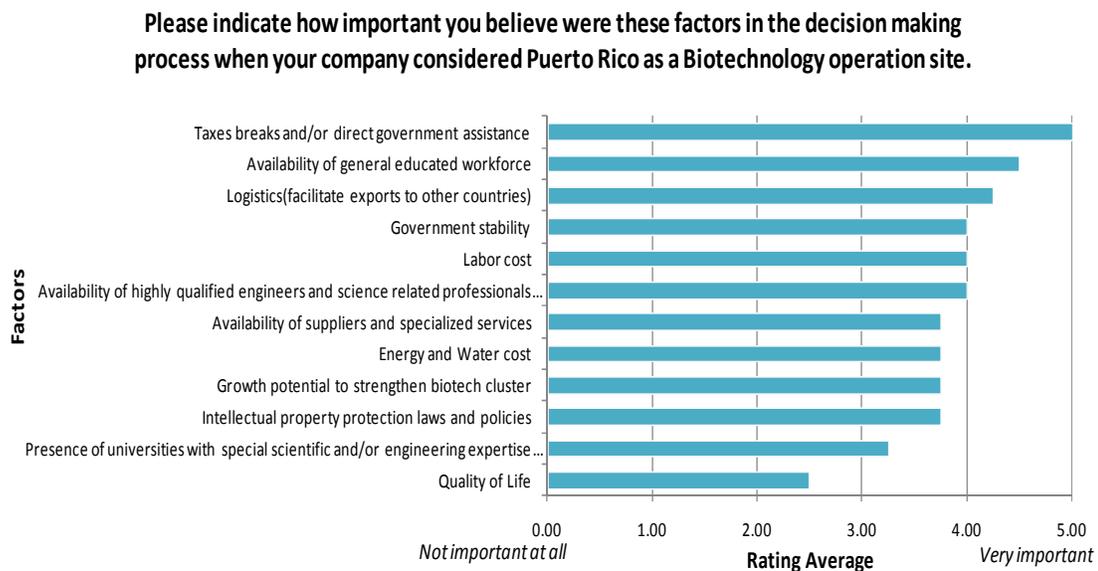


Figure 4.9 Importance of different factors in the location decision process for biotechnology operations

The participants were asked in the survey if they are familiar with a recently established or soon to be established Biotechnology facility outside Puerto Rico. Fifty

percent (50%) of the participants indicated they are familiar. When asked more in detail about the decision process of the new location outside Puerto Rico, they indicated that the new location is in Europe. They also were asked if they agreed with several statements about the Biotechnology location outside Puerto Rico. Respondents were given a five point Likert scale (one being strongly disagree ,and five being strongly agree) to indicate how much they agreed with the statement. They strongly agreed that the country has strong intellectual and property laws, highly qualified engineers and science related education professionals, and universities with special scientific or engineering expertise available to collaborate with the industry. They also strongly agreed that the company was offered tax breaks and/or direct government assistance. The respondents agreed that the country or region has a large pool of general educated workforce, a high growth potential to strengthen the biotechnology cluster, a reasonable availability of suppliers and specialized services, government stability, a high quality of life and low water and energy costs. They disagreed that the country has low labor costs. (See Figure 4.10)

**Please indicate if you agree with the following statements about the  
Biotechnology location outside Puerto Rico**

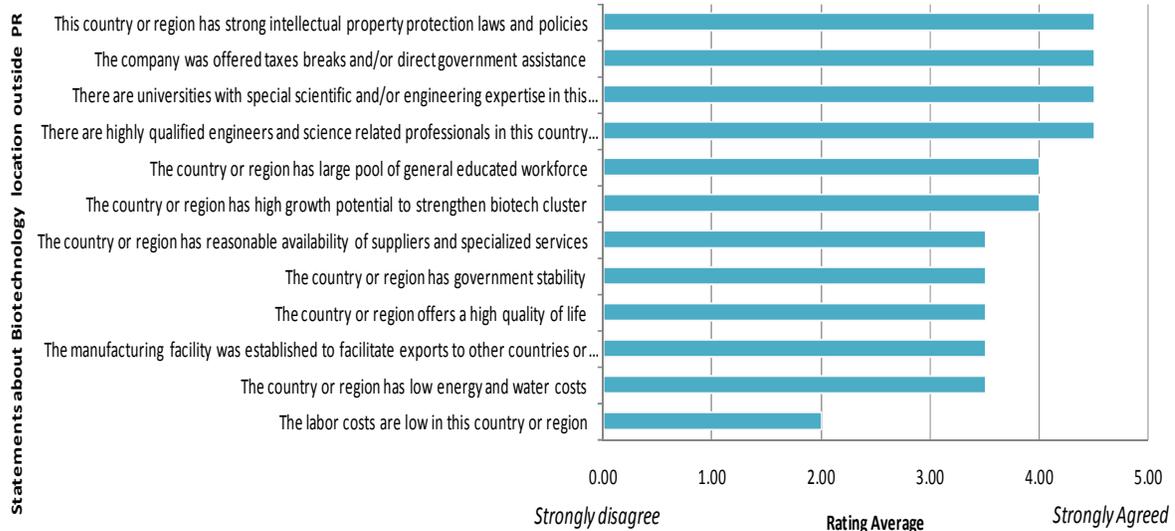


Figure 4.10 Statements about biotechnology location outside PR

The participants that are familiar to location decisions in other locations than Puerto Rico were also asked about how important were several factors in the company decision to establish new operation in this location. Respondents were given a five point Likert scale (one being not important at all ,and five being very important) to indicate how much importance they allocate to the factor. The tax breaks and/or direct government assistance was the only factor identified as very important. Other factors, such as the availability of general educated workforce, government stability, logistics, energy and water costs, growth potential of the country, strong intellectual property protection laws and policies, presence of universities with special scientific and/or engineering expertise available for collaboration, availability of highly qualified engineers and science professionals, availability of suppliers

and specialized services, and quality of life were all considered important. Lower labor cost was considered neutral and was the factor with the lower rating average.

**Please indicate how important you believe were these factors in the decision making process to choose this country as the new biotechnology operations site.**

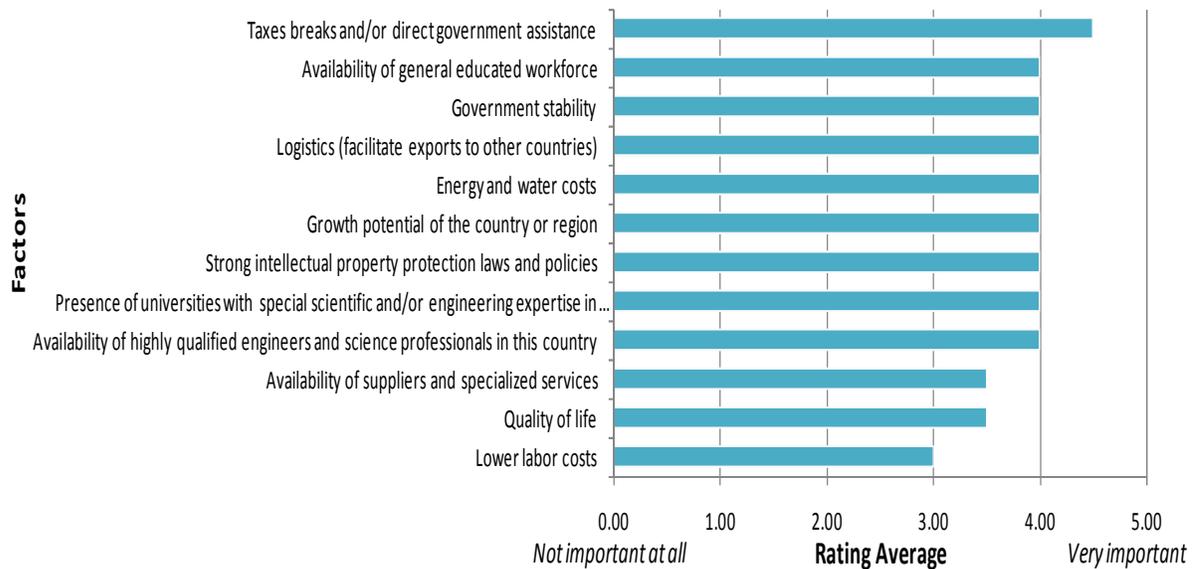


Figure 4.11 Importance of different factors in the decision process to choose a location outside of Puerto Rico for biotechnology operations

All the participants were asked what factors, in their opinion, are desirable for the biotechnology industry to succeed in Puerto Rico. The factors that have the higher response percent are: tax regulations, electricity cost, access and reliability, as well as high availability of engineers and science related professionals. All of them had a 75% rate of response. Water cost, access and reliability, and adequacy of the physical infrastructure had a 50% of response each. Table 4.2 shows all factors respondents selected and their correspondent percents

**Please indicate the five most important factors from the following list that are, in your opinion, desirable for biotechnology industry to succeed in Puerto Rico**

<b>Answer Options</b>	<b>Percent</b>	<b>Response Count</b>
Tax regulations	75.0%	3
Electricity costs, access and reliability	75.0%	3
High availability of engineers and science related	75.0%	3
Water services costs, access and reliability	50.0%	2
Adequacy of other physical infrastructure (roads, ports, Availability of specialized services	50.0%	2
Supportive public institutions working with industry	25.0%	1
Pro business labor regulations	25.0%	1
Cost of export regulations	25.0%	1
Incentives to bring your smaller alliance partners (Ex. NOL carry forward transfers, equity, low cost debt, ready facilities for co-development and co-manufacturing in Puerto Rico)	25.0%	1
Efficient government bureaucracy	25.0%	1
Industrial economic incentives	25.0%	1
Efficient communications infrastructure	0.0%	0
Stability of government policies	0.0%	0
Good quality of life	0.0%	0
Research and Development shared facilities	0.0%	0
Other (please specify)	0.0%	0

Table 4.2 Desirable factors for the succeed of biotechnology industry in Puerto Rico

The participants were asked to rate the importance of a list of factors for the success of a biotechnology company. Respondents were given a five point Likert scale (one being not important at all ,and five being very important) to allocate the importance to each factor . All the respondents indicated the presence of low taxes is very important and it was the factor with the highest rating average. Other factors that were considered very important are: the availability and reliability of electricity, the availability of engineers and science related professionals, water availability and reliability, water costs, energy costs, communications

infrastructure, and intellectual property protection. Figure 4.12 shows all the factors and the allocated importance.

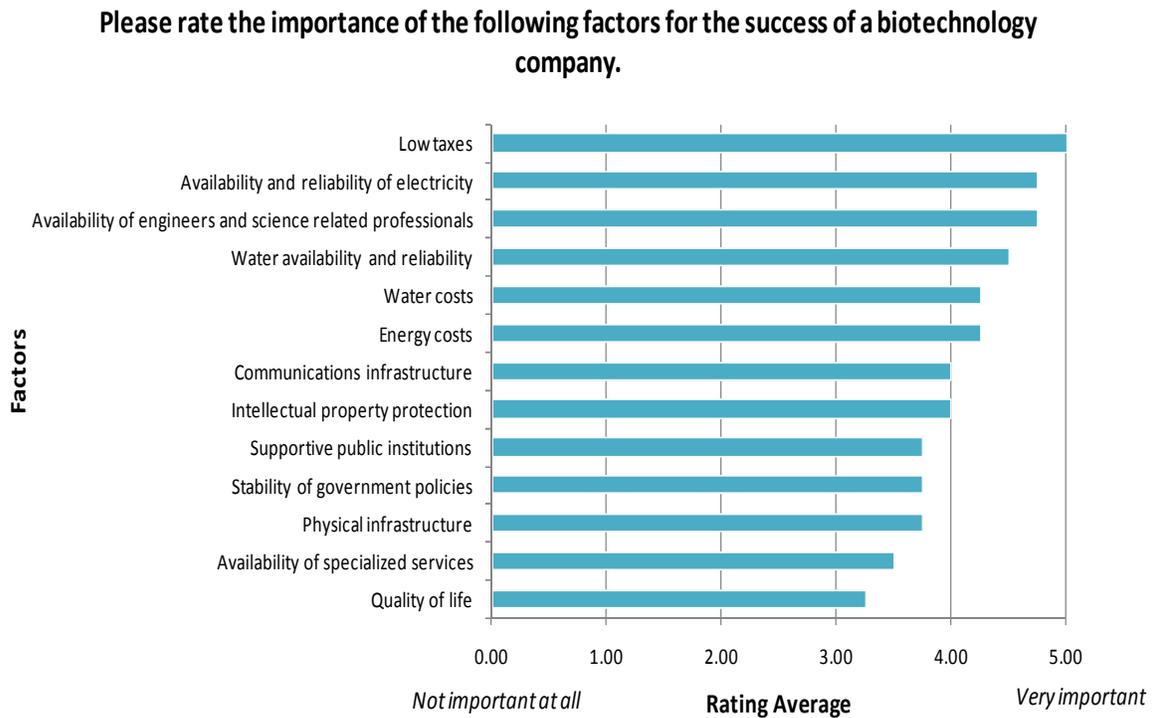


Figure 4.12 Important success factors for a biotechnology company

The participants were asked to rate the quality of different factors in Puerto Rico for the success of a biotechnology company. Respondents were given a five point Likert scale (one being very poor, and five being excellent) to rate the quality of each factor. The availability and quality of engineers and science professionals, the communications infrastructure and the physical infrastructure were rated as excellent. Other factors like water availability and reliability, availability and reliability of electricity, tax rates, availability of specialized services and supporting public institutions were rated as good. Energy costs were considered poor with a rating average of 2.00, as presented in Figure 4.13.

**In your opinion, please rate the quality of the following factors available for the success of a biotechnology company in Puerto Rico.**

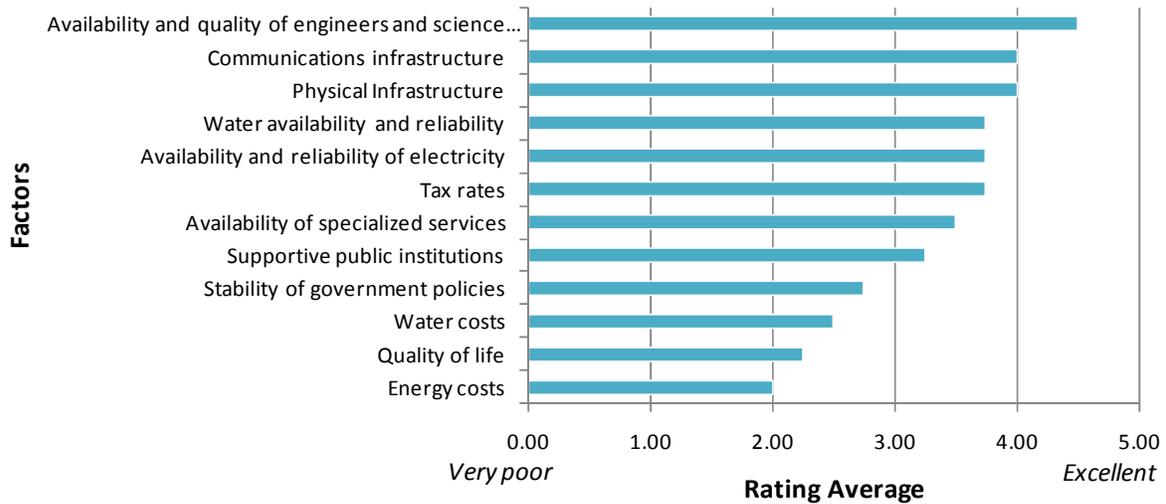


Figure 4.13 Quality of factors available in Puerto Rico

The study also explored the reason why companies have decided not to establish biotechnology operations in Puerto Rico. Trying to access this information the respondents were asked to identify the major factors they believe influence a company not to establish biotechnology operations in the island. All the respondents indicated a reason not to establish operations in the island is the high transportations costs related to exports, as well as the high utilities cost. Figure 4.14 shows other factors identified by the respondents like restrictive labor regulations, scarce tax incentives, and poor quality of life. One participant mentioned strong FDA regulations in the “other” answer option.

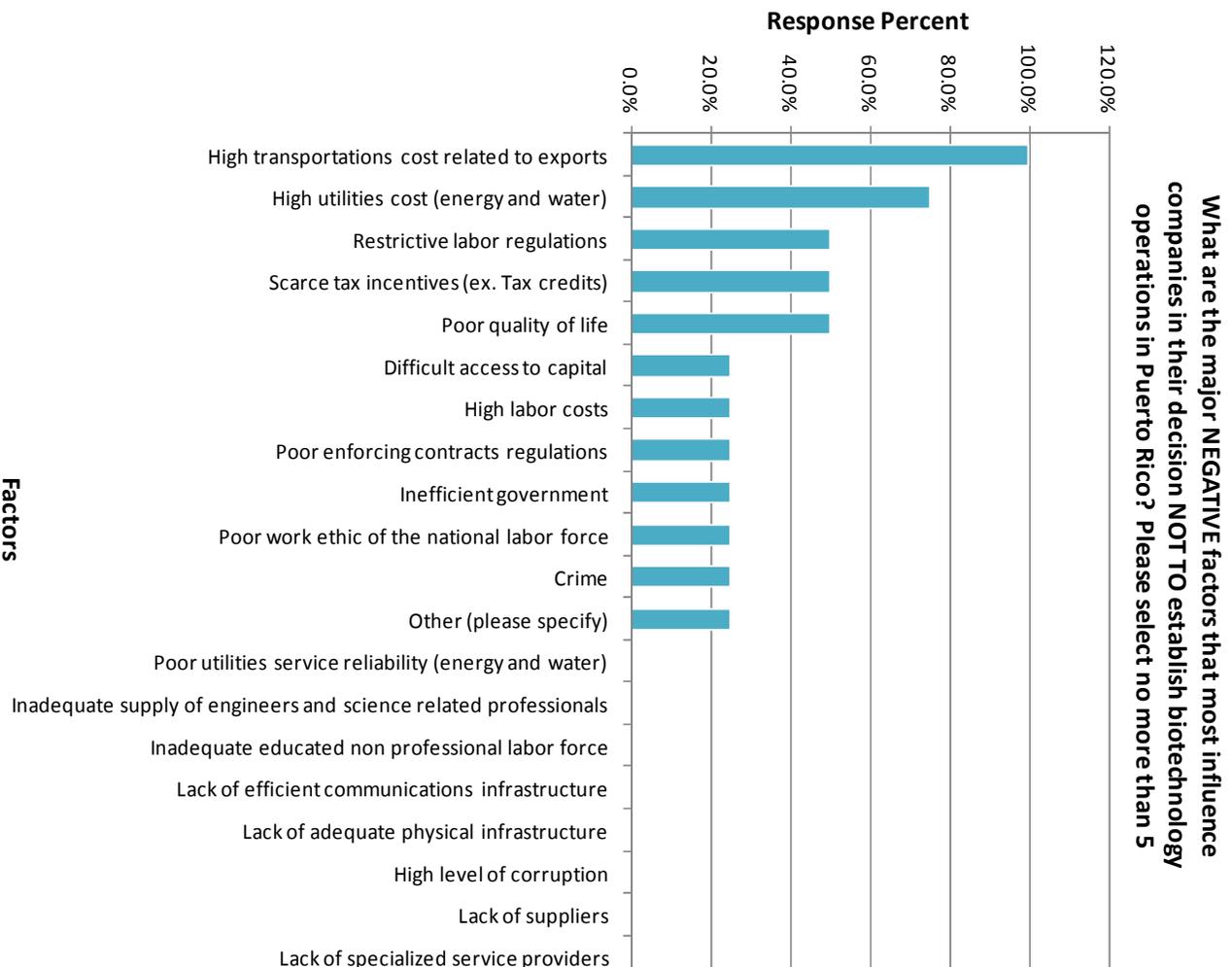


Figure 4.14 Major negative factors that influence companies in their decision to not establish biotechnology operations in Puerto Rico

In order to identify and consider new opportunities for Puerto Rico, the participants were asked which areas they understand Puerto Rico can develop in order to find a niche and

differentiate from other centers of the world. In Figure 4.15 is shown that the respondents identified clinical development, pharmacogenomics, toxicology, continuous manufacturing, manufacturing process optimization and Hispanic biostatistics as possible areas for development.

**Taking into consideration Puerto Rico capabilities and limitations, as well as the Biotechnology Industry needs, what areas do you understand PR can develop in order to find a niche and differentiate from other Biotechnology Centers in the world?**

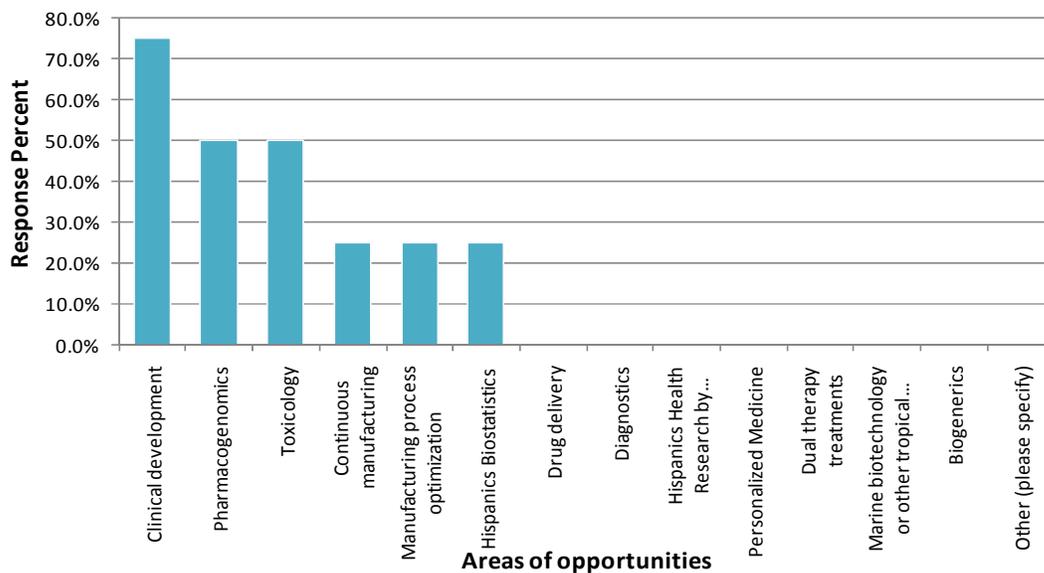


Figure 4.15 Opportunity areas for Puerto Rico

As presented in Figure 4.16, a 75% of participants indicated that the company is currently considering to establish a biotechnology facility in Puerto Rico and identified Singapore and Ireland as the two locations the company also considers when planning to establish new operations or expand existing ones.

**At present, is your company considering establishing or expanding its biotechnology operations in Puerto Rico?**

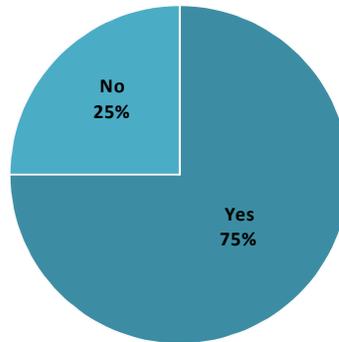


Figure 4.16 Current considerations for the location of biotechnology operations in Puerto Rico

The expressions about the status of the biotechnology industry in Puerto Rico by the respondents are:

- “It is improving. Bid biopharma industries recognized education and proficiency of professionals as well as line operators and this is improving how they see the island. In the other hand lack of tax incentives and high utilities cost are killing the opportunities when compared with other countries.”
- “Growing – Better than 10 years ago”
- In overall the pharma/bio industry is going through very difficult times. Sales and profits are going down”
- “Well, but need to evolve to more process development”

The participants express they are committed with PR if the country establishes an efficient and realistic economic development plan in favor of new ventures.

## 4.4 Discussion

Knowing the Critical Success Factors for an industry may give Puerto Rico a good idea of what factors may be crucial for a location to work out in order to retain existing companies and to attract new ventures.

In a knowledge economy and for a knowledge based company, it is important the availability of science professionals and engineers. Several studies have highlighted the necessity for a highly educated labor force. This factor is the one that most participants believed influenced the company decision to establish itself in Puerto Rico. A 75% of participants selected it as an influential factor. The participants strongly agreed that PR has highly qualified engineers and science professionals and indicated it was an important factor in the decision making process. The quality of Puerto Rican science professionals and engineers was rated as excellent, which is desirable and an important factor for the biotechnology industry to succeed in Puerto Rico.

Countries like Singapore have chosen to nourish their scientific base in order to attract and sustain companies in their location. Although Singapore has been able to attract world class researchers, they need to enrich local talent. They have developed scholarships that seek to nurture 1,000 local Ph.D. graduates (Singapore Agency for Science, Technology and Research, 2009). California had identified educated human resources, management skills, and entrepreneurship as key success factors (Rautiainen, 2001). The state indicated that a highly educated labor force is needed for the biotechnology industry and they are trying to meet this necessity with various special programs in higher education systems. The presence of world renowned universities, being the birthplace of many companies and the

fact that it is the place with the largest number of IPOs may be the reasons for California's biotechnology experts to allocate extremely importance to knowledge assets. The European Union agreed that a competitive knowledge base has to be set up and renewed in order to be successful in the biotechnology field. In UK, the factor of a strong science base was identified as critical for the success of their biotechnology cluster (Zechendorf, 2004). The lack of interest for pursuing science careers in UK presented in Zecherondof's study can result in a long term lack of science related professionals. One way Puerto Rico is trying to reach more students to develop an interest for science careers is by traveling laboratories and by other programs sponsored by government entities. Ireland has focused its government strategy on building an industrial profile and developing world class researchers (Johnston, Henry, & Gillespie, 2005). For India, the challenge has been to attract scientific talent and they are trying to expand Ph.D. programs, to enhance the quality of undergraduate and graduate education and to stimulate innovation and creativity. They also created programs to gain back the emigrant Ph.D.'s

To be able to compete globally, the different locations around the world are trying to increase and maintain their scientific pools. Puerto Rico has been identified as a place with a pool of educated science professionals and engineers, but it still has to sustain it and retain it in the island. Puerto Rico's high unemployment rate and inability to create enough jobs can result in a future workforce less educated due to the existence of fewer incentives for individuals to make the time and financial investment in higher education. Unemployment is also the cause of many exports of talents to other locations (New Economy Strategies, 2005).

The participants identified the presence of a well educated workforce as one of the factors they believe influenced their company decision to establish operations in Puerto Rico. They agreed Puerto Rico has sufficient availability of a well educated workforce and that this was very important when considering Puerto Rico as a location site. A well educated workforce is needed for manufacturing operations and the benefits of manufacturing as downstream employment as taxes and indirect employment is what Massachusetts is trying to reach (The Massachusetts Biotechnology Council, The Boston Consulting Group, 2002). California is also involved in biotechnology workforce development. They foster labor training and education in community colleges requiring that they contribute to economic growth through continuous workforce development (Zhang & Patel, 2005). In Canada, employee education was ranked third among the knowledge assets and this reflects the necessity for qualified personnel in the industry. UK indentified a strong science base and a skilled workforce as critical factors for biotechnology cluster success (Zechendorf, 2004).

The respondents state that their largest biotechnology operations are located in low tax zones and in relevant basic and applied research and knowledge zones. Tax incentives and tax breaks are one of the most common used policies by states (Rautiainen, 2001) (Zhang & Patel, 2005). In a study from Critical Success Factors of California and Finland, Biopharmaceutical businesses indicated they did not support tax reductions as a success factor. The study suggested that either the tax reduction plays a less important role than other factors or was not mentioned because they did not exist in these areas (Rautiainen, 2001). In Puerto Rico, tax rates and tax incentives were identified as factors that are believed to influence the company's decision to establish operations in Puerto Rico. The participants

indicated that they believe tax breaks or direct government assistance was a very important factor when the company considered Puerto Rico as an Operation site. They agreed the company was offered tax breaks and/or direct government assistance. In general, respondents believe that low taxes are a desirable factor for the success of a biotechnology company. In terms of location, survey studies tend to find taxes have little effect but some authors argue that taxes may be a factor at certain stages of the location decisions as the ones related to manufacturing (Zhang & Patel, 2005). Because most of the activities realized in Puerto Rico are related directly to manufacturing and not R&D, for example, the location decision may be more sensitive than taxes.

The presence of universities available for collaboration was mentioned as one of the factors that influenced the company's decision to establish operations in Puerto Rico, but it was not mentioned as much as a high supply of engineers and science related professionals, tax rates and general educated workforce. Even this, they believe the presence of universities is an important factor. In California, in order to support and sustain their strength in biological research, the state encourages Industry and University cooperative research and provides matching funds programs in order to conduct research that can be commercialized. Proximity of Research institutions is identified by Californian and Finland's experts as a critical success factor. But this networking toward academia was seen more important to Californian experts than to Finnish ones (Rautiainen, 2001). One of Ireland's weaknesses was identified as an underdevelopment of science, technology and innovation at academic levels. The Strategy for Science, Technology and Innovation in their economic development plan provides for the continued development of a world class research system and to double

the number of Ph.D. graduates. They also foster the recruitment of top level researchers from home and abroad.

Most biotechnology companies established in P.R. have made partnerships with universities and/or made significant contributions for science research. P.R. academic research per capita is higher than its Latin American competitors but is considerably below US.

When a company decides to establish a manufacturing facility, it is also essential for it to have no delays since it represents a delay in time to market and this represents a loss of money. The state of Massachusetts has always been attractive for research, but not so much when it is considered for manufacturing and the delay in establishing a manufacturing facility is identified as a reason. The perceived unpredictability of their local regulatory and permitting environment is a factor that is affecting them in a negative way (The Massachusetts Biotechnology Council, The Boston Consulting Group, 2002). A respondent pointed out the regulatory and permitting environment of PR as a factor that they believe influenced the company to establish operations in the island, but was not mentioned as much as a good supply of engineers and science related professionals, tax rates and general educated workforce. Ready to use facilities like Tuas biomedical park in Singapore may reduce time to market and this, as a result, may represent a plus when a company decides where to locate new operations.

Puerto Rico's political relationship with United States brings out the intellectual and property laws factor that was mentioned by a respondent as something that influenced the

company in establishing operations in the island. The fact that companies' intellectual property (mostly the American ones) is regulated and protected by US law may influence the company to establish operations in the island. Although for United Kingdom, which has become the leader in biotechnology business in Europe, one of its major disadvantages is the difference between the patent and legal systems between UK and USA (Zechendorf, 2004). In Canada, intellectual property protection was top ranked as a critical factor which presents the importance of the protection of intellectual property from competitors giving the company the opportunity to recoup research and development costs and make a profit (Vanderbylt & Kobelak, 2007). The Asian biotechnology sector, for example, is in need of a solid regulatory frame and strong intellectual property protection (Ernst & Young Global, 2008). In order to protect intellectual property, India's government has drafted a bill related to protection, utilization and regulation of intellectual property (The Department of Biotechnology, India Government, 2007).

The intellectual property laws and policies were identified as an important factor that influences a company's decision making to establish operations in Puerto Rico. It was even considered important, but not as important as tax breaks, availability of an educated workforce, and logistics, among others. The participants do believe it is an important factor for the success of a biotechnology company and agreed Puerto Rico has strong intellectual property protection laws and policies.

The availability of specialized services was identified as another factor that respondents believe to influence the companies' decision whether to establish themselves in

Puerto Rico. In contrast, specialized services were not deemed important by either Finland or California (Rautiainen, 2001). In these locations, it seems that as long as the service provider or supplier is one day away by mail, or flight, and differences in time did not make it difficult to contact, the service provider does not need to be around. In the case of Puerto Rico, its condition as an island may influence the fact that this factor was mentioned as important. The distance, time and cost constraints that are related with bringing a service provider to an island from a different location, can be the reason why companies that are considering Puerto Rico as a location seek also reliable local service providers that can fulfill the companies' needs. This contrasts with the fact that no respondents mentioned the availability of suppliers as a factor that influenced the decision making process. This may be due to the same reason it didn't seem important to California and Finland. In UK, businesses support services and the presence of large companies in related industries was identified as one of ten success factors for their biotechnology industry (Zechendorf, 2004). The respondents agreed that Puerto Rico has sufficient availability of suppliers and specialized services providers and rated the quality as good.

General physical infrastructure was not identified as a factor influencing company decisions to establish operations in Puerto Rico, but it was considered an important factor. In the Global Competitiveness Report, PR is in position 33 in the infrastructure pillar and it's the first when we refer to Latin America (World Economic Forum, 2009). We can suggest it was not mentioned because they take it for granted because of the later facts. In Ireland's case, one of their weaknesses is their significant infrastructural deficit and their national development plan then assigns infrastructure the highest priority and budget including areas

as transport, communications, energy, waste disposal, and energy among others (Ireland Government, 2007). Singapore has world class infrastructure (World Economic Forum, 2009). United Kingdom identified premises and infrastructure as one of the ten factors they consider critical for the success of biotechnology cluster development (Zechendorf, 2004).

High utilities cost was one of the major negative factors identified to influence companies in their decision not to establish biotechnology operations in Puerto Rico. Energy and water costs were important factors for the respondents believe were important in the company decision making process when they were considering P.R. as a location. In general, the participant understanding of the availability, reliability and cost of utilities is very important. The quality of these utilities in Puerto Rico is good but the costs are high, especially for energy. Energy sector is vital, and locations such as Ireland are focusing on increasing efficiency of energy use in order to reduce energy demand and are working on bringing forward promising energy technology (Johnston, Henry, & Gillespie, 2005).

Respondents agreed that P.R. and the other locations have government stability, but they agreed more with the statement when it was related location's outside P.R. They indicated the factor was important in the decision making process. One of Ireland's strengths is its macroeconomic stability reflected in a very low debt and general government surpluses (Johnston, Henry, & Gillespie, 2005). Puerto Rico's actual economic deficit may affect the perception of government stability, specifically when compared with competitors such as Ireland. Government level of debt and consistency of government policies are some of the aspects that affect government stability.

Strategic location was not a factor selected as the ones influencing the most in the company's decision to establish operations in Puerto Rico, but it was rated as an important factor when considering Puerto Rico as an operations site. With US' continued liberalizing trading policy, Puerto Rico's access to US markets is becoming less exclusive. For example, Mexico's geographical proximity to US , specifically to San Diego where there is a large concentration of biotechnology firms, and the liberalization of commerce by free trade agreements as NAFTA (North America Free Trade Agreements) may use the advantages of this factor (Crossborder group, 2007). In the case of Ireland, its membership in the European Union gives them access to a really large market (Johnston, Henry, & Gillespie, 2005).

The participants of the study do not mentioned supportive public institutions as one of the factors that influenced their company to establish biotechnology operations in Puerto Rico, but they do belief supportive public institutions are important for the success of a biotechnology company and understand that Puerto Rico has "good" public institutions. Institutions are one of the basic requirement pillars in the global competitiveness report and it indicates that the quality of institutions have a strong bearing on competitiveness and growth. Puerto Rican institutions are ranked 42 out of 133 economies (World Economic Forum, 2009). The UK identified supportive public environment as one of ten success factor for their biotechnology cluster (Zechendorf, 2004).

Cluster policies are among the most commonly used and have been adopted by policy makers in order to localize innovation and economic development. California has constructed several parks or incubators dedicated to biotechnology (Zhang & Patel, 2005). These

clustering have been identified as one of California's success factors (Rautiainen, 2001). Several locations have adopted similar policies (The Department of Biotechnology, India Government, 2007) (Zechendorf, 2004). Puerto Rico has initiatives related to clustering; the soundest one is the "science city" to be localized in San Juan. The participants agreed P.R. and the outside location has high growth potential to strengthen a biotech cluster and also they think this factor is important in their decision making process, but we may notice they agreed more towards the other location's high growth potential and they also allocate more importance to these factors .

Literature has discussed quality of life as a key success factor for biopharmaceutical success (Rautiainen, 2001) (Zhang & Patel, 2005). The quality of life concept may include several factors, such as crime, living cost, education, wealth, employment, health and recreation among others. In the case of California, a high cost of living is believed to affect the ability to attract new professionals and drives away talent. This may force firms to move manufacturing facilities and marketing operations to low cost regions. California experts do identify Quality of life as a key success factor. In Finland's case, the overall good quality of life with good infrastructure, good water and energy services, may be the reason why Finnish experts do not consider the factor as crucial for them. In Singapore's case, the high standard of living was considered important (Maralitharan, Agricola, & Chandler, 2006). The fact that they have been attracting world renowned researchers from abroad and qualified personnel may be a reason for the allocated importance in quality of life. World renowned researches may have several opportunities to relocate globally and even they do want an innovative environment, it is important to recognize these researchers may also want locations with

good quality of life for themselves and their families. The respondents of our survey disagreed with the statement that Puerto Rico has a good quality of life and it was the factor that they allocated as the least important in the decision making process when their company considered Puerto Rico as a location. The lack of the necessity to import qualified personnel may be a reason they do not allocate such importance to quality of life but we may remember that a low quality of life added to a lack of specialized employment may worsen the brain drainage of local resources to other locations. Even though quality of life was considered the least important of all factors, it was rated inside the “important” range of response.

The factor that was mentioned the most by participants as negative is the high transportation costs related to exports. This may be primarily because an island will necessarily have transportation limitations when moving merchandise offshore. It is important to develop and strengthen other factors in order to offset the high export costs. Locations such as Mexico and Canada with a closer geographical proximity to the U.S. may have the opportunity to benefit from lower transportation costs in relation to exports to the US. Similar examples may be applied to European Countries.

Participants disagreed that P.R. or the other locations have low labor costs. In Puerto Rico, it was considered an important factor but the least important in the decision making process for other locations. Their opinion about considering labor costs important in the decision making process may be because labor costs in Puerto Rico are still lower than those in other US jurisdictions (New Economy Strategies, 2005).

Comparing the results about how much participants agreed with some statements about PR and about locations outside P.R., some differences can be identified about

participants' perceptions between locations. We can interpret from Figure 4.17 shows that respondents mostly agree that locations outside P.R. have more reasonable energy and water costs than Puerto Rico. Ireland, for example, has identified energy costs as vital and has focused on increasing the efficiency of energy and on bringing forward promising renewable technology. (Ireland Government, 2007) The other factor that really received a big difference from respondents is the quality of life. They agreed that the location outside US has a high quality of life while they disagree PR have a high quality of life. Compared to P.R., they also agreed more that an outside P.R. location has government stability, has high grow potential to strengthen biotech cluster, has strong intellectual property laws, has universities with special scientific and engineering expertise available for collaboration, that they were offered tax breaks and/or direct government assistance and that the facility was established or wanted to be established to facilitate exports to non US markets. The participants had more agreement about P.R. having sufficient availability of suppliers and specialized services, having pool of a well educated workforce and having highly qualified engineers and science professionals. Because the participants mentioned Singapore and Ireland as locations the company usually considers establishing biotechnology, we can explain this last results with these locations' effort to attract researchers from abroad and nourish local ones (Singapore Agency for Science, Technology and Research, 2009). All the participants disagreed with both locations about having low labor costs.

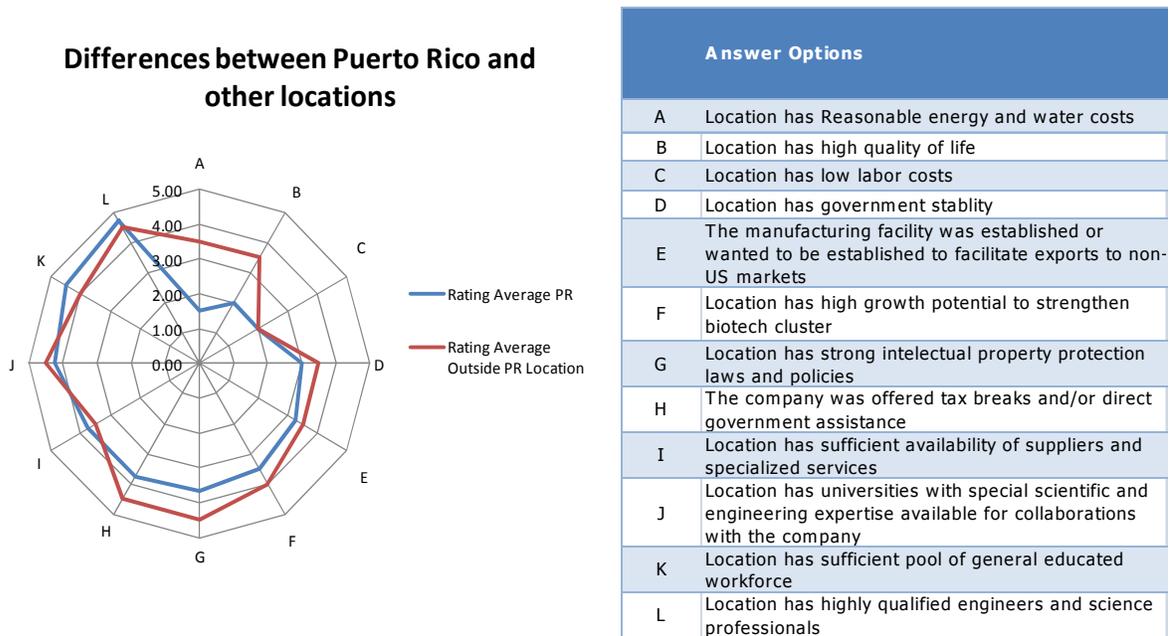


Figure 4.17 Statement agreements by location

Taking into consideration the importance of the factors, the participants were asked about the importance they allocate to them in the decision making process for Puerto Rico and other location. Figure 4.18 presents the different allocated importance to factors between locations. The quality of life was seen as a more important factor when considering other countries than when considering Puerto Rico as a location. The literature studies have mentioned that these other locations besides P.R., may have a lack of scientific and engineer personnel, and a lack of an educated workforce and they have direct efforts in recruiting qualified personnel from abroad (Ireland Government, 2007) (Singapore Agency for Science, Technology and Research, 2009) (The Department of Biotechnology, India Government, 2007). They may need to convince educated and specialized resources to relocate to a location and it's easier to do so when the location has a high quality of life. In Puerto Rico's

location decision process, they allocate more importance to tax breaks/ or direct government assistance, labor cost, availability of suppliers and specialized services, and availability of educated workforce. The importance to tax breaks and tax incentives may be due to the fact that Puerto Rico’s operation is directed mainly towards manufacture as has been suggested that in this stage taxes play an important role (Zhang & Patel, 2005). In the decision making process for locations outside PR they allocate more importance to the presence of universities with special scientific expertise available for collaboration, intellectual property protection laws, the growth potential to strengthen biotechnology cluster, and energy and water costs.

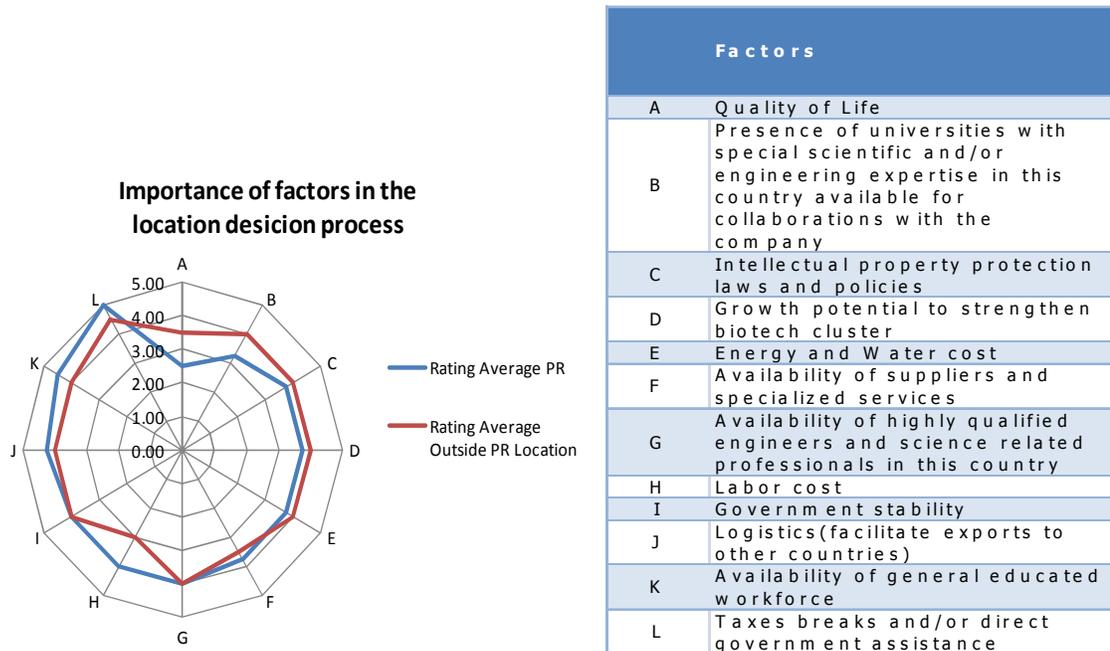


Figure 4.18 Importance of Factors in the Decision Process for Locating a Biotechnology Facility in Puerto Rico and other locations.

Biotech’s strategy planning as identifying niches is one of the most commonly used practices identified by Battelle (Battelle, 2008). The participants were asked what areas they understand PR can develop in order to find a niche and differentiate from other

biotechnology centers in the world. Most of the participants identified clinical development as one opportunity. In Massachusetts for example, clinical trials in hospitals is too costly and very slow (The Massachusetts Biotechnology Council, The Boston Consulting Group, 2002). Pharmacogenomics, toxicology, continuous manufacturing, manufacturing process optimization and Hispanics biostatistics were also considered by them as possible areas of opportunities. Target unmet needs put you on the spot and P.R. should take advantages of differentiation opportunities.

## 5 CONCLUSIONS

Based in our objectives and after the analysis and discussion of the results from the study the following can be concluded.

- The main reasons for existing biotechnology operations established in the island are the reliable supply of engineers and science professionals, the low tax rates, and a generally well educated workforce.
- The main strengths Puerto Rico has when it is being considered as a possible location for biotechnology operations are : (1) large supply of quality engineers and science related professionals, (2) low tax rates, (3) generally well educated workforce, (4) availability of specialized services, (5) adequate intellectual property protection , and (6) presence of universities available for collaboration with industry.
- The main deficiencies Puerto Rico has when being considered as a possible location for biotechnology operations are: (1) high transportation costs related to exports; (2) high utilities costs; (3) restrictive labor regulations; (4) scarce tax incentives; and (5) poor quality of life.
- The Critical Success Factors for the biotechnology biopharmaceutical sector in Puerto Rico are: (1) low taxes; (2) availability, reliability and cost of energy; (3) availability, reliability and cost of water; (4) availability of engineers and science professionals; and (5) the general adequacy of physical infrastructure.

- The overall perception from general and operations managers about the state of the biotechnology industry in Puerto Rico is that even the industry is going through hard sales/profits times, the Puerto Rican Industry has improved, but it still has several aspects to work with relative to other locations.

## **5.1 Limitations**

This study exhibits three main limitations related to our population: (1) identification of the population, (2) limited population and (3) respondent identity. First, the population was identified from a list of biotechnology promoted companies supplied by the Puerto Rico Industrial Development Company (PRIDCO) and PRIDCO manufacturing facilities directory using North America Industry Classification System (NAICS). The companies classified under NAICS, sector 3254, were investigated through their websites and through direct phone calls in order to identify whether the company has Biotechnology operations in Puerto Rico or other countries. Incorrect or incomplete information in PRIDCO's directory or in the company's disclosure of operations may affect the identified size of the population. Second, the belief that top management has knowledge of a company's decision making and the uncertainty of whether other coworkers have direct relation to this decision can affect the complete access to available information. The small population limits the use of other statistic resources and tests. We cannot make further inferences due to the population size and the possible effect on results if one of the respondents changes his or her perception about the biotechnology industry in Puerto Rico. Third, online survey and any other non on-

site surveys present the limitations of not knowing for sure that the information is being provided by the person and not a representative.

## **5.2 Recommendations**

Taking into consideration the study findings and the reviewed literature, the following recommendations are offered:

- Puerto Rico should focus on fostering and incentivizing K-12 students to pursue science & managerial related careers needed along the biotechnology value chain. Science and mathematics curriculums in public schools should be strong and consistent throughout the school years from K to 12.
- Drastic measures should be taken to manage the high rate of unemployment in Puerto Rico. If the current unemployment rate continues to create a “brain drain” of our best resources and discourage local talent to pursue higher education it may as well discourage high school students to continue into higher education.
- The government should take steps to improve its efficiency and minimize government bureaucracy in order to expedite the regulatory and permitting processes. A delay in the establishment of a manufacturing plant may have a negative effect of its products' time to market. It should speed up the creation of the “science city” and establish a “plug and play” facility that can contribute to reduce time to market of companies’ products.

- There is a need for entrepreneurship skills in Puerto Rican researchers. Puerto Rico's number of patents compared to other locations is considerably low and the presence of research that can lead to a commercial product is important for the development of the biotechnology cluster in the island. Puerto Rico should offer assistance in patent filing procedures to researchers and provide incentives for patent applications.
- The study and the reviewed literature show the importance of energy resources. The government should study the possibility of tax credits for companies that conduct capital investments on renewable energy technologies.
- Even though quality of life was not rated as highly as other factors, the importance other locations attribute to it may represent a red flag for Puerto Rico. The government should work towards a better quality of life and market it to positively change the perception of companies.
- Taking into consideration its resources, capabilities, limitations and strengths, Puerto Rico should target unmet needs with a substantial potential market in order to find a niche for differentiation and gain competitive advantages.
- Puerto Rico's economic development initiatives require patience and a long term perspective. Inaction is what really kills a true opportunity. Puerto Rico has to take action. If ideas and proposals stay in paper and are not applied, they will become useless.

### **5.3 Future Work**

Further work should focus in identifying other areas Puerto Rico can develop in order to differentiate itself from other locations. A realistic assessment of these areas to identify the best choices for the island should be performed, all the while taking into consideration Puerto Rico's resources, strengths, weaknesses, economic realities and advantages, among others .

Puerto Rico's condition as an island may lead to a specific study of the possibilities for the development of a marine biotechnology cluster. Furthermore, the development of agro biotechnology and agricultural science (the next more important federal funding sector in Puerto Rico after life sciences) industries in Puerto Rico should be considered. It may be worth it conduct a study about the success factors of agro biotechnology in Puerto Rico, with the intent of attracting new venture capital to the island.

California's public supports stem cell research. Massachusetts intends to activate a public outreach program so that the community is educated about the benefits of biotechnology in order to garner public support. The Mexican community's different points of view about genetic manipulated organisms, along with Ireland's communication strategies to increase public awareness and participation, all have brought the importance of accessing public support towards investments in biotechnology. Further work should be done in order to increase the general public's knowledge, perception and support.

Quality of life was considered important by locations as California. In the Puerto Rico case, it was not allocated as much importance when compared to other factors mentioned. This does not mean Puerto Rico should not pay attention to this factor. Because quality of

life is a broad concept, a quality of life index of several indicators may be created in order to identify and quantify the different factors that constitute the overall quality of life in Puerto Rico. Further study and comparison of quality of life determinants among countries should be done.

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# Appendixes

## Appendix A INFORMED CONSENT LETTER

### University of Puerto Rico

#### Mayagüez Campus

College of Business Administration

Graduate Studies

#### Informed Consent

The following questionnaire is part of a research study for Enid M. Colón Ronda's Master's thesis titled "*Critical Success Factors for the Biotechnology Industry in Puerto Rico*". The findings of the survey will serve as a guide in determining the factors, in order of priority, that biotechnology companies consider critical to their success when launched in Puerto Rico. We will study the perception of the general and operations managers about the state of the biotechnology industry in Puerto Rico. Our aim is to identify the positive and negative factors that affect Puerto Rico in the companies' search for future locations, as well as the factors that have contributed to attracting these companies to operate in the island.

Participation in this survey is voluntary. The information provided by the participants is confidential, and will be used for educational purposes only. A secure online survey tool is used, and the researchers guarantee that all responses will be held in confidence. Once reviewed and used, the responses will be discarded. The researchers will be the only persons authorized to access the responses. Only aggregate responses will be reported. Company names and/or contact information will not be linked to the questionnaire responses or disclosed in any way. After the study is completed and properly approved by the University, the results will be shared with the participants, educational entities, and the general public.

By answering and submitting the following questions you agree with the terms and conditions of this survey stated above, and give your consent to the researcher to use the information to be provided as part of the research methodology to ensure the success of the study.

Thank you for your time and cooperation. If you have any questions, please contact Enid M. Colón Ronda at (787) 590-7957 or at [enidmcolon@gmail.com](mailto:enidmcolon@gmail.com). You can also contact Mario Córdova, Ph.D., JD, CAPM, at (787) 832-4040, ext. 5345, or Dr. Yolanda Ruiz, director of graduate studies, at (787) 832-4040, ext. 3887.

## Appendix B QUESTIONNAIRE

What is your current position title?

- General Manager
- Biotechnology operations manager
- Other senior management position (please specify below) \_\_\_\_\_

You have completed studies in which of the following areas :

***Please select all that apply***

- Management
- Accounting
- Finance
- Human Resources
- Engineering
- Chemistry
- Biology
- Microbiology
- Biochemistry
- Other/s (please specify) \_\_\_\_\_

In which of the following areas you have work experience?

- Product development – Formulation, Clinical Phases, Manufacture)
- Product development – Technology Transfer
- Product Development – Production Scale –Up and Optimization
- Facilities – Design and Construction
- Facilities – Commissioning and qualification as Risk Management Strategy
- Facilities – Operation and Maintenance
- Facilities – Controls and Automation
- Information Systems
- Supply Chain Management – Materials Management
- Supply Chain Management – Operational Economics

- Supply Chain Management – Warehouse and Distribution Management
- Production Systems – Production Unit Operations – drug (small molecule) and biologics
- Production Systems – Production Management
- Production Systems – Production Control
- Regulatory Compliance – Government Regulations
- Regulatory Compliance – Standard, Practices and Guides
- Quality Systems – Risk Management and Quality Management Systems
- Quality Systems – Quality Validations
- Accounting
- Human Resources
- Finance
- Marketing and Sales
- Other (please specify) \_\_\_\_\_

Are you a member of a committee in your company involved in making new location decisions or advisory?

- Yes
- No

Is a PR colleague of yours a member of a committee in your company involved in making new location decisions or advisory?

- Yes
- No

What areas of your business are more related to the new locations decision process?

- Production/Operations
- Logistics
- Engineering
- Accounting (Taxes)
- Finance
- Top Management
- Other (please specify) \_\_\_\_\_

Your company's largest biotechnology operations (in general) are located in which of the following regions? **Please select all that apply**

- Low tax zones

- Logistics and distribution center
- Relevant basic and applied research and knowledge zones
- Low cost workforce location
- Other (Please Specify \_\_\_\_\_)

Which of the following activities are included in your company's Biotechnology operations in Puerto Rico? **Please select all that apply**

- Research and Development
- Product Development
- Process Scale –up
- Manufacturing
- Packaging
- Global and/ or Regional Logistics
- Marketing and Sales
- Other (please specify \_\_\_\_\_)

What are the factors that you believe influence the most your company's decision to establish operations in Puerto Rico?

- Strategic location
- Tax rates
- Tax incentives (ex. Up front cash grants, Tax deductions by job created, for R&D, others)
- General educated workforce
- High supply of engineers and science related professionals
- Availability of specialized services
- Availability of suppliers
- Supportive public institutions
- Efficient communications infrastructure
- Adequate and efficient physical infrastructure
- Regulatory and permitting environment
- Labor costs
- Utility costs and quality (energy and water)
- Presence of universities available for collaboration with industry
- Intellectual property laws and policies
- Other (pls. specify) \_\_\_\_\_

Please indicate if you agree with the following statements about Puerto Rico and/ or about Biotechnology operations in Puerto Rico on a scale from 1 to 5, with 5 being “strongly agree”, 1 being “strongly disagree” and 3 being “neither agree nor disagree”.

Puerto Rico has highly qualified engineers and science related professionals.

1      2      3      4      5

Puerto Rico has universities with special scientific and or engineering expertise available for collaborations with the company

1      2      3      4      5

The company was offered taxes breaks and/ or direct government assistance.

1      2      3      4      5

Puerto Rico has strong intellectual property protection laws and policies.

1      2      3      4      5

Puerto Rico has low labor costs

1      2      3      4      5

Puerto Rico has high growth potential to strengthen biotech cluster

1      2      3      4      5

Puerto Rico has reasonable energy and water costs.

1      2      3      4      5

The manufacturing facility was established or wanted to be established to facilitate exports to other non- us markets.

1      2      3      4      5

Puerto Rico has a sufficient pool of general educated workforce.

1      2      3      4      5

Puerto Rico has sufficient availability of suppliers and specialized services.

1      2      3      4      5

Puerto Rico offers a high quality of life.

1      2      3      4      5

Puerto Rico has government stability

1      2      3      4      5

Please indicate how important were these factors in the decision making process when your company considered Puerto Rico as a biotechnology operations site, on a scale from 1 to 5, with 1 being ‘not important at all’ and 5 being ‘very important’.

Availability of highly qualified engineers and science related professionals in this country.

1    2    3    4    5

Presence of universities with special scientific and/or engineering expertise in this country available for collaborations with the company.

1    2    3    4    5

Taxes breaks and/ or direct government assistance.

1    2    3    4    5

Intellectual property protection laws and policies.

1    2    3    4    5

Labor costs.

1    2    3    4    5

Growth potential to strengthen biotech cluster

1    2    3    4    5

Energy and water costs.

1    2    3    4    5

Logistics (facilitate exports to other countries)

1    2    3    4    5

Availability of general educated workforce

1    2    3    4    5

Availability of Suppliers and Specialized Services

1    2    3    4    5

Life Quality

1    2    3    4    5

Government stability

1    2    3    4    5

Are you familiar with the location decision process of one recently established or soon to be establish Biotechnology facility outside Puerto Rico.

Yes

No

*If you answered **yes** to the last question please continue with the questionnaire. If you answered **no** to the last question please proceed from question number 16 ahead.*

Indicate in which Country /or Region was recently established or may be establish this Biotechnology facility outside Puerto Rico

- United States
- Canada
- Central America and Caribbean
- South America
- Europe
- Asia
- Africa
- Other

Please indicate if you agree with the following statements about the Biotechnology Location outside Puerto Rico on a scale from 1 to 5, with 5 being “strongly agree”, 1 being “strongly disagree” and 3 being “neither agree nor disagree”.

There are highly qualified engineers and science related professionals in this country or region.

1      2      3      4      5

There are universities with special scientific and or engineering expertise in this country available for collaborations with the company.

1      2      3      4      5

The company was offered taxes breaks and/ or direct government assistance.

1      2      3      4      5

This country or region has strong intellectual property protection laws and policies.

1      2      3      4      5

The labor costs are low in this country or region.

1      2      3      4      5

The country or region has high growth potential to strengthen biotech cluster

1      2      3      4      5

The country or region has low energy and water costs.

1      2      3      4      5

The manufacturing facility was established to facilitate exports to other countries or regions.

1      2      3      4      5

The country or region offers a high life quality

1 2 3 4 5

The country or region has government stability

1 2 3 4 5

The country or region has a large pool of general educated workforce.

1 2 3 4 5

The country or region has reasonable availability of suppliers and specialized services.

1 2 3 4 5

Please indicate how important were these factors in the decision making process to choose this country as the new biotechnology operations site, on a scale from 1 to 5, with 1 being 'not important at all' and 5 being 'very important'.

Availability of highly qualified engineers and science related professionals in this country.

1 2 3 4 5

Presence of universities with special scientific and or engineering expertise in this country available for collaborations with the company.

1 2 3 4 5

Taxes breaks and/ or direct government assistance.

1 2 3 4 5

Strong intellectual property protection laws and policies.

1 2 3 4 5

Low labor costs.

1 2 3 4 5

Growth potential of the country.

1 2 3 4 5

Energy and water costs.

1 2 3 4 5

Logistics (facilitate exports to other countries)

1 2 3 4 5

Life Quality

1 2 3 4 5

Government stability

1 2 3 4 5

Availability of general educated workforce.

1      2      3      4      5  
 Availability of Suppliers and Specialized Services  
 1      2      3      4      5

Please indicate the five most important factors from the following list that are, in your opinion, desirable for biotechnology industry to succeed in Puerto Rico.

- Efficient communications infrastructure
- Electricity Cost, Access and Reliability
- Water Services Cost, Access and Reliability
- Adequacy of other physical infrastructure (roads, ports, wastes, other)
- High availability of engineers and science-related professionals
- Availability of specialized services
- Supportive public institutions working with industry
- Pro-business labor regulations
- Cost of export regulations
- Stability of government policies
- Tax regulations
- Incentives to bring your smaller alliance partners (NOL carry-forward transfers, equity, low cost debt, ready facilities for co-development and co-manufacturing in PR)
- Efficient government bureaucracy
- Industrial economic incentives
- Good quality of life
- Research and Development Facilities
- Other (please specify \_\_\_\_\_)

Please rate the importance of the following factors for the success of a biotechnology company on a scale from 1 to 5, with 1 being 'not important at all' and 5 being 'very important'.

	1	2	3	4	5
Physical infrastructure	<input type="radio"/>				
Intellectual property protection	<input type="radio"/>				
Communications infrastructure	<input type="radio"/>				
Availability of engineers and science-related professionals	<input type="radio"/>				
Low taxes	<input type="radio"/>				
Quality of life	<input type="radio"/>				

Stability of government policies	<input type="radio"/>				
Supportive public institutions	<input type="radio"/>				
Availability of Specialized Services	<input type="radio"/>				
Availability and Reliability of Electricity	<input type="radio"/>				
Energy Costs	<input type="radio"/>				
Water Availability and Reliability	<input type="radio"/>				
Water Costs	<input type="radio"/>				
Other _____ (pls. specify)	<input type="radio"/>				

In your opinion, please rate the quality of the following factors available for the success of a biotechnology company in Puerto Rico on a scale from 1 to 5, with 1 being 'Poor' and 5 being 'Excellent'

	1	2	3	4	5
Physical infrastructure	<input type="radio"/>				
Communications infrastructure	<input type="radio"/>				
Availability and Quality of engineers and science-related professionals	<input type="radio"/>				
Tax rates	<input type="radio"/>				
Quality of life	<input type="radio"/>				
Stability of government policies	<input type="radio"/>				
Supportive public institutions	<input type="radio"/>				
Availability of Specialized Services	<input type="radio"/>				
Availability and Reliability of Electricity	<input type="radio"/>				
Energy Costs	<input type="radio"/>				
Water Availability and Reliability	<input type="radio"/>				
Water Costs	<input type="radio"/>				
Other _____ (pls. specify)	<input type="radio"/>				

What are the major negative factors that influence companies in their decision not to establish biotechnology operations in Puerto Rico? **Please select no more than 5**

- \_\_\_\_ Restrictive labor regulations
- \_\_\_\_ Difficult access to capital
- \_\_\_\_ Scarce tax incentives (ex. Tax Credits)
- \_\_\_\_ High utilities cost (energy and water)
- \_\_\_\_ Poor utilities service reliability (energy and water)
- \_\_\_\_ High labor costs
- \_\_\_\_ Inadequate supply of engineers and science related professionals

- Inadequately educated non-professional labor force
- High transportations cost related to exports
- Poor enforcing contracts regulations
- Lack of efficient communications infrastructure
- Lack of adequate physical infrastructure
- Inefficient government bureaucracy
- Poor work ethic of the national labor force
- High level of corruption
- Lack of suppliers
- Lack of specialized service providers
- Poor quality of life
- Crime
- Other (pls. specify) \_\_\_\_\_

Taking in consideration PR capabilities and limited resources as well as the Biotechnology Industry needs, what areas you understand PR can develop in order to find a niche and differentiate from other Biotechnology Centers in the World?

***Please select no more than 2.***

- Continuous Manufacturing
- Manufacturing Process Optimization
- Drug Delivery
- Clinical Development
- Diagnostics
- Hispanic Biostatistics
- Hispanic Health Research by Therapeutic Area
- Pharmacogenomics
- Personalized Medicine
- Toxicology
- Dual – therapy treatments
- Marine biotechnology or other tropical resources biotechnology
- Biogenerics
- Other (pls. specify) \_\_\_\_\_

At present, is your company considering establishing or expanding its biotechnology operations in Puerto Rico?

- Yes
- No

Which of the following countries or US jurisdictions does your company consider most when planning to establish new or increased biotechnology operations?

**Please select no more than 2**

- Singapore
- Ireland
- California, US
- Massachusetts, US
- New Jersey, US
- Germany
- Canada
- Spain
- Other (pls. specify) \_\_\_\_\_

In your opinion, what is the state of the biotechnology industry in Puerto Rico? (e.g. is it doing well, badly, improving, etc.) Please explain.

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How committed and available are you and your company with Puerto Rico if the country establishes an efficient and realistic economic development plan in favor of new ventures?

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