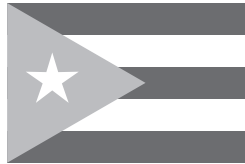


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# Contract Manufacturing in Puerto Rico



*Compliments of:*

**PATHEON**

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## EXECUTIVE SUMMARY

In an era characterized by the need to continuously evaluate and bolster R&D pipelines, the increasing complexity and overall cost to develop and approve drug products, the trend toward genericization, and mounting pressures to both decrease prices and maximize profitability, the pharmaceutical industry has sought competitive advantage in lower cost manufacturing jurisdictions.

The Commonwealth of Puerto Rico provides unparalleled value as a location for high quality cost effective pharmaceutical manufacturing. Companies capitalize upon the advantages and safeguards of conducting business within a U.S. jurisdiction, while gleaning the benefits of operating within a favorable tax structure. In addition, the Puerto Rican government offers a low corporate tax rate and incentive program to eligible companies. The Island has developed an efficient infrastructure for the conduct of business, has cultivated a highly skilled and knowledgeable workforce, and has attracted a comprehensive network of support services over its 40 year history in pharmaceutical manufacturing.

Contract manufacturing is a proven model and a strategy long adopted as a mechanism to manage risk, gain access to additional capacity, contain cost, maintain flexibility and minimize capital expenditure. Contract Manufacturing Organizations (CMOs) situated in Puerto Rico provide an attractive way, for companies with an existing presence on the Island of Puerto Rico, and for those without, to make the most of the advantages Puerto Rico has to offer.

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## Advantages of Pharmaceutical Manufacturing in Puerto Rico

- **Strong Infrastructure for the Conduct of Business**

- As a Commonwealth of the United States, entities operating in Puerto Rico experience the same legal and governmental assurances as businesses operating within the continental U.S.A.
- The island is favorably situated proximate to mainland U.S.A., and at the intersection of trade routes from North America and Europe to Latin America and the Caribbean
- A wide choice of sea and air transportation options enable the efficient and reliable delivery of goods worldwide
- Trade barriers are minimized as dealings with the continental U.S. are considered domestic, and free trade agreements throughout North America and Central America facilitate the exchange of goods
- An extensive highway system and communications infrastructure support business processes on the island

- **Well Established and Growing Pharmaceutical Presence**

- With over 40 years of experience in the pharmaceutical industry, Puerto Rico maintains a position of leadership in the areas of Pharmaceutical Manufacturing, Medical Devices & Equipment and Research
- Puerto Rican universities generate a high proportion of science, engineering and technology graduates contributing to the Island's highly educated and dedicated workforce
- A resource rich network of suppliers and services has arisen over time to meet the needs of the pharmaceutical industry
- Strong relationships exist between industry members on the Island and the FDA, and with various European, Asian and Latin American regulatory bodies. Over the life span of the industry an expansive knowledge-base regarding compliance practices has been developed
- Significant industry investment in the biopharmaceutical and biotechnology sectors has highlighted Puerto Rico as a center of excellence and has well positioned the Island for future growth

- **Attractive Tax Infrastructure & Employer Incentives**

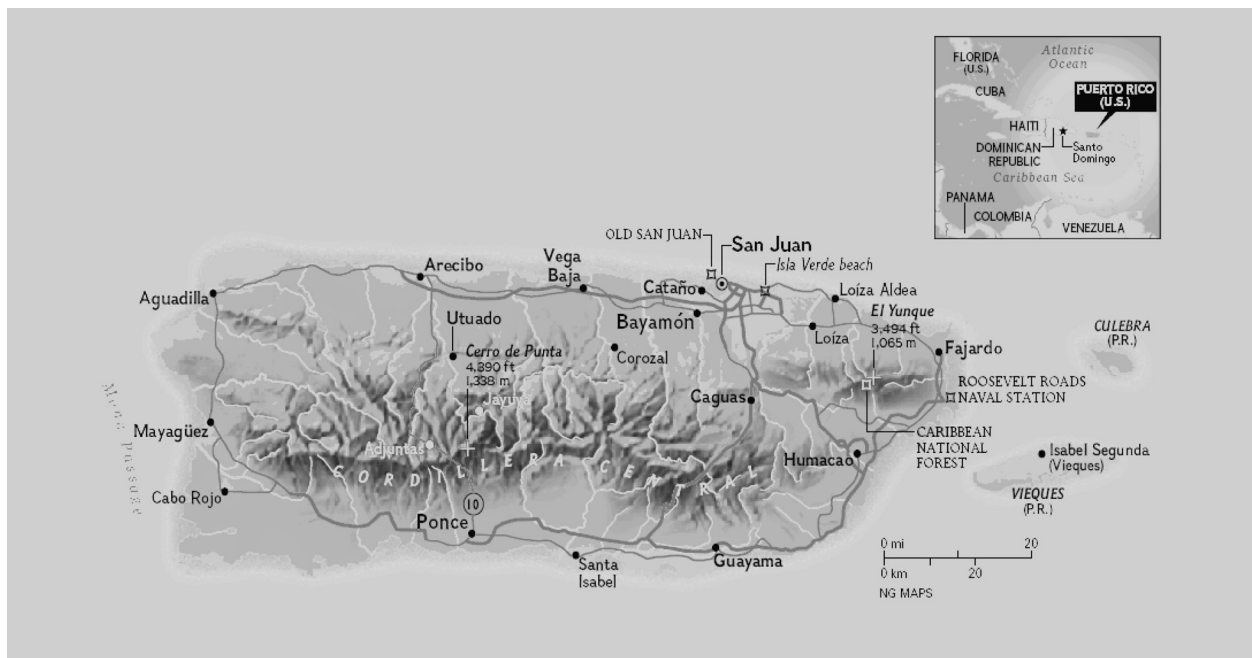
- Companies with an established legal entity on the island of Puerto Rico qualify for a local corporate income tax rate of seven (7) percent or less
- U.S. companies have the opportunity to establish a foreign entity within a U.S. territory
- European companies have the opportunity to repatriate earnings without further taxation
- Deductions, exemptions and tax credits are available for research and development expenses, employee training expenses, and for the purchase of equipment, machinery and raw materials

## PUERTO RICO: AN OVERVIEW

With an average temperature of 82°F (28°C), a lush coastal plain and mountainous interior it is not surprising that tourism continues to be one of the key industries for Puerto Rico's 3.9 million Spanish and English speaking citizens. In the late 1940's, following the introduction of an industrialization program, known as 'Operation Bootstrap,' the economic development strategy of Puerto Rico shifted from its roots in the growth and export of agricultural products such as sugar and coffee, to manufacturing.

Key contributors in Puerto Rico's manufacturing sector include the pharmaceutical, biotechnology, medical device, aerospace, electronic and food product industries. Over one half of the United States' Fortune 500 Companies, have made placement of their operations on the Island an integral part of their business success. Fiscal 2006 saw Puerto Rico ship \$60 billion worth of goods, receive \$42.6 billion in inbound shipments and record a GDP of \$86.5 billion, 42.2 percent of which came from the manufacturing sector that hums along in 2,300 industrial plants. In 2007-2008, Puerto Rico ranked 36th out of 122 countries in the World Economic Forum's Global Competitiveness Index. Rankings were based on a number of factors including infrastructure, higher education, goods and labor market efficiencies, financial market sophistication, technological readiness and innovation.

Puerto Rico is among the world's most densely populated centers in the world at 1,100 people per square mile. Just under half of the population is centralized within the Island's urban and suburban hubs. The overall literacy rate of Puerto Rico's inhabitants is 94 percent, while one in five people age 25 and older have a bachelor's degree or higher.



Source: National Geographic Society

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## Highly developed infrastructure

In early colonial days, Puerto Rico was known as *La Llave de las Americas* ("The Key of the Americas") based upon the advantages its location presented to the Spanish en route to conquering the Americas. Situated in the Caribbean, southeast of mainland U.S.A. approximately 1,000 miles (1,600 km) off the coast of Florida, Puerto Rico's well established transportation and communication systems advantageously position it as an access point to worldwide markets.

The Island of Puerto Rico has an area of 3,508 square miles (9,104 km), and is 110 miles (180 km) in length, and 40 miles (65 km) in width at its outermost points. Thanks to an extensive system of highways and expressways no point on the Island is more than two hours travel from either an airport or seaport.

Air transport is predominantly handled by Puerto Rico's Luis Muñoz Marín International airport, which in 2006 ranked 25th among U.S. airports in cargo movements, supporting more than 1,500 cargo flights weekly to and from worldwide destinations. Aguadilla's Rafael Hernández airport, in the western part of the Island, is ranked 44th.

When it comes to sea travel, the Port of San Juan is deemed the 14th busiest container port in the western hemisphere based on the number of trailer-equivalent units (TEUs) handled. There are 80 domestic and foreign ports in operation that are serviced by 40 different shipping lines.

Given the multitude of air and sea options for the transport of goods, average shipping times from Puerto Rico to North America and Gulf ports are only three to four days; 10 days to the North American West Coast, and 14 days to Europe.

When it comes to telecommunications, Puerto Rico's high-speed third generation technologies well-equip the Island for 'business as usual'. More than 90 satellites connect Puerto Rico to the rest of the world, as does a high capacity undersea network of fiber optic cables. Inland communication services are provided by several world-class telecom companies via an entirely digital switching telecommunications network. In addition, wireless voice and data networks provide Island-wide coverage.

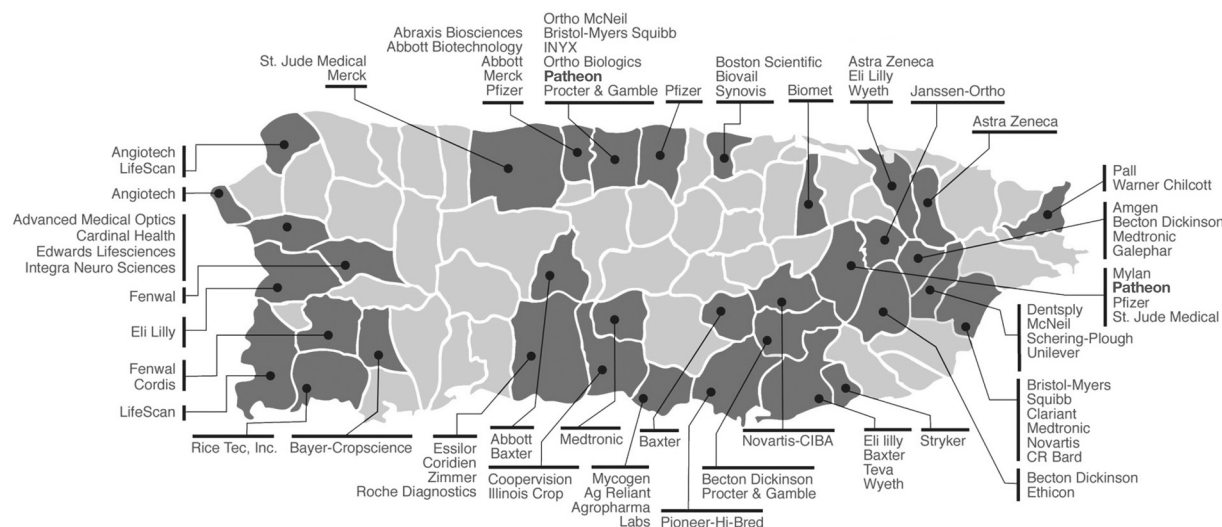
## Commonwealth – close ties to the United States

Puerto Rico - officially the Commonwealth of Puerto Rico - is an unincorporated, organized territory of the United States of America. While Puerto Rico is self governing for all concerns local in nature, the Island falls under the jurisdiction of the U.S. federal government for virtually all areas of governance and business, including but not limited to applicability of the U.S. constitutional and legal protections, matters of currency, defense, external relations, interstate commerce, the postal system and social security, among others. Puerto Ricans are citizens of the U.S. and carry U.S. passports.

# PUERTO RICO PHARMACEUTICAL INDUSTRY

U.S. Internal Revenue Code (IRC) Section 931 (1954), and later Section 936 (1976), enabled companies to repatriate Puerto Rico source income into the U.S. free of federal taxes. These IRC privileges, combined with a series of incentives sponsored by the Puerto Rican government, were aimed at encouraging economic development on the Island. They proved an extremely powerful catalyst in attracting labor and capital intensive industries to the Island and were responsible for the establishment of a veritable pharmaceutical manufacturing Mecca in Puerto Rico. With the elimination and phase out of Section 936 in 2005, Internal Revenue Code 901 rose to prominence. IRC Section 901 allows companies to operate as Controlled Foreign Corporations (CFCs), and has facilitated the continued enjoyment of substantial tax savings.

Due in large part to the opportunities afforded by the taxation climate on the Island, Puerto Rico evolved into one of only four U.S. jurisdictions specialized in the biosciences, specifically within the areas of Drugs & Pharmaceuticals, Medical Devices & Equipment and Research. As of 2006, the pharmaceutical world had invested \$60 billion in industry infrastructure on the Island. With a local network of 89 U.S. FDA-approved pharmaceutical and biopharmaceutical plants, Puerto Rico is considered the world's 5th largest pharmaceutical manufacturing region, after the U.S., the U.K., Japan and France. **In fact, Puerto Rico supports the manufacture of 8 of the top 20 biologics sold in the United States, as well as 13 of the top 20 prescription drugs.** The biopharmaceutical industry represents 26% of the Island's Gross Domestic Product and generates approximately 26,000 direct jobs or 25% of the Island's 100,900 manufacturing industry jobs.



Source: PRIDCO

Having recognized the current momentum in the biopharmaceutical arena, Puerto Rico has tailored its focus accordingly. As of October 2006, the Island maintained 25% (371,000 L) of the world's biological manufacturing capacity – the largest share of any one location worldwide. Over the last 5 years industry leaders, such as Abbott Laboratories, Amgen, BD Biosciences, Bristol Myers Squibb, Eli Lilly and Johnson & Johnson have invested more than \$4 billion dollars to build bulk and fill/finish biotechnology facilities on the Island, and are on course to mold Puerto Rico into a resource capital for the biotechnology and biopharmaceutical sectors.

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## Workforce expertise

In parallel to Puerto Rico's emergence as a center of excellence for the pharmaceutical industry, Puerto Rico's education system has worked successfully to keep pace with the demand for well trained graduates. Its strength is evidenced by the fact that more than 90% of the management positions within the Puerto Rico pharmaceutical industry are held by Puerto Ricans. On the Island more than 90 public and private university and college campuses award over 23,000 degrees each year, of which more than 9,000 are science, engineering and technology-based. The University of Puerto Rico (UPR), Mayaguez and Polytechnic University of Puerto Rico rank 11th and 19th, respectively in the U.S. in engineering enrollment. Furthermore, the UPR Mayaguez Campus ranks 1st in the U.S. in the number of chemical engineering graduates.

Academic programs geared toward the pharmaceutical industry are supported by the UPR as well as various private institutions offering opportunities for research funding and for industry collaboration. Sources of U.S. federal research funding include:

- National Science Foundation (NSF)
- National Institutes of Health (NIH)
- National Cancer Institute (NCI)
- National Oceanic and Atmospheric Administration (NOAA)
- National Air and Space Administration (NASA)

In addition, the non-profit Puerto Rico Science and Technology Trust provides:

- grants for R&D projects in science and technology
- financial support for construction of R&D infrastructure projects

These projects include the emerging Puerto Rico Knowledge Corridor, which will be home to the Molecular Sciences Building and the Puerto Rico Cancer Center. The Bioprocess Training and Development Complex, located in Mayaguez near the UPR campus, will provide a venue for conducting research and training on bioprocesses.

While the Puerto Rico workforce is known to contain a significant proportion of highly educated individuals, it similarly acknowledged for its low turn-over rate and high productivity level. Wage rates in Puerto Rico, when compared to earnings for equivalent positions on the mainland, are 20-30% lower, contributing to a greater productivity rate per dollar in Puerto Rico than that experienced in the continental U.S.

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## Advanced supply chain

A successful track record, 40 years in the making, in the life science sector has attracted other businesses to support the industry. The result has been a dynamic and resource-rich network benefitting its participants by way of time savings and the development of synergistic relationships. Key pharmaceutical resources represented on the Island include:

- Consulting Services
- Contract Manufacturing Organizations
- Contract Research Organizations
- Laboratory Services
- Packaging Machinery
- Pharmaceutical Grade Supplies
  - Packaging Materials and Components
  - Raw Materials and Components
- Plant Engineering/Plant Maintenance
- Process Machinery and Equipment
- Transportation and Shipping
- Validation Support
- Warehousing and Distribution
- Waste Management

## Strong regulatory environment

As a territory of the United States, regulation of Puerto Rico's pharmaceutical industry falls under the jurisdiction of the U.S. Food and Drug Administration (FDA). Given the volume of pharmaceutical activity taking place on the Island, and given the U.S. FDA's mandate to ensure the safety and efficacy of all drug products developed and manufactured for consumption in the United States, the U.S. FDA has localized a district office, employing 22 inspectors, to the Island's capital city, San Juan. Routine plant inspections are conducted on average once every two years, and due to the intimate nature of the Island's pharmaceutical industry, the opportunity exists for close communication between industry members and the U.S. FDA for the purpose of achieving and maintaining compliance.

While Puerto Ricans have over 40 years of history adhering to the guidelines set forth by the U.S. FDA, significant experience also exists within the workforce for the observation of compliance practices defined and imposed by the regulatory bodies governing Europe, Asia and Latin America.

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# ADVANTAGES OF CONDUCTING BUSINESS IN PUERTO RICO

Designation of the Island of Puerto Rico as a location conducive to the conduct of business was supported by the World Bank Group in their 'Doing Business 2008' report. The island ranked 28th out of 178 countries on the Ease of Doing Business Index.

Businesses operating in Puerto Rico are uniquely positioned to operate in a tax advantaged jurisdiction, while benefitting from the ability to conduct business in much the same way as American companies. Transactions are conducted using the U.S. banking system and currency, and mail is distributed via the United States Postal System. Businesses enjoy the protection of the American constitution and legal system. Moreover, intellectual property is protected under U.S. law and the Bayh-Dole Act applies in all aspects in the Commonwealth of Puerto Rico. Transportation between Puerto Rico and the continental United States is considered domestic, eliminating any customs issues for people and cargo flowing between the two locations and similarly preventing the imposition of tariffs for the flow of goods. Both the North American Free Trade Agreement (NAFTA) and the Dominican Republic–Central America Free Trade Agreement (DR-CAFTA) apply in full to Puerto Rico, effectively eliminating trade barriers for applicable markets. In short, Puerto Rico enjoys the majority of the strategic advantages of any American state – while remaining outside of the U.S. Federal tax jurisdiction.

## Tax advantages

Puerto Rico's tax incentives have proven a powerful engine to fuel the Island's economy. They have effectively distinguished Puerto Rico as an epicenter for the manufacturing sector by attracting industry from mainland U.S., and from the rest of the world.

- **Tax rate**

U.S. federal income tax does not apply to Puerto Rico source income. Furthermore, companies engaged in manufacturing, research & development or the exportation of services, are charged a local corporate income tax rate of seven (7) percent or less. The rate is negotiated on the basis of the company's employment and investment commitment to Puerto Rico, among other factors.

Parties within various levels of the Puerto Rican government are currently working with members of the private sector to review and improve the tax legislation that has well-served the pharmaceutical manufacturing industry, among others, for the past 60 years.

- **Controlled Foreign Corporations**

Designation as a Controlled Foreign Corporation (CFC) is representative of a company's operational status as a legal entity within the jurisdiction of Puerto Rico and their ownership or control within another. CFC status enables U.S.-based companies to defer their profits from U.S. taxation until they are repatriated back into the country.

European companies have the potential to repatriate earnings into EU member countries without incurring any further taxation.

- **Additional incentives**

As additional commitment to the generation of business on the Island of Puerto Rico, the Puerto Rican government offers a series of special tax credits, exemptions and deductions for eligible companies. For instance, R&D expenses are deductible at a rate of 200 percent, as are training expenses. In addition, the Workforce Investment Act reimburses either up to 50 percent of an incumbent employee's salary during training, or up to 50 percent of an employee's costs for customized training.

For owned or rented machinery and equipment, and for raw materials used in manufacturing processes, companies are eligible for a 100 percent tax exemption. Additionally, a 25 percent tax credit is available for the incremental purchase of locally manufactured goods.

Companies that create jobs for Puerto Ricans, source products or services locally or perform R&D on the Island may be eligible for further cash grants from the Puerto Rico Industrial Development Company (PRIDCO).

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## CONTRACT MANUFACTURING IN THE PHARMACEUTICAL INDUSTRY

Puerto Rico's tax incentives, and status as a territory of the United States, have successfully distinguished it as an advantageous location for industry, particularly for sectors like pharmaceutical manufacturing where labor and capital requirements are high. Importantly, the Island's benefits are not restricted only to those pharmaceutical companies desiring to establish operations on the Island, but are also applicable to companies wishing to manufacture drug product by enlisting the services of a Contract Manufacturing Organization (CMO).

A niche for contract manufacturing within the pharmaceutical sector was borne out of an industry need for the flexibility of a variable cost-structure, and for the purposes of cost containment, capacity, and speed to market. Traditionally, the services of CMOs were sought after to supplement product volumes in response to unexpected sales, to accumulate sufficient stock for product launch, to access expertise in non-core areas, and to limit risk when pioneering new technologies.

A number of powerful influences within the pharmaceutical sector today have elevated contract manufacturing to a place of heightened importance within the industry and have prompted the evolution of sponsor-contractor relationships from basic project-specific arrangements to value-added partnerships:

- Merger and Acquisition (M&A) activity, globalization and stock market pressures have highlighted the need for lean operations and practices, and improved earnings per share. Pressure to reduce pricing has further compounded the drive to capitalize upon the efficiencies of scale afforded by the contract manufacturing industry.
- M&As have created larger and more complex pipelines. Additionally, they have resulted in plant redundancies and excess capacity which have contributed to a decrease in overall supply chain efficiency. Where internally operated facilities traditionally function in a structured manner, CMOs are able to offer flexible manufacturing as they are well versed in operating versatile and adaptable facilities that are able to reconfigure swiftly for different products and processes.
- More than ever, contract manufacturing is being looked to for improved speed to market as regulatory forces continue to increase the complexity and expense associated with the drug product approval process. Moreover, pressures to enter the market as soon as possible in an effort to fully exploit the patent life of a drug product, are compounded by looming pressures from generic competitors and alternative therapies. CMO partnerships can positively impact timelines by condensing development cycles, eliminating bottlenecks and by providing access to innovative technologies.
- The number of pharmaceutical technologies entering the marketplace is ever growing and the CMO industry must evolve accordingly in order to remain competitive. As such, pharmaceutical companies are able to access new technologies and trained operators, without incurring risk and committing capital. Having access to a greater pool of candidate technologies gives pharmaceutical companies the opportunity to conduct a more comprehensive evaluation en route to finalizing their strategy, and provides more options to companies looking to offer a range of solutions across different segments of their customer base.
- Taking into account the exposure that CMOs have to a wide range of products and processes, and given that a high proportion of the projects CMOs take on are technically challenging in nature, companies who choose to partner with a CMO stand to benefit greatly from their experience and knowledge base.

Contract manufacturing has gained acceptance from the pharmaceutical industry as an invaluable resource for achieving operational efficiency and effectiveness – much in the same way that Puerto Rico has established itself with the pharmaceutical industry as an advantageous location for cost effective manufacturing.

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## **Capitalizing Upon the Advantages of Pharmaceutical Manufacturing in Puerto Rico**

Whether by the in-house management of an operation on the Island, or by enlisting the services of a CMO, there are a number of strategies at the disposal of the pharmaceutical industry to maximize the advantages of manufacturing drug product in Puerto Rico.

### **New Pharmaceutical Operations in Puerto Rico**

A company without a previous presence in Puerto Rico that is interested in capitalizing upon the Island's tax benefits is able to do so by acquiring or building their own facility, or by contracting the services of a manufacturer on the Island. In order to accomplish the latter, the company would be required to 1) establish a CFC on the Island, and 2) establish a contractual relationship with the manufacturer, following which they would be in a position to apply for a tax exemption grant.

Notably, to enjoy Puerto Rico's tax advantages through a contract manufacturing relationship, the client company must establish a Puerto Rico subsidiary and establish a long term contractual relationship for production. Additionally the client must hire one or more employees to oversee production at the host's facility and must retain the risk and ownership of the product throughout the production process.

### **Existing Pharmaceutical Operations in Puerto Rico**

For companies who have already established a presence on the Island of Puerto Rico, the technology transfer of a new or existing project to a contract manufacturer located on the Island, can be accomplished using the company's existing tax structure.

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## CONCLUSION

Puerto Rico is uniquely positioned to offer the best of both worlds – the security and ease of conducting business in the United States with the tax benefits of operating under a Controlled Foreign Corporation (CFC) structure. Companies have been capitalizing upon these advantages for 40 years and in doing so have stimulated the growth of a vibrant pharmaceutical community, backed by a well-tailored workforce and support services infrastructure. Key industry players continue to invest in the Island fuelling the technological advancement and growth of the sector.

The strategic use of a contract manufacturer with operations in Puerto Rico presents an attractive way to access the tax benefits that the Island has to offer. Patheon Inc. operates facilities within the Puerto Rican municipalities of Caguas and Manatí and is an advantageous outlet through which to attain high quality manufacturing services on the Island. For more information please visit [www.patheon.com](http://www.patheon.com).

## ACKNOWLEDGEMENTS

Data compiled by PRIDCO, the Puerto Rico Planning Board, the World Economic Forum, Patheon Inc., The World Bank Group, the Federal Aviation Administration, the U.S. Department of Transportation and the American Society for Engineering Education has been cited in this paper.

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## APPENDIX I

### About Patheon

Patheon Inc. is a leading provider of drug development and manufacturing services to the pharmaceutical and biotechnology industries. From early phase development through to high volume commercial manufacturing, Patheon offers a full range of conventional and specialized dosage form services. Patheon currently manufactures more than 700 commercial products and has over 190 new drug products in development on behalf of more than 250 clients globally.

Patheon operates two pharmaceutical manufacturing facilities on the island of Puerto Rico within the municipalities of Caguas and Manatí:

Patheon's Caguas Operations is focused on the manufacture of oral solid and oral liquid drug products. The manufacturing facility comprises 250,000 ft<sup>2</sup> (23,200 m<sup>2</sup>) and contains 7 packaging lines as well as 50 suites that can be configured to accommodate a variety of equipment and technology trains. The Caguas Operations hold U.S. DEA registrations for the manufacture (schedule III, IV and V) and analytical testing (schedule II, III, III-N to V) of controlled drugs for the U.S. market. The site also possesses regulatory approval from the U.S. FDA, the MHRA (UK), and the MPA (Sweden, European Union).

Patheon's Manatí Operations is focused on the high-volume manufacture of tablets, capsules and powders. The site is well equipped to handle controlled release products, particularly those employing pelletization, matrix and coating technologies. The 410,000 ft<sup>2</sup> (38,100 m<sup>2</sup>) facility is situated on 104 acres, and includes three independent manufacturing areas with separate HVAC systems, 57 manufacturing rooms and 13 packaging bays. The site's environmental controls and ventilation systems facilitate explosion-proof manufacturing and solvent coating, and low-humidity provisions make possible the manufacture of moisture-sensitive tablet formats. The facility is registered with the U.S. DEA for the manufacture (schedule III-N and IV) and analytical testing (schedule II, III, III-N to V) of controlled drugs. The site has regulatory accreditation from the U.S. FDA, the MHRA (UK), the MPA (Sweden, European Union) and Swissmedic (Switzerland).

## APPENDIX II

### About PRIDCO

The Puerto Rico Industrial Development Company (PRIDCO) is a government-owned corporation dedicated to promoting Puerto Rico as an investment destination for companies and industries worldwide. Since its establishment in the 1950's, PRIDCO has led the efforts in the industrialization of the Island. PRIDCO continues to be a catalyst for Puerto Rico's economic development, leading the transformation from a traditional industrial economy to an economy based on knowledge. PRIDCO emphasizes on promoting high technology industries among sectors such as the life sciences, technology, computing and services that leverage on Puerto Rico's unique combination of tax incentives, skilled workforce, strong infrastructure and excellent business climate.



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