

Reaping the benefits of contract manufacturing in Puerto Rico

A white paper

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Executive Summary

In a “flattening” world, manufacturers have more choices than they ever did before when deciding how they will bring their goods to market. They can build their own plants or outsource production to other parties. Production itself can happen in any number of different locations around the world.

While options may continue to expand and change, the one constant companies do face is the imperative to make sound business decisions. When choosing production locations, decision makers must weigh a variety of factors. These include: availability of qualified labor; proximity to the market served; any trade barriers between the production facility and the market; political and economic stability of the production region; protection of a company’s intellectual property; and flexibility in setting up production arrangements.

Advantages of Pharmaceutical Manufacturing in Puerto Rico

For nearly half a century, American and European pharmaceutical companies have descended on Puerto Rico to establish production, research and development facilities to further their global business goals.

In addition to the advantages all manufacturers enjoy in Puerto Rico, life sciences businesses find support for both facility development and ongoing commercial activities. The supply chain available has matured over 40 years of development, while the island’s strong regulatory environment ensures that every facility on the island complies with FDA regulations.

Puerto Rico: an overview

In early colonial days, Puerto Rico was known as *La Llave de las Americas* ("The Key of the Americas").

Today’s Puerto Rico has built on those promising beginnings and myriad Fortune 500 firms make their operations on the island a key part of their business success. Fiscal 2005 saw Puerto Rico ship \$56.5 billion worth of goods, receive \$39 billion in inbound shipments and record GDP of \$82 billion, 43 percent of which came from the manufacturing sector that hums along in 2,300 industrial plants.

The economic health of the eighth-largest trading partner of the United States enhances the lives of its 3.9 million citizens. For instance, they enjoy an average 78.29-year life expectancy, comparable to that of the European Union. Over 60 percent of the population over 25 has a high school degree and more than 18 percent of the same group has a college degree.

Post-Secondary Education

To adapt to its place in the world economy, Puerto Rico has made itself into a major centre of learning. More than 90 public and private university and college campuses award over 22,000 degrees each year, and more than 18 percent of the island’s population over 25 holds a college degree.

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Science education at Puerto Rico's schools compares favorably to other American universities. For example, the University of Puerto Rico at Mayagüez and the Polytechnic University of Puerto Rico rank 13th and 16th respectively in the United States in engineering undergraduate enrollment. Each year, science, engineering and technology graduates account for more than 9,200 of Puerto Rico's university degrees.

Undergraduate

Examples of undergraduate degrees offered by Puerto Rico's universities that are relevant to the life sciences industry include:

- Chemical, Industrial, Electrical, Mechanical, Environmental, and Computer Engineering
- Industrial Biotechnology (high school students can attend a biotechnology summer camp)
- Biology
- Chemistry
- Microbiology
- Biotechnology (emphasis on Molecular Biology)
- Industrial Chemistry
- Medical Technology

Postgraduate

For postgraduate studies, the University of Puerto Rico system currently offers 29 doctoral degrees, 17 of them in science, technology and engineering. These include:

Master of science degrees	Doctoral degrees
Biochemistry	Applied Chemistry
Chemical Engineering	Biochemistry
Clinical Research	Biology
Computer Engineering	Biomedical Sciences
Computer Science	Biotechnology (currently in development)
Electrical Engineering	Chemical Engineering
Industrial Engineering	Chemistry
Manufacturing Competitiveness	Computer Science.
Manufacturing Engineering	Computing and Information Science Engineering
Mechanical Engineering	Industrial Chemistry
Microbiology	Marine Sciences
Pharmacology	Microbiology
Public Health	Pharmacology
	Physical Chemistry
	Physiology

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Research funding

Puerto Rican universities and research centers receive federal research funding from agencies like:

- 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, the Puerto Rico Cancer Center and the Bioprocess Training and Development Complex.

The biopharmaceutical business in Puerto Rico

The pharmaceutical industry is in a state of flux around the world. Manufacturers are shifting from the pharmaceutical manufacturing to biopharmaceuticals, and as they do, they are adapting their facilities worldwide to face these changes. Since Puerto Rico is a major producer, the industry on the island is in the vanguard of efforts to adapt.

Advantages of Conducting Business in Puerto Rico

Whenever businesses contract manufacturing to overseas facilities, they take a number of risks. Will the contract manufacturer's country maintain the political and economic stability businesses need to reap the rewards of globalization? Do laws in that country protect intellectual property? Could fuel prices spike to the point that transportation costs outweigh the value of other advantages the outsourcer offers?

Commonwealth – close ties to the United States

None of these risks concern companies that outsource production to Puerto Rico, since it is a *commonwealth* of the United States. While the island does govern its own internal affairs and administration, it does so subject to relevant portions of the United States Constitution and laws.

For instance, U.S. law, specifically the Bayh-Dole Act, protects intellectual property. Business is transacted using the American banking system and currency. Businesses are sheltered by the U.S. constitution and legal system, and can settle disputes via the American federal court system. Postage in Puerto Rico moves via the United States Postal System.

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Party to international trade agreements

Trade barriers are of little concern to Puerto-Rico based producers. The island resides within U.S. Customs, which means one barrier less for products made there to cross on their way to American markets. The North American Free Trade Agreement (NAFTA) ensures trade-barrier-free access to the United States, Canada and Mexico, while the Dominican Republic–Central America Free Trade Agreement (DR-CAFTA) extends similar benefits between the United States and the Central American countries of Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and the Dominican Republic.

Distance is hardly a barrier either. Mainland access to the continental United States, Canada and Latin America is very convenient, given Puerto Rico's location in the north Caribbean Sea.

In short, Puerto Rico enjoys all of the advantages of any other American state – at a fraction of the tax rate.

Tax advantages

Just as Section 936 is thought to have spurred commerce on Puerto Rico, many people expected its demise to sound the death knell for business on the island. In fact, the opposite is true: commerce continues to thrive on the island thanks to myriad reasons including its developed business community, infrastructure and friendly tax environment.

Consider the latter point. Even though the island offers the advantages of manufacturing in the United States, U.S. federal tax does not apply to companies that produce there. Instead, Puerto Rico imposes a corporate tax rate that can reach a maximum of seven percent for companies engaged in manufacturing, R&D and exportation of services.

There are many ways of reducing taxes on income generated in Puerto Rico. For instance, R&D and training expenses are deductible at a rate of 200 percent. Any R&D investments yield ownership of the intangibles to the parent company.

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 Corporation (PRIDCO). They can also investigate infrastructure grants, training grants and competitive financing options with PRIDCO's help. And should they start projects of strategic importance on the island, special fund incentives are available.

Any prospective producer needs facilities on the island. To help offset the cost of qualified capital investments, companies who build can accelerate depreciation with an unlimited loss carry-forward. The island will exempt the investor from 100 percent of property taxes during construction and for the first year after the facility is complete. Afterwards, the investor enjoys a 90 percent property tax exemption.

Firms that choose to not build their own facilities in Puerto Rico can qualify for competitive rental rates at PRIDCO buildings. If these buildings do not precisely meet a renter's needs, any permanent leasehold improvements the renter makes are fully reimbursed.

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Own or rent, the investor enjoys a 100 percent tax exemption on machinery, equipment and raw materials used in the manufacturing process, as well as a 25 percent tax credit for purchase of locally manufactured goods.

Puerto Rico fosters investment in its people as well as the buildings where they work. That's why 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. Some PRIDCO incentives also apply, even to training conducted overseas.

European companies specifically can repatriate earnings from Puerto Rico operations with no further taxation using existing treaty networks. Certain companies even allocate more profit to lower-taxed Puerto Rico operations to reduce their worldwide effective tax rate. And the increase in earnings this arrangement permits can then fund other corporate initiatives.

Specialized financing programs

Certain organizations help investors raise the funds they need to do business long-term on Puerto Rico.¹

For instance, the Puerto Rico Investment for Development Initiative (PRIDI) enables companies operating under a tax-exemption decree to issue tax-exempt debt. To help bona-fide Puerto Rico residents finance investors, income paid on PRIDI bonds is exempt from federal and Puerto Rico income taxes as well.

For tax-exempt debt used to finance facility construction, investors can look to the Puerto Rico Industrial Investment Corporation (PRIICO) for assistance. This non-profit subsidiary of PRIDCO can help companies raise funds via either private or public debt.

Finally, if the proceeds of a debt issue are slated for capital investments in qualified private projects, the investor can borrow low-cost funds at tax-exempt fixed rates for up to 30 years thanks to the Puerto Rico Industrial, Tourist, Educations, Medical and Environmental Control Facilities Financing Authority (AFICA is the Spanish acronym).

Highly developed infrastructure

While Puerto Rico may elicit exotic images of tropical bliss, it is also a commercial bastion of the Caribbean.

Puerto Rico's international and regional airports handle more than 4,300 cargo flights every month. As well, 40 different shipping lines that service 80 domestic and foreign ports make the Port of San Juan the seventh-busiest container port in the western hemisphere in terms of the handling of trailer-equivalent units (TEUs). And thanks to a modern system of highways, no point on the island is more than two hours from either an airport or a seaport.

¹ Each organization makes specific requirements of prospective investors. To learn more, visit that organization's web site.

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The island is wired for the digital age too. More than 90 satellites connect Puerto Rico to the rest of the world. Once signals reach the island, they travel via an entirely digital switching telecommunications network. For greater communications bandwidth, many businesses take advantage of plentiful fiber optic cable that covers the whole island.

Advantages of Pharmaceutical Manufacturing in Puerto Rico

Puerto Rican life sciences product manufacturers boast more than 40 years of experience. These forty years have led to one of the most mature manufacturing sectors around the world.

Development activities

Firms that seek to build their own facilities on the island need look no farther than its shores for the professionals who can bring their plans to fruition. From *architectural design and engineering* all the way to *commissioning and validation*, every building need can be met by Puerto Rico's robust industrial construction industry, which also includes experts in:

- Construction and construction management.
- Project management.
- Procurement.
- Quality and regulatory compliance
- Equipment and equipment installation
- Automation and process control

These experts have been extraordinarily busy thanks to continued expansion of Puerto Rico's life sciences manufacturing capacity. Businesses have invested more than four billion dollars to build bulk and fill/finish biotech facilities on the island in the past five years.

Commercial activities

Today, more than 28,000 people on the island work in the biopharmaceutical industry, which shipped more than \$36 billion worth of pharmaceutical products in calendar year 2005. An additional 10,600 work for medical device manufacturers who, during 2005, exported more than \$3.9 billion worth of products. The island's life sciences workforce of close to 39,000 makes up eight percent of the US total in the sector.

A portion of the former group contributes to Puerto Rico's 25 percent share of the world's biologics manufacturing capacity, more than anywhere else on earth. In fact, six of the top ten biologics sold in the United States are manufactured in Puerto Rico, as well as 16 of the top 20 prescription drugs and 50 percent of all pacemakers and defibrillators. Both the pharmaceutical and the medical device manufacturing groups benefit from Puerto Rico's educated, experienced life sciences workforce and a robust supply chain network. This network includes packaging, raw materials, and financial and legal service providers.

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Puerto Rico is one of only four U.S. jurisdictions considered specialized in three bioscience sub sectors: Drugs and Pharmaceuticals, Medical Devices and Equipment, and Research.

Advanced supply chain

A successful track record 40 years long in life sciences manufacturing attracts other businesses to support the industry. These firms form strong links in the tight Puerto Rico life sciences industry supply chain.

Once the facility is commissioned, Puerto Rico offers abundant resources to keep it in operation. These include:

- Raw materials and components.
- Packaging.
- Plastics extrusion and molding
- Warehousing and distribution.
- Transportation and shipping.
- IT and Business Integration Solutions.
- HR Recruitment.
- Legal and financial services.
- Waste management.

Strong regulatory environment

Like other regions that host a high concentration of life sciences businesses, Puerto Rico has built up a sophisticated and rigorous FDA inspection infrastructure.

The many inspectors on the island frequently inspect its large number of facilities, so like their colleagues in New Jersey and California, they develop incisive techniques more quickly than would inspectors who cover regions with fewer facilities. Since they can commute to the sites they check, inspections usually last longer and afford greater opportunity for observation. Puerto Rico's individual inspectors tend not to examine the same facility twice in a row.

And since the FDA has full statutory rights in the American commonwealth of Puerto Rico, rights that are limited outside the United States, they can take stringent regulatory action if the need arises.

As a result, Puerto Rico's strong regulatory environment help keep its facilities among the best to be found anywhere in the world.

The Contract Manufacturing Case

Globalization has created options for companies that produce goods. Some create those goods themselves. Others outsource manufacturing to another party.

Companies that build business cases for outsourcing generally aim for benefits like lowering costs per unit manufactured, quickly accessing manufacturing facilities, reducing time to market and, ultimately, increasing profitability.

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However, these aims might not always be met. In addition, outsourcing could produce problems like inadequate quality control and loss of intellectual property, among others. Increasingly, manufacturers leery of such issues seek to take back control of manufacturing while continuing to benefit from the advantages contract manufacturing offers. That's why they seek a specific type of contract manufacturing arrangement, one that affords greater control over a third party's manufacturing facilities.

In such scenarios, the company hires one or more of the host's employees to manage production and perform other functions. The company and host spell out remaining terms in an agreement.

Companies who pursue such agreements benefit in several ways. They avoid the cost of building and maintaining a production facility. They gain the expertise of an experienced manufacturer. That manufacturer's overhead is distributed to all of its clients. These and a host of other factors promise to reduce the overhead cost allocated to each product as well as the responsibilities that cost represents, such as hiring, facility maintenance and so forth, while ensuring greater value for the business.

When a business case supports contract manufacturing, companies can seek incentives from regions eager to host them. Places such as Puerto Rico proffer a situation – favorable tax system, qualified workforce, extensive infrastructure and an ongoing track record of contract manufacturing success – that helps to ensure companies create the additional value that their shareholders want.

Conclusion

Never before have companies faced so many variables when planning how they will produce goods for the international markets they serve. Perhaps the biggest decision manufacturers face is where to locate their all-important production facilities. Inputs may change, markets may shift, but manufacturing plants and other buildings must thrive for years before a company can claim a return on investment.

Little wonder, then, that so many of the major players in the worldwide pharmaceutical industry invest heavily in Puerto Rico. With all of the advantages of an American presence at a fraction of the taxes, Puerto Rico continues to play a central role in the business plans of a variety of life sciences companies.

For more information, contact your Puerto Rico Industrial Development Corporation representative.