

# HEALTHCARE & LIFE SCIENCES REVIEW

 PHARMA  
BOARDROOM

ATTRACTING  
INDUSTRIAL  
INVESTMENT  
PAGE 12

R&D IN PUERTO RICO:  
A GROWING  
PALM TREE  
PAGE 26

BACK  
TO SCHOOL  
PAGE 36

HEALTHCARE  
SPOTLIGHT  
PAGE 40



COVER STORY *page 22*

*MADE IN Puerto Rico*

# PUERTO RICO

JANUARY 2016



## *Acknowledgements*

---

PharmaBoardroom would like to thank:

Jaime García, Carlos Rivera and Francisco García, Puerto Rico  
Manufacturers Association

Bob Maroney, Ivan Roman and Rafael Castro, Pharmaceutical  
Industry Association of Puerto Rico

Antonio Medina, Pedro Cuellar, Ricardo Soto and Jan Modesti,  
Puerto Rico Industrial Development Company

We greatly appreciate your continued support and enthusiasm  
throughout the project, and hope you enjoy reading this report  
as much as we did creating it!



Improving  
Healthcare While  
Cutting Costs  
*Interview*  
16



Made in Puerto  
Rico  
*Cover Story*  
22



The Road to  
More Efficient  
Innovation  
*Interview*  
20

The Healthcare & Life Sciences Review was produced  
by PharmaBoardroom.

**Project Director:** Cameron Rochette  
**Project Coordinator:** Carla Verdera  
**Contributors:** Alison Mowat, Lisa Diericks, Ariana H.Rodrigues  
**Report Publishers:** Diana Viola, Julie Avena  
**Graphic design:** Carmen Reyes

For exclusive interviews and more info, please log onto  
[www.pharmaboardroom.com](http://www.pharmaboardroom.com) or write to [contact@focusreports.net](mailto:contact@focusreports.net).

Copyright: All rights reserved. No part of this publication may be reproduced in any form  
or by any means, whether electronic, mechanical or otherwise including photocopying,  
recording or any information storage or retrieval system without prior written consent of  
Focus Reports. While every attempt is made to ensure the accuracy of the information con-  
tained in this report, neither Focus Reports nor the authors accept any liabilities for errors  
and omissions. Opinions expressed in this report are not necessarily those of the authors.

# CONTENTS

—January 2016

2	<b>ACKNOWLEDGEMENTS</b>
4	<b>FOREWORDS</b>
7	<b>PREFACE</b>
8	<b>SNAPSHOT IN FIGURES</b> Puerto Rico
12	<b>ATTRACTING INDUSTRIAL INVESTMENT INTERVIEW</b> Antonio Medina Comas, PRIDCO
16	<b>HEALTH INSURANCE POLICY INTERVIEW</b> Ricardo A. Rivera Cardona, PRHIA
18	<b>PUERTO RICO AS A R&amp;D HUB INTERVIEW</b> Iván Lugo, INDUNIV
20	<b>DEVELOPMENT WITH PRODUCTION INTERVIEW</b> Ricardo Zayas, BMS
22	<b>MADE IN PUERTO RICO COVER STORY</b>
24	Janssen: Manufacturing Goliath
25	Uncle Sam: Here Today, Gone Tomorrow
26	R&D in Puerto Rico: A Growing Palm Tree
29	Evolving the Manufacturing Model: Less is More
31	Industrial Spotlight: Medical Technology
33	Pharma-Bio Serv: A Model to Follow
33	A Generation of FDA Experience
35	No Choice but to Be the Best
36	Back to School
37	Support for Life Science is brought to you by..
38	Circumnavigation of the Caribbean Nucleus
39	To the Caribbean and Beyond
40	Healthcare Spotlight
43	New Beginnings
45	Bi-Cultural Skill Sets
46	Beyond Regular Tourism
47	Made in Puerto Rico
48	<b>INTERNATIONAL MANUFACTURING POTENTIAL INTERVIEW</b> Juan Sénquiz, JC Automation
52	<b>PUERTO RICO'S MANUFACTURING TALENT INTERVIEW</b> Ana Myriam Irizarry, LifeScan Puerto Rico
56	<b>ENVIRONMENTAL CHALLENGES INTERVIEW</b> Pedro Tejada, Right Way Environmental Contractors Inc.



Distinguished readers,

As executive director of the Puerto Rico Industrial Development Company (PRIDCO), I am pleased to introduce this special report dedicated to one of Puerto Rico's strongest assets. For decades, the Commonwealth of Puerto Rico has evolved and thrived as a powerful investment destination for businesses of all sectors, from life sciences to aerospace. Today, as we execute our economic development agenda with outstanding achievements, we reaffirm our commitment to offering the best business environment.

Puerto Rico is home to an exceptional workforce that has evolved over decades of industrial development, accounting for one of the highest STEM profiles in the hemisphere. The quality and excellence of our human capital capabilities combines with our exceptional economic incentives allow companies to operate more competitively in Puerto Rico than in other places. As a jurisdiction of the United States, Puerto Rico also represents the most competitive gateway to doing business in the US market.

The Commonwealth continues to focus on a comprehensive industrial development strategy to protect and expand both traditional and established manufacturing segments that have found fertile ground to grow in our economy. These include aerospace, biopharmaceuticals, medical devices, agricultural biotechnology, information technology, electronic, BPO, apparel and even an outstanding rum industry. Companies currently investing in Puerto Rico such as Lufthansa Technik, Honeywell Aerospace, Lilly, and Coopervision are some of our recent business partners that can attest to their positive experience.

As you read through these pages, you will learn about the benefits that Puerto Rico offers for those joining our business community. Puerto Rico is ready to do business with you. Make the Smart Move!

Antonio Medina-Comas  
Executive Director, PRIDCO





Dear members of the healthcare and pharmaceutical communities,

On behalf of the Department of Health of Puerto Rico, I am pleased to introduce this special *Healthcare and Life Sciences Review* of Puerto Rico.

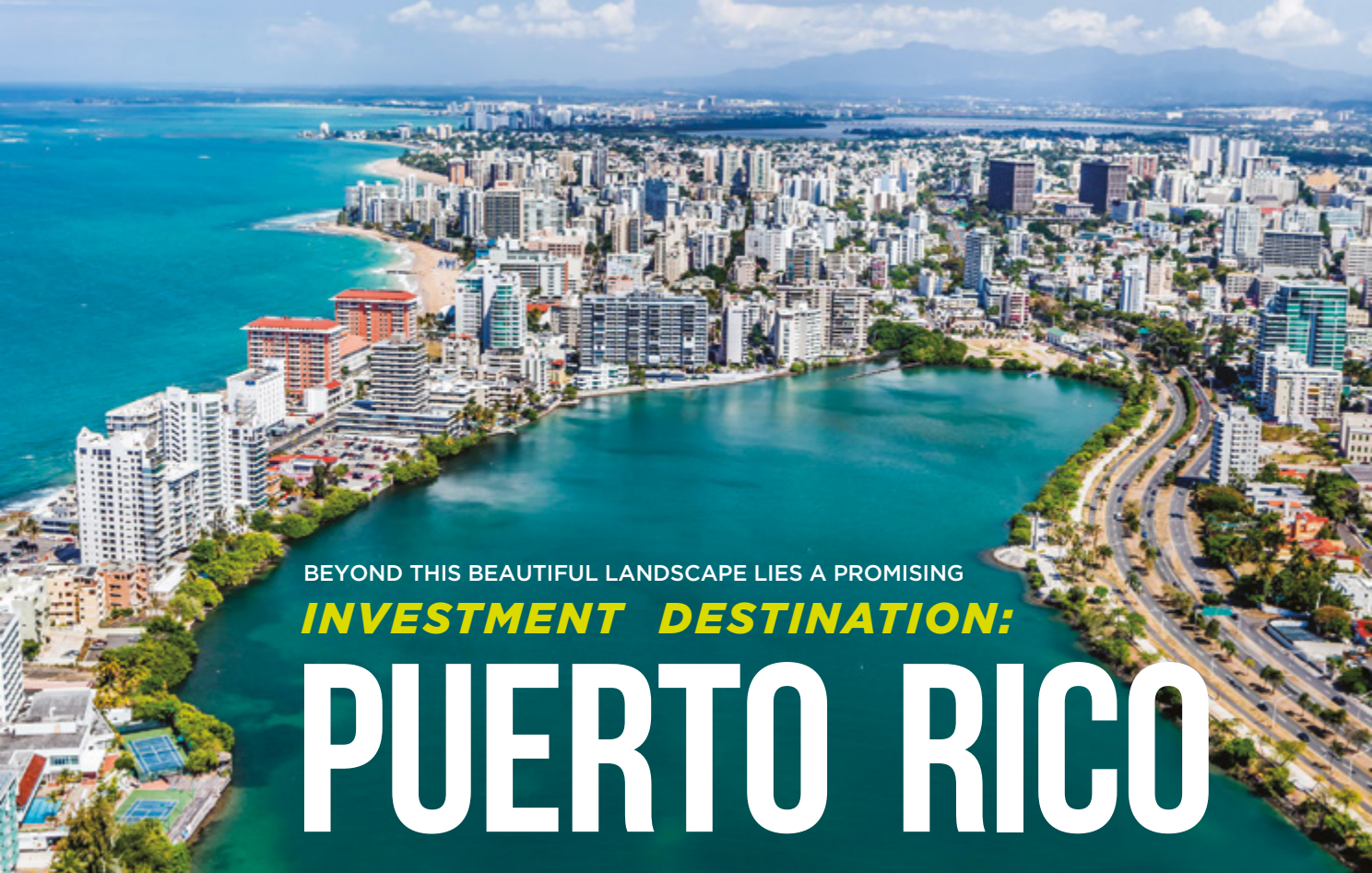
The quality of Puerto Rican healthcare is second-to-none in the Caribbean. Widespread coverage of Puerto Rican citizens that rivals most US states, as well as solid access to the most innovative medicines being developed are but a few examples of this country's progress towards a healthier future. Our commitment to providing services and medicines to Puerto Ricans most in need aptly reflects the country's development towards becoming a strong player in the region.

Puerto Rico is not only becoming an increasingly attractive country again for investment in the pharmaceutical industry, but also boasts an excellent healthcare system. As Secretary of Health of Puerto Rico I invite you and the healthcare community at large to have a look at the exciting developments our country is making through this in-depth report.

Best regards,

Ana Rius  
Secretary of Health of Puerto Rico





BEYOND THIS BEAUTIFUL LANDSCAPE LIES A PROMISING

**INVESTMENT DESTINATION:**

# PUERTO RICO

The world's leading companies are investing in Puerto Rico. From life sciences manufacturing to aerospace services and technology, they recognize the advantages of doing business here. They have made the smart move.

**ADVANCED  
INFRASTRUCTURE**

**COMPETITIVE  
ECONOMIC INCENTIVES**

**U.S. LEGAL  
FRAMEWORK**

**SOLID GOVERNMENT  
SUPPORT**

**TOP QUALITY  
HUMAN CAPITAL**

Puerto Rico is an industrial economic powerhouse that continues to move forward with a well-defined vision and economic development strategy, attracting new companies and investments. Businesses from a wide range of industries, including AbbVie, Lilly, Coopervision, Lufthansa Technik and Honeywell Aerospace are among the recent companies investing in the island. Overall, more than \$750 million have been committed in new investment during the past 32 months, validating that Puerto Rico is a Smart Move.

**PUERTO RICO  
IS A SMART  
MOVE FOR  
BUSINESS.**

**LETS  
TALK  
ABOUT  
THIS.**



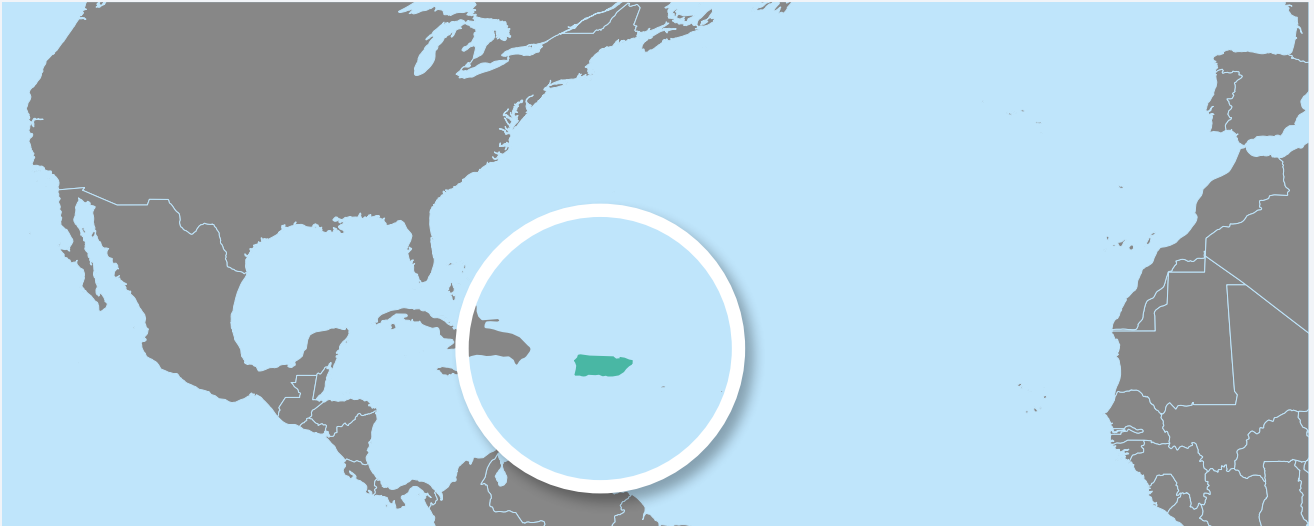
pridco



@fomentopridco

[www.pridco.com](http://www.pridco.com)





## Preface

Puerto Rico is a small island with a big global pharma impact. It is the fifth largest territory in the world for pharma manufacturing, and in recent years has significantly ramped up its capabilities for research and development, and medical and diagnostic devices as well.

In recent years, however, it has faced significant challenges. Its pharma sector is still reeling from the phasing out of Section 936 which exempted corporations from paying federal tax on income earned in the territory. Its economy has stagnated, and it has suffered a crippling debt crisis which has become the pivot for political conflict with Washington.

But this report paints a picture of a territory making a vigorous effort to work its way out of a tough period, and its pharmaceuticals and medical devices and diagnostic sectors are at the centre of that.

That means, first, expanding that sector. Nearly two thirds of Puerto Rico's manufacturing output is pharmaceuticals, and life sciences still makes up 25% of GDP. This report illustrates how Puerto Rico is doing its best to make the most of its advantages: its reputation for high quality, technologically advanced work, the fact that it is regulated by the FDA, and its status as a place where companies can work under US nationality and intellectual property protection but still enjoy lower taxes [and long-term deferral].

Supporting Puerto Rico's recovery has also meant trying to retain at least some of the economic incentives which make the island attractive, such as the incentives, tax exemptions and tax credits provided by the Development of Puerto Rico Act of 2008.

But the territory is also starting to move towards greater R&D activity. World class research centers in cardiovascular, oncology, and soon molecular science are putting the territory on the global map for pharmaceutical research as well as manufacturing. The report details the opening of world class Cardiovascular and Cancer Centers, and a new Molecular Sciences Building as part of the University of Puerto Rico. And the territory is moving forwards in terms of clinical trials too; the research center Fundación de Investigación houses the only Phase I clinical trial unit in the Caribbean, used by Sovaldi.

The territory's medical device and diagnostics market is also growing - faster than its pharma industry. Buoyed by favorable costs compared to the US, our report explains how companies such as Stryker and Roche came to site their operations there.

We also devote our attention to the significant advantage the territory enjoys given its FDA-regulated status: its workforce have had no choice but to maintain the skill and discipline to meet these standards, which has a spillover effect when new companies seek to invest.

Finally, the report also looks at homegrown companies. The country is teaching students entrepreneurship at high school and university level and creating an ecosystem in which new companies can, it is hoped, power the Puerto Rican economy in the future.

In terms of pharma, Puerto Rico is a veteran. Pharma has made up a quarter of its GDP for generations. What is becoming clear more recently is that the sector is that, even without Section 936, the territory is working out its own way to strive and thrive. ✨



## PUERTO RICO BY THE NUMBERS



**50 DECADES** of life sciences manufacturing experience



**50% OF THE WORLD'S LEADING PHARMACEUTICAL COMPANIES** operate in Puerto Rico



**20-35 % AVERAGE LOWER WAGES THAN THE US**, with a highly-qualified, bilingual workforce



**13 OF THE TOP 20 TOP-SELLING PATENTED DRUGS** are manufactured in Puerto Rico



**12 OF THE TOP 20 PHARMACEUTICAL COMPANIES** manufacture in Puerto Rico



**80 FDA-APPROVED FACILITIES** operate in Puerto Rico



**13 OF THE TOP 20 MEDICAL DEVICE COMPANIES** manufacture in Puerto Rico



**86 COUNTRIES** of exporting bioscience products

(Source: PRIDCO)

## WORLD ECONOMIC FORUM GLOBAL COMPETITIVENESS REPORT 2014-2015 (PUERTO RICO RANKING)

PUERTO RICO WAS RANKED #32 OUT OF 144 COUNTRIES IN TERMS OF ITS "GLOBAL COMPETITIVE INDEX 2014-2015"

### TALENTS COMPONENT

- #27 "Higher education and Training"
- #6 "Availability of Scientist and Engineers"
- #10 "Production Process Sophistication"

### INFRASTRUCTURE COMPONENT

- #29 Highways
- #22 Seaports
- #25 Air Transport

### INNOVATION COMPONENT

- #20 Capacity for innovation
- #35 Quality of scientific research institutions

### TECHNOLOGICAL READINESS

- #20 Availability of latest technologies
- #18 Firm-level technology absorption
- #16 FDI and technology transfer

## EMPLOYMENT IN PUERTO RICO'S PHARMACEUTICAL INDUSTRY

### DIRECT JOBS

18,000

### PAYROLL

USD 1.1 bn +

### AVERAGE SALARY

USD 62,000

### INDIRECT JOBS

68,000

### TOTAL JOBS

86,000

Source: World Economic Forum

Source: PIA

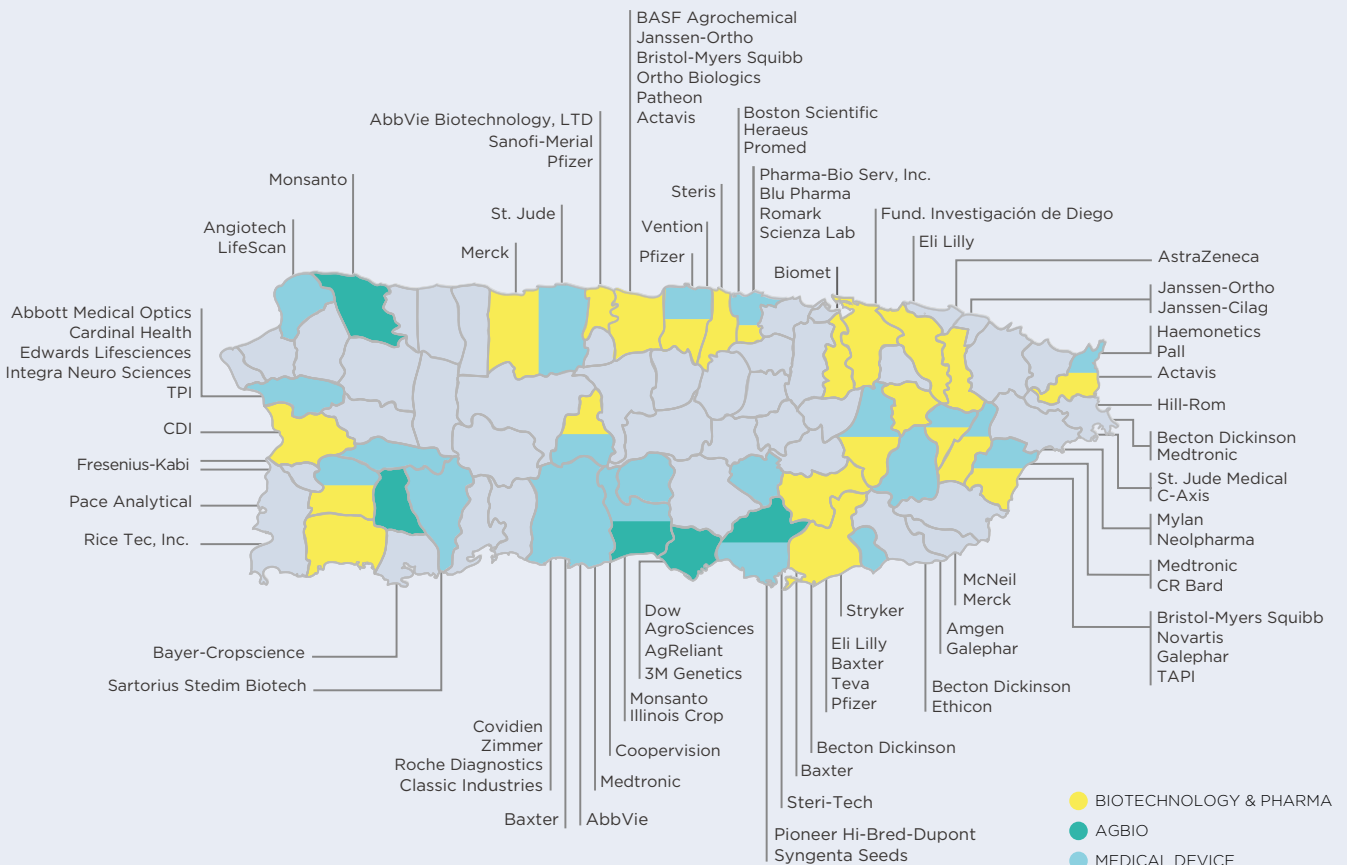




### TOP FACILITIES IN PUERTO RICO

	AMGEN	JANSSEN ORTHO	PFIZER	BMS (MANATÍ)	BMS (HUMACAO)
YEAR OF INCEPTION IN PUERTO RICO	1992	1981	1972	1972	1970
NUMBER OF EMPLOYEES	1,800	1,000	2,700	442	225
TOP 3 PRODUCTS MADE IN PUERTO RICO	Neulasta, Prolia, Enbrel	Prezista, Xarelto, Invokana/Invokamet	Lipitor, Celebrex, Lyrica	Orencia, Opdivo, Yervoy	Eliguis, Sustiva, Glucophage

### MAP OF PUERTO RICO'S LIFE SCIENCE MANUFACTURING FACILITIES



Source: PRIDCO



**CELEBRATING TEN  
YEARS IN PUERTO RICO**

**QUALITY ENGINEERING,  
ARCHITECTURAL  
PLANNING & DESIGN,  
PROGRAM  
MANAGEMENT,  
AND ENVIRONMENTAL  
CONSULTING SERVICES**

**HEADQUARTERS**

ROAD #1 KM 34.4. PLAZA BAIROA  
SUITE 205. CAGUAS, PR 00725.  
PO BOX 1330. CAGUAS, PR 00726-1330

TEL +1 787-720-5869

FAX +1 787-720-2318

EMAIL [info@sharetechgroup.com](mailto:info@sharetechgroup.com)

[www.sharetechgroup.com](http://www.sharetechgroup.com)

**RECENT INVESTMENTS IN PUERTO RICO**

**2015**

**LUFTHANSA TECHNIK (November):**

Developed a maintenance, repair and overhaul facility, an investment valued at USD 60 million, creating 400 jobs by 2017 and generating an estimated economic impact of USD 2.2 billion over the next 30 years

**MERIAL (October):**

Acquired a Merck formulation and packaging facility, retaining 200 employees with chewable technology expertise, driving additional new investment worth USD 6 million over the next year

**AMERICAN INDUSTRIAL ACQUISITION CORP (April):**

Purchased another Merck plant, retaining all 200 employees

**INFOSYS BPO (March):**

Established a 12,000 square-foot center, aimed at delivering complex order-to-cash business processes for its aviation clients, investing USD 9 million and creating another 300 jobs

**ABBVIE (March):**

Invested USD 30 million for the expansion of their local facilities, generating an additional 100 new jobs

**2014**

**ROMARK LABORATORIES(December):**

Announced investment of USD 110 million in building a facility, employing 200 people over the next three years

**HONEYWELL (December):**

Honeywell (December 2014): Developed a USD 35 million R&D laboratory, focused on electromagnetic interference, creating an additional 250 jobs

**LILLY (October):**

Invested USD 40 million on top of a USD 200 million investment in 2013 to strengthen its production of insulin and solid dosage products

**2013**

**COOPERVISION (May):**

Expansion of 15 new production lines, adding 350 new jobs as part of a USD 250 million investment

Source: PRIDCO

**PUERTO RICO EDUCATIONAL FACTSHEET**



More post-secondary institutions per square mile than anywhere in the world



College of Engineering at UPR Mayagüez the number one producer of Hispanic engineers in the US (source: American Society for Engineering Education)



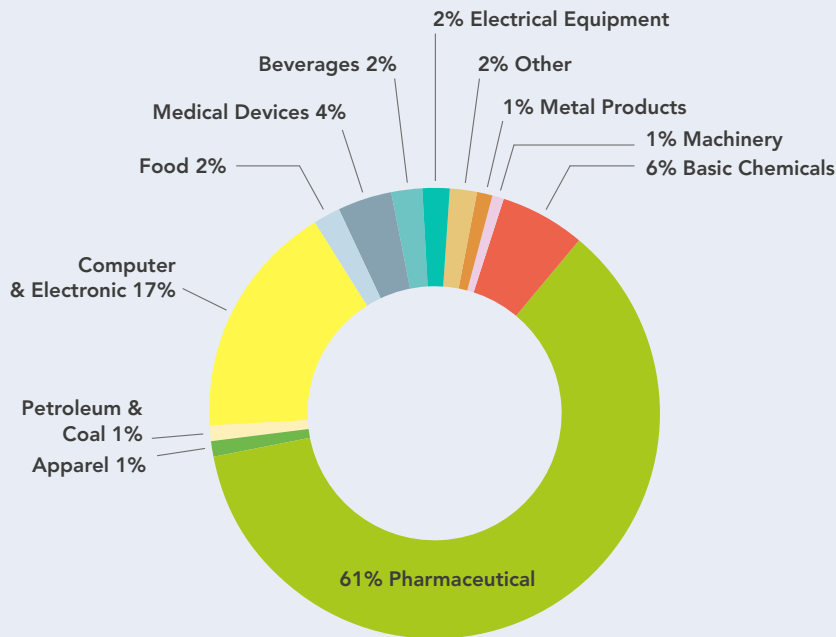
UPR Mayagüez's R&D Center (CRD) receives USD 20 million a year for research projects



The Center for Pharmaceutical Engineering and Learning (CPEDaL) at UPR Mayagüez has projects with Janssen, BMS and Lilly, among others



## MANUFACTURING INDUSTRIES GROSS DOMESTIC PRODUCT SHARES FISCAL YEAR 2012



Source: Puerto Rico Planning Board, 2013.

## CURRENT TAX BENEFITS OF PUERTO RICO

**4 PERCENT** FIXED INCOME TAX RATE

**0-1 PERCENT** INCOME TAX RATE FOR PIONEER ACTIVITIES

**100 PERCENT** EXEMPTION ON DIVIDEND DISTRIBUTIONS

**100 PERCENT** SPECIAL DEDUCTIONS FOR BUILDING, MACHINERY AND EQUIPMENT INVESTMENTS

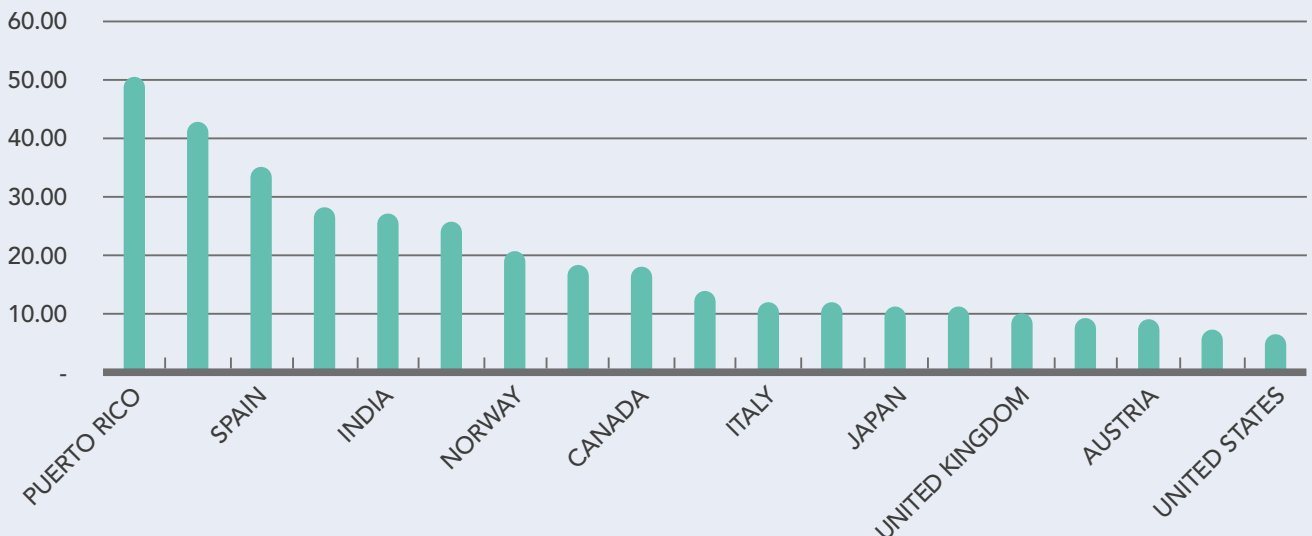
**90 PERCENT** EXEMPTION FROM PROPERTY AND REAL ESTATE TAXES

**60 PERCENT** EXEMPTION FROM MUNICIPAL LICENSE TAXES

**50 PERCENT** ON R&D TAX CREDITS

Source: PRIDCO

## R&D TAX CREDITS UNITS = PERCENTAGE



Source: Puerto Rico, Economic Incentives For the Development of Puerto Rico Act (Act no. 73 of May 28, 2008) Others. National Center for Policy Analysis, Brief Analysis No. 764 February 28, 2012



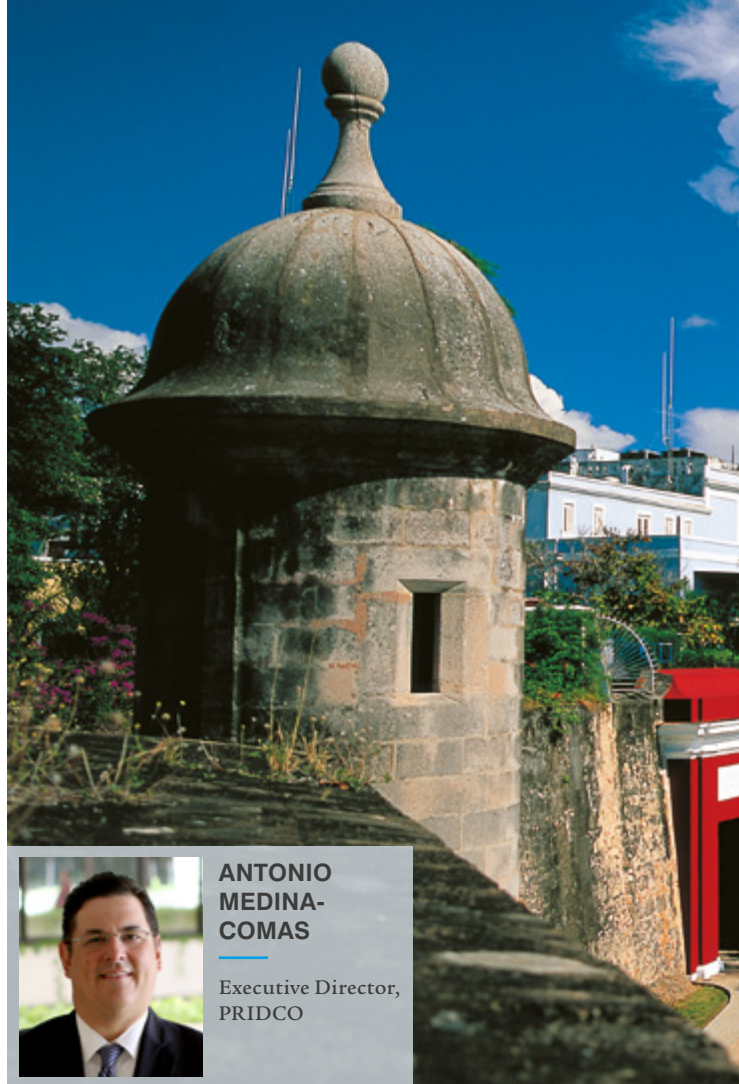
# STIMULATING ECONOMIC RESURGENCE

**Preface:** The Puerto Rico Industrial Development Company (PRIDCO) is a government agency underneath the Puerto Rican Department of Economic Development and Commerce designed to facilitate industrial investments in the country from abroad. Antonio Medina Comas, PRIDCO's executive director, discusses the agency's critical job in stimulating the economy while highlighting recent successes.

**HCLS:** Puerto Rico has been in the news a great deal lately due to its debt crisis; does this attention provide new opportunities for the country?

**ANTONIO MEDINA COMAS:** The life sciences industry is the workhorse of Puerto Rico economy, representing 25 percent of GDP. Some of the largest life sciences companies operate in Puerto Rico in both commercial and manufacturing functions and to some extent R&D as well. We have significant breadth among fields like small and large molecules, medical devices and agricultural biotechnology, which has shown tremendous growth over the last few years. Puerto Rico continues to be a leader worldwide in life science manufacturing. PRIDCO's focus is first and foremost to protect the industrial base and ensure that companies here continue to thrive and achieve expansion either through new products or facilities, and to bring new companies and segments to Puerto Rico.

In that sense, we are very proud that over the last two and a half years, we have had five new pharmaceutical companies come to Puerto Rico:



**ANTONIO  
MEDINA-  
COMAS**

Executive Director,  
PRIDCO

“We are very proud that over the last two and a half years, we have had five new pharmaceutical companies come to Puerto Rico: Neolpharma, Sanofi (Merial), the American Industrial Acquisition Company, Romark and Allergan”

Neolpharma, Sanofi (Merial), the American Industrial Acquisition Company, Romark and Allergan (known before as Actavis). This demonstrates a restart of growth in life sciences. In spite of global consolidation, by having a very targeted strategy to preserve our industrial base and ensure



that facilities come to the market, PRIDCO's life sciences team works hard with companies that might be divesting but ensures that new tenants come into old facilities. The medical device industry has grown as well; CooperVision has invested over \$250 million in expanding their facility for contact lenses. Medtronic, St. Jude, and a number of other medical device companies have increased their production in Puerto Rico.

**HCLS:** Why do you believe all these companies come to Puerto Rico?

**AMC:** These companies come here because we provide tremendous human capital. Puerto Rico has over 60 years of experience in the life sciences business, employing approximately 50,000 individuals in total. Our total employment in the island is about one million, which means five percent are employed in the life sciences.

**HCLS:** Is the talent here so outstanding that it trumps other characteristics of Puerto Rico?

**AMC:** In general terms, people come here because Puerto Rico is a US jurisdiction, has a bilingual workforce, runs an excellent education system particularly in science and technology, and has over 60 years of industrialization and a focus on life sciences. Because of this long history there are many very well-developed assets in Puerto Rico. Sanofi-Merial came to Puerto Rico because they were able to acquire some very strong assets from the former agricultural-veterinary division of Merck. Neolpharma is a growing Mexican company that wants to expand its business into the US. Given that the company is Mexican and its employees speak Spanish, they find the Puerto Rican environment favorable because they can still work in Spanish but all the employees they hire here are already trained in US regulatory processes and requirements. Companies that



“Puerto Rico is a high quality, high technology and high regulatory market where you can work under the US flag and under US intellectual property protection, while simultaneously receiving the benefits of working in a low tax rate jurisdiction and achieving long-term deferral”

come here can hire employees that are knowledgeable not only in the US regulatory system, but facilities here tend to supply the global market. This means that employees have experience with EMEA, ANVISA or PMDA. This provides great value; in Mexico you have to pay a premium for a professional that understands US regulations, but in Puerto Rico everybody has that plus global experience.

**HCLS: How is PRIDCO promoting itself worldwide to attract investments?**

**AMC:** PRIDCO engages in many business trips overseas, from emerging markets like Brazil to mature European countries like Germany or the UK. We must also be present in conventions like BIO, where the most important leaders in the field are present, and we must also have a presence. We also work with the US Commerce Department at the federal level in efforts like SelectUSA to ensure that we can attract jobs to the US, since Puerto Rican jobs are American jobs.

**HCLS: What is your assessment in terms of how that is progressing?**

**AMC:** I think there is a lot of education that has to take place because of changes in Congress since the last major taxation reform, which happened in the 1980s. The Section 936 changes happened in the 1990s; most of the people involved with that at both the staffer and congressional level have changed. It is important to share with members

of Congress the relationship between Puerto Rico and the US, and to ensure they understand the economic base of Puerto Rico and how changes to the federal level could affect corporations operating in Puerto Rico.

**HCLS: What are some of the successes of the last two and a half years?**

**AMC:** We are very proud of the different projects that PRIDCO has accomplished. It starts with a strategy that focuses on traditional segments like rum and textiles. Of course, we still want to protect and grow established segments like life sciences, but emerging segments like aerospace, electronics, information technology or knowledge service outsourcing are also vital.

**HCLS: Ultimately, what do investors truly need to know about Puerto Rico?**

**AMC:** I welcome everybody to explore Puerto Rico as an alternative. We believe Puerto Rico is in the middle of resurgence in terms of different manufacturing segments while growing its industrial base. We have demonstrated that Puerto Rico is a high quality, high technology and high regulatory market where you can work under the US flag and under US intellectual property protection, while simultaneously receiving the benefits of working in a low tax rate jurisdiction and achieving long-term deferral. ❁



## Continuous Regulatory Compliance

### Risk-Based Validation Services

- Validation, Commissioning and Qualification
- Computerized Systems Validation
- Process, Cleaning, Equipment, Utilities, Facilities

### Complete Quality Systems Support

- Gap Analysis
- Compliance Assessments
- Investigations and Resolutions
- CAPA's
- Systems Troubleshooting
- Documentation and Training Support
- Quality Systems Development / Improvement/ Compliance
- Quality Audits / Inspection Readiness

## On-Time Workforce Enhancement

### Flawless Project Execution

- Project Management
- Organizational Improvement
- Strategic Planning and Execution

### Technical Resources As Needed

- Contract to Hire Services
- Placement Services
- Project Based Consulting

### Flexible Testing Laboratory Capacity

- Analytical Testing Services
- Microbiology Testing Services
- Finished goods, water, raw material testing / Environmental
- Method Development / Validation / Transfer

## Calibration Services

- Calibration Program Management
- Laboratory Calibration Services and On-site
- Instrument Tolerance and Calibration Frequency Assessments

## Effective Risk Management

- Product and Process Risk Assessment
- Critical Process Parameters (CPP) Assessment
- Critical Quality Attributes (CQA) Assessment
- Quality Risk Management (QRM) Tools Implementation
- Sustainability Strategy Development
- QRM Integration to Quality Systems

## Advanced Knowledge Management

### Information Technology (IT) Services

- Mobile Application Development
- Key Progress Indicators (KPI) Dashboards
- Systems Integration
- Document Management Solutions
- Highly Graphical Documents

### Technical Training Services

- Good Knowledge Management Practices™ (GKMP™)
- Project Management Preparation Courses
- Technical Training and Seminars



+1 787 278 2709

6 Road 696 Dorado, PR 00646-3306  
info@pharmabioserv.com

Puerto Rico | United States | Spain | Brazil | Ireland

www.pharmabioserv.com



© Pharma-Bio Serv Inc. All rights reserved.



# IMPROVING HEALTHCARE WHILE CUTTING COSTS

**Preface:** Ricardo A. Rivera Cardona served as the Secretary of Economic Development and Commerce Department and Executive Director of the Puerto Rico Trade & Export Company before being appointed in 2013 as the Executive Director for the Puerto Rico Health Insurance Administration (PRHIA/ ASES for its Spanish acronym). He describes how the agency has cut major costs while improving quality of care for the 1.4 million beneficiaries of the Puerto Rico Government Healthcare Plan (GHP).

**HCLS: What was your original objective upon taking up this position?**

**RICARDO A. RIVERA:** When I assumed leadership, ASES had a \$200 million operational deficit. We immediately established a very aggressive plan comprised of various administrative cost containment initiatives, audits to insurers, renegotiations with pharmaceuticals, handling of exceptions, among others. Gradually we have been able to save more than \$300 million in the last two years and have not only closed the gap in deficit but simultaneously accommodated the normal yearly increases that the health industry has, including the addition of the mandatory essential healthcare benefits required by Obamacare. As of right now we are breaking even and we are maintaining various initiatives moving forward for the future.

**HCLS: What are some of the specific measures that ASES has taken in order to achieve that?**

**RAR:** We decided to challenge the general assumption



that the only way to reduce cost is to reduce benefits. We defied normal standard operating procedures and created savings while improving quality.

Firstly, we established an Audit Plan that would allow us to know the reality of the system in order to: 1) develop and implement measures to strengthen and improve the network of providers for the beneficiaries, 2) facilitate communication and interaction of hospitals and other providers, and mainly, 3) increase operational efficiency.

We went straight to the financial core of the GHP by renegotiating all contracts with insurance companies, resulting in more than \$50 million in savings. We also sat down with the pharmaceutical companies and renegotiated rebates for medicines prescribed to the beneficiaries, from \$50 million to \$120. Simultaneously, we established a mathematical formula so that when companies increase their prices, the rebates we receive recalculate themselves so that the net we pay stays fixed for the next two years. We even periodically conduct audits





“ASES is about to launch a program that will measure the quality of services provided at the primary level of the GHP, or the medical groups. This kind of evaluation has never been done before in Puerto Rico and goes above and beyond what the federal government requires”

to make sure the MCO's are paying appropriately and in compliance with their contracts.

On the other hand, to improve quality of services offered by the providers to the beneficiaries we established a program called “ASES Actúa”. This is a community outreach program aimed to improve efficiency in health care provided to the GHP beneficiaries, in which our staff makes unannounced visits to different health-care providers around the island, in order to inspect firsthand the delivery of services.

Additionally, ASES is about to launch a program that will measure the quality of services provided at the primary level of the GHP, or the medical groups. This kind of evaluation has never been done before in Puerto Rico and goes above and beyond what the federal government requires. We believe this is needed in order to weave out medical groups that are not complying with the standards to improve quality of service for our beneficiaries.

Thirdly, I inherited a corporation that was not CMS compliant, putting at risk the federal funding assigned for the GHP. Today, ASES is in compliance with every single regulation required, securing the \$1.5 billion needed to provide the required services. This represents 55% of the \$2.7 billion needed to maintain the GHP. The remaining 45% comes from the government general funds and ASES' own funds.

Securing our finances, as well as reducing fraud and abuse, is a top priority. This is especially important considering the fact that the GHP beneficiaries total 1.6 million people, which represents 48% of Puerto Rico's entire population. We are the jurisdiction among the 50 states and territories with the most lives enrolled in Medicaid, followed by a distant second by the District of Columbia with only 24 percent.

**HCLS:** ASES now contracts many more companies than in the past through GHP to cover the regions of Puerto Rico. What are the benefits of this new system and has it fostered more competition among insurance providers?

**RAR:** When I assumed the direction of ASES in 2013 we found that our agency was under a Corrective Action Plan imposed from our federal regulators, CMS, which put at risk the \$1.5 billion that we receive in federal funds to address the health of uninsured medical indigents in our island. Immediately we addressed this issue by outlining an aggressive plan aimed to correct each of the 80 findings.

An essential component to fulfill this plan was the transition from a Third Party Administration Model (not approved under the federal regulations) to an administrative structure for the Government Health Plan that will meet the parameters established by CMS. After much consideration and analysis, in April 2015 the administration structure selected was the Managed Care Organization model (MCO), which was in compliance with the federal regulations. Under this model the contracted insurance providers assume 100 percent of the risk of all services, including reinsurance. Moreover, this change allows ASES to focus on: 1) strengthening control mechanisms to ensure the quality of services offered to the beneficiaries, 2) developing initiatives for better quality measures of the services provided, and 3) ensuring the best use and distribution of the GHP funds.

The value of having more insurance providers is that you diversify the risk and keep them humble, doing what they should be doing for the benefit of the patient and beneficiary, not themselves. ✨



**IVÁN LUGO**

Executive Director  
of the Industry  
University Research  
Center Inc.  
(INDUNIV)

# PROMOTING THE WHOLE VALUE CHAIN

**Preface:** Puerto Rico is not only an important manufacturing hub, but is also positioning itself as a state-of-the-art center for R&D and clinical research. Iván Lugo, the executive director of the Industry University Research Center Inc. (INDUNIV), which brings together private sector, academia and government, discusses some of the island’s most recent initiatives as well as future plans.

**HCLS:** Could you please briefly introduce the activities of INDUNIV to our readers?

**IVÁN LUGO:** INDUNIV is a non-profit organization managed by a board of directors with representatives from some of the most important public and private institutions of the island that brings together private sector, academia and government to create an ecosystem promoting innovation and knowledge sharing in life sciences in Puerto Rico. To do so, INDUNIV manages three clusters: the Pharmaceutical Industry Cluster, the Puerto Rico Bioscience Alliance and the Puerto Rico Healthcare Council.

Through its Educational Infrastructure Committee and as an active member of the BIO’s Coalition of States BioSciences Institutes, INDUNIV is also deeply involved in supporting local academic institutions to develop domestic technical and scientific workforce to enhance the island’s competitiveness in the life science sector, locally as well as internationally.

**HCLS:** How attractive is Puerto Rico as an investment destination in the life science sector?

**IL:** The BIO Bioscience Report from the Battelle Institute indicates Puerto Rico has an impressive

distinction in life sciences in the US that is shared only with New Jersey, with a high specialization in four of the five major industry subsectors: drugs and pharmaceuticals; medical devices; bioscience-related distribution; and research, testing, and medical labs. According to Boston Consulting Group, the island is positioned very well also worldwide to other life science hubs such as Singapore. Today Puerto Rico is an important hub for the sector and exports an estimated total amount of USD 66 billion to more than 86 countries, with the US capturing nearly 80 percent of it.

**HCLS:** What are some of Puerto Rico’s latest initiatives with regard to life sciences?

**IL:** Puerto Rico’s model for the pharma industry is to attract new potential blockbuster products. To do so, we need to have highly skilled people, the best and latest technology and be able to develop, register and do technology transfer to launch products as fast as possible. INDUNIV has appointed itself the mission not only to promote manufacturing, but the whole value chain. As a result, we have supported the construction of innovation centers bringing together academia and private sector for Phase II development. If we formulate and develop the process the product here, it is also very likely to launch and manufacturing will continue on the Island.



A further example is the development of the state-of-the-art Molecular Science Complex, a 154,000 square feet state-of-the-art translational research facility with an entire floor destined to incubation, animal house and the material characterization and analysis, featuring the most sophisticated instruments. Puerto Rico's Comprehensive Cancer Center, is currently under expansion with an investment of USD 90 million, which will help the island step up to the next level in cancer research. The 15,000sf BDTC (Biotechnology Development & Training Center) incubates four Biotech startups. This newest addition to our life sciences ecosystem, coupled with the best incentives for R&D, makes Puerto Rico one of the most attractive hubs for the life sciences.

**HCLS: On the other hand, what challenges is the island facing today?**

**IL:** Between 2005 and 2010 the island has received more than USD 4 billion in investments in biotech and hosts today the largest biotech manufacturing and development complex in the world, indicating the country's talent and unsurpassed incentives are highly attractive to the international investors' community.

Consolidation affects the footprint of the industry, not only in Puerto Rico but worldwide. When Pfizer acquired Wyeth, for instance, the company decided to divest some of the production plants it had in Puerto Rico. One of the plants was bought by the Mexican

drug manufacturer Neolpharma, which decided to take advantage of local manufacturing, development and regulatory knowhow to commercialize its products in the US and also provide contract manufacturing services. What was initially seen as something negative was actually a big move, which resulted in being a strategic choice for the company.

**HCLS: What has been your most important objective over the past few years?**

**IL:** We have been working hard to maintain Puerto Rico's leadership as a manufacturing hub, but also to be positioned as an attractive location for the product development and clinical research. We identify where opportunities and gaps were, as a result, we started developing more CRO's with capabilities from Phase I through IV and identifying and building a physicians/patients asset mapping to map the capacity we have in clinical research. The objective here is to help attract more clinical trials between Phase I and Phase IV. In addition, we will continue to support the development of world class infrastructure for research and development on the future Science City tax-free zone.

**HCLS: What do you see as Puerto Rico's positioning in the world 20 years from now?**

**IL:** Any economy in the world needs diversification as well as a focus; for the last 60 years the biopharmaceutical industry has been our anchor, and today Puerto Rico's focus continues to be in the life sciences. We continue to develop highly skilled scientific and engineering resources with regulatory knowledge in all areas of life science – pharmaceutical small/large molecules, medical devices, biotech as well as bio-agriculture and medical research – and we are putting together the best elements to foster competitiveness. Today we are a global leader in pharmaceutical manufacturing, but in 20 years from now we will also be a global leader in the development of new products and molecules and next-generation manufacturing launch platform to the world. ✨



# THE ROAD TO MORE EFFICIENT INNOVATION

**Preface:** Bristol-Myers Squibb (BMS) has made major restructuring efforts to its manufacturing processes. Ricardo Zayas, senior vice president of global pharmaceutical manufacturing for BMS, outlines these changes while underscoring the importance of development teams working in tandem with production to become more efficient in launching new innovation.

**HCLS:** What do you see as a major consequence of big pharma's consolidation in the last decade or two?

**RICARDO ZAYAS:** Product volume and technology trends have become an increasingly important part in the future of pharmaceutical manufacturing networks and individual facilities. Consolidation has created a significant amount of excess capacity in small molecule manufacturing around the world, prompting companies to repurpose, close or sell their facilities. With consolidation changing the landscape, a good leader will always stay ahead of the curve, managing not only the next five days, but the next five years.

**HCLS:** That is also reflected in the dwindling R&D pipelines of major multinationals; plant managers need to rationalize what they are producing, especially given the patent expiries of many major products in recent years.

**RZ:** Indeed, each manufacturing facility should have a short and a long term plan. Those companies



**RICARDO ZAYAS**

Senior Vice President, Global Pharmaceutical Manufacturing, BMS

focused on innovative science are moving towards lower volume, higher value products. The challenge is many plants were not designed for this model and will have to redefine their mission, strategy and operating model. Smaller plants that optimize space utilization are better equipped to handle changing demands of the industry. This is especially true in Puerto Rico where energy costs are relatively high. Space requires conditioning, cleaning, and maintenance. At Bristol-Myers Squibb we are looking into continuous manufacturing suites that, among many other benefits, can produce in a fraction of the space that conventional facilities need.

**HCLS:** How does that affect the manufacturing area?

**RZ:** For manufacturing this is a different model. Industry wide, the global pharmaceutical manufacturing footprint generally has been built on the pillars of high volume products, historically. The future in many ways revolves around the concept that smaller and more focused is better. In addition, products would be developed using the same technology platform, ideally, but that perfect world, especially in today's competitive environment, is virtually impossible. Trends in the industry point to smaller footprints, agility and flexibility to quickly install equipment made for products that are produced using different technologies.



**HCLS:** What specific changes need to happen to transition to this new model?

**RZ:** One example that comes to mind is that of a company which restructured a plant that was losing a significant amount of its volume. The location was strategically important for the company, but costs would increase significantly if the company did nothing. The plan took the plant from one million square feet to 300,000 square feet with a corresponding reduction in costs: a conversion cost per thousand tablets from the high double digits to almost single digit levels. The payback was extremely attractive and the engineers did a wonderful job of repurposing the plant. In many cases, it is not a simple adjustment that is required. If the situation warrants it, a major facility or network repurposing might be the answer.

**HCLS:** How is this implicated in the BMS manufacturing structure?

**RZ:** Over the past decade, many companies have moved to greater use of external manufacturers, and BMS has not been the exception. In order to support that diversification, we have built a strong, central external manufacturing organization at BMS that works with many companies around the world. External collaboration in manufacturing has become an important part of our strategic focus and we continue to develop it as a core competency.

**HCLS:** What do you find to be the biggest challenge in making that restructuring happen on a global level?

**RZ:** It is important that you have a process in place and the change is approached in an organized and structured manner. I think that as a Site Leader, it is necessary to gain acceptance from your management on the need to make the changes that are required; in other words, build a business case. This requires a lot of thought, planning and an ability to forecast what the landscape will be in the coming years. Once you build a case and secure buy-in from leadership, communication is key to ensuring clear understanding of what has to be done. In my view, this process, i.e. business case, alignment, planning, and communication, is an effective model.

**HCLS:** Will that trend of development converging with production become more apparent as time goes by?

**RZ:** It makes a lot of sense. First launch in market, followed by a rapid deployment to target markets around the world can help get medications to patients who need them. The primary focus during the development-to-launch process in terms of lead time have typically been the clinical and regulatory processes, but in today's world, any time manufacturing and development teams can work together to reduce development-to-launch cycle time means that timelines can be accelerated. 🌟

# PUERTO RICO



Puerto Rico only covers a small area – if it were independent it would be only the 162<sup>nd</sup> largest country in the world – but when it comes to pharmaceutical manufacturing, it is the fifth largest territory on the planet. Its preeminence in pharmaceuticals has been hard won and but for the last four decades, the industry has generated about a quarter of Puerto Rico's entire income. But new threats have emerged in recent years: a debt crisis and a stagnating economy. In response, the local government has looked to industry – and life sciences in particular – for new sources of economic growth.

---

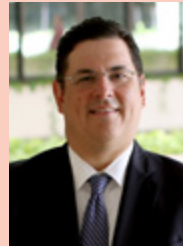


**A**NTONIO MEDINA COMAS, executive director of the Puerto Rico Industrial Development Company (PRIDCO), has been tasked with the monumental responsibility of attracting foreign investment to the “Enchanted Island.”

Medina and his team work to ensure that foreign businesses recognize the benefits Puerto Rico offers. The island, which has consistently been a major attraction for foreign corporations looking to benefit from its tax incentives, is home to the production sites of many industries, including life sciences, aerospace, automotive, electronics and IT. 48 percent of Puerto Rico’s GDP is comprised of manufacturing, making this particular sector the largest source of income in the territory today.

In the “Rum Room” at PRIDCO’s headquarters, Medina eagerly describes how in just the last couple of years, five new pharmaceutical companies have come to the country, including Sanofi, Neolpharma, Romark Laboratories, the American Industrial Acquisition Corporation, and Allergan. “Puerto Rico is a high quality, high technology and high regulatory market where you can work under the US flag and under US intellectual property protection,” he explains, “while simultaneously receiving the benefits of working in a low tax rate jurisdiction and achieving long-term deferral.”

“The life sciences industry is the workhorse of Puerto Rico’s economy, [still] representing 25 percent of GDP,” continues Medina. “Some of the largest life sciences companies operate in Puerto Rico in both commercial and manufacturing functions and R&D as well. We have significant breadth among fields like small and large molecules, medical devices and agricultural biotechnology, which has shown tremendous growth over the last few years.



**ANTONIO  
MEDINA COMAS**

Executive director,  
PRIDCO



**CARLOS RIVERA**

President, PRMA



**JAIME  
GARCÍA**

Former executive  
director, PRMA

Puerto Rico continues to be a leader worldwide in life science manufacturing. PRIDCO’s focus is first and foremost to protect the industrial base and ensure that companies here continue to thrive and achieve expansion either through new products or facilities, and to bring new companies and segments to Puerto Rico.”

Carlos Rivera, president of PRMA and vice president and general manager of Edwards Lifesciences in Puerto Rico, emphasizes that for every direct manufacturing job, three indirect jobs are generated in Puerto Rico, and one job in the US. “This is especially important to communicate to politicians in Washington, which PRMA has been doing consistently,” he remarks. “PRMA have been knocking on every Congressman and Congresswoman’s door, reminding and educating this new generation of politicians. This island became a manufacturing powerhouse between the 1960s and 1990s. Now we have a new generation in Congress that might not remember the importance of Puerto Rico, and this association wants to ensure that our politicians know how important we are for the US economy. If our manufacturing suffers, that has broad implications for the US. While Puerto Rico’s economy only amounts to USD 105 billion, it is bigger than many countries in Latin America and thus has important influence around the world.”



## Janssen: Manufacturing Goliath

John O'Hara, general manager of Janssen Ortho Puerto Rico and head of the Johnson and Johnson (J&J) campus in Puerto Rico, discusses the latest advances of the affiliate as a leading manufacturer on the island.



**JOHN O'HARA**  
—  
General manager,  
Janssen Ortho  
Puerto Rico

### What are the origins of Janssen's manufacturing operations in Puerto Rico?

Janssen Ortho started in Gurabo in 1981 as a small molecule facility, or in other words, a facility that made APIs to be used in oral solid dosage tablets in Johnson and Johnson (J&J). Today, we are one of two launching sites for oral solid dosage for Janssen Supply Chain, which is our pharma division of J&J.

In the last few years, J&J's portfolio has delivered key products like Prezista for HIV, Xarelto for deep vein thrombosis, the Cana family (Invokana and Invokamet), an SGLT2 inhibitor used for type-2 diabetes. Most recently in the Prezista family, Janssen launched Prezcobix; as most HIV patients take a cocktail

of drugs; this really works towards reducing the tablet load for a patient.

### How do you convince top management to invest in Puerto Rico compared to other sites?

The world is flat; we do not have the laws in Puerto Rico that give us particular exemptions. Having said that, there are things we can do to help our position when I'm having those discussions. 18 months ago we implemented a foreign trade zone here. Ideas like that will provide us a better position when we are at that table. As an example, we have increased our workforce from 700 three years ago to almost 1000 today. I am also having conversations about where to put new products not only in terms of how we can be competitive but the fact that I have access to great people, be it engineers, technicians, QC analysts, QC managers or supervisors. We have a new lyophilization facility to make finished Remicade is the first such

facility in the Americas in part due to our great access to talent.

### Do you feel there is a re-energizing of Puerto Rico to bring the country back to its former capacity?

We are one of two launching sites; we earn that right to be competitive every day. It is not only about being safe and compliant, but about local and global competitiveness. Companies operate here not just because of Puerto Rico's tax structure, but because of the infrastructure and talent that they can develop, and the innovation that they can perform within their sites. This puts individual companies in a competitive advantage over other jurisdictions. The government will be part of the equation, so on the other side you have to bring all these elements to the table in order to fulfil every manufacturing necessity. That has positioned Janssen as a world-class manufacturer and launching site.



The Edwards Lifesciences campus in Añasco

And clearly something's working. Puerto Rico's total manufacturing sector remains dominated by the pharmaceutical sector; 61 percent of its total manufacturing is in pharmaceuticals. In just the last couple of years, many of the companies that have operated in Puerto Rico for decades continue to demonstrate their commitment to the country. Puerto Rico's contribution to the manufacturing of medicines for the global market is paramount. As an example, 75 percent of Abbvie's





Humira, the world's top-selling drug in 2014, is manufactured in Puerto Rico. AstraZeneca's top-selling drug Crestor is made exclusively in Puerto Rico.

---

## UNCLE SAM: HERE TODAY, GONE TOMORROW

The driving force behind much of the interest in Puerto Rico as an alternative for manufacturing was Section 936 of the Federal Tax Code, which exempted corporations from paying federal tax on income earned in Puerto Rico. Consequently, just about every major life science company invested in Puerto Rico between the 1970s and 1990s. In 1996, Section 936 was repealed

with a ten-year phase out period. The removal of this exemption caused an outcry at the time, and many in Puerto Rico today still describe the impact of this situation using a variety of colorful metaphors, from "tidal wave" to "heart attack".

Indeed, many companies did suffer. "The removal of Section 936 provoked many pharmaceutical companies doing business in Puerto Rico to move abroad, especially to Ireland and Singapore, two of our most important competitors," recalls Jaime García, former executive director of the Puerto Rico Manufacturers Association (PRMA). "In 1996, 150,000 employees worked in the Puerto Rican pharmaceutical industry, and after the repeal and phase-out, only 80,000 remained."

# What science can do



---

### Cardiac regeneration

AstraZeneca is investigating the role of different signalling proteins in stem cell activation for self repair of heart muscle tissue.

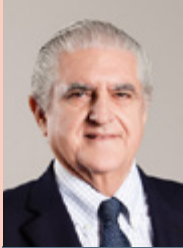


©2015 AstraZeneca Pharmaceuticals PL. All rights reserved 3130636



**BOB MARONEY**

President, PIA



**EDUARDO  
NEGRÓN- NAVAS**

Attorney-at-law,  
Fiddler, González  
& Rodríguez

However, there is a new spirit of optimism on the island. “While Section 936 tax benefits have expired, the Puerto Rican government remains focused on ensuring that people are well-incentivized to do business here, comments Bob Maroney, president of the Puerto Rico Pharmaceutical Industry Association (PIA). “This is important not only for existing companies but also for new companies coming here.”

Eduardo Negrón-Navas, attorney-at-law at local firm Fiddler, González & Rodríguez explains that at both the federal and local level, incentives for companies still exist. “The Economic Incentives for the Development of Puerto Rico Act of 2008 provides economic incentives, tax exemptions and tax credits to businesses engaged in eligible activities in Puerto Rico,” he notes, “while IRC Section 901 provides for the U.S. tax deferral of income earned in Puerto Rico, which is considered as a foreign tax jurisdiction. The combination of these two economic incentives makes Puerto Rico an attractive place to site manufacturing facilities.”

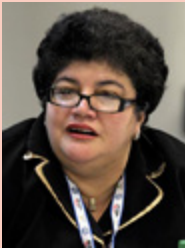
---

## **R&D IN PUERTO RICO: A GROWING PALM TREE**

Puerto Rico is starting to move beyond manufacturing and towards greater R&D activity. Puerto Rico’s

Cardiovascular and Cancer Centers are considered world-class and leaders in the region. In 2013, the University of Puerto Rico invested USD 72 million in a 153,000 square foot Molecular Sciences Building (MSB) that aims to accelerate the licensing and commercialization of patents, and has already sparked interest among a number of major pharmaceutical companies. The research center Fundación de Investigación houses the only Phase I clinical trial unit in the Caribbean and played a critical role in the development of Sovaldi, and has also conducted studies for many of the biggest names in the industry.

Driving much of the growth in the research area is the Puerto Rico Science, Technology and Research Trust, an autonomous entity designed to help stimulate innovation and provide funding for infrastructure and projects in the area of technology across a number of sectors, and the life sciences are no exception. Lucy Crespo, a former executive at Hewlett Packard, was named director of the Trust in March 2015 and has been working non-stop to bring more capital funding to the island, including partial funding for both the MSB and the Cancer Center. Both buildings are part of a 72-acre “Knowledge Corridor” that the Trust is building in the coming years to support the promulgation of innovation across 11 hospitals.



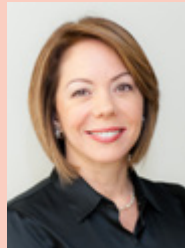
**LUCY CRESPO**

CEO, Puerto Rico Science, Technology and Research Trust



**IVÁN LUGO**

Executive director, INDUNIV



**VERÓNICA CRUZ**

Executive vice president and COO, ReComS Group

as a one-site-solution for clinical trials,” explains Crespo. “STRT is going to facilitate the process and infrastructure to ensure that we can make those trials and innovative treatments available to Puerto Ricans.”

How will all of this activity come to fruition in a realistic way? “We need to have highly skilled people, the best and latest technology and be able to develop, register and engage in technology transfer to launch products as fast as possible, says Iván Lugo, executive director of the non-profit organization Industry University Research Center (INDUNIV), which aims to solidify the link between Puerto Rican industry, academia and government. “INDUNIV has appointed itself the mission not only to promote manufacturing, but the whole value chain.

The Trust also recently received approval to work with every clinical trial unit in the territory. “From this, we formulated a unique value proposition to work together in one office to promote Puerto Rico



## DOING NOW WHAT PATIENTS NEED NEXT

---

Roche Diabetes Care helps people with diabetes everywhere in the world to think less of their diabetes and therapy management routines, and to experience true relief. With our solutions, we will support them in being less occupied by their disease.





**CARIBE, LLP**  
ENGINEERS • ARCHITECTS

### OUR VISION

To be the preeminent team of planners and designers providing integrated solutions to advanced technology industries.

### OUR SERVICES

- Project Planning
- Feasibility Studies
- Site Selection/Due Diligence
- Concept Design
- Project Cost Estimating
- LEED Accredited Professionals
- Energy Assessments
- Development of BOD
- Detailed Design/Construction Documents
- Construction and Use Permitting
- O&Pe Designated Inspectors
- HAZOP Reviews
- Equipment Bidding/Purchasing Specification
- Bid Review and Support Procurement



### CONTACT

Tom Forester, General Manager  
Phone: 787.622.2720 • Fax: 787.622.2725  
tom.forester@crbusa.com  
Oriental Bank Center, Mail Box #21  
1738 Amarillo Street, Suite 314  
San Juan, PR 00926



crbusa.com | 787.622.2720

THE RELENTLESS PURSUIT OF SUCCESS. **YOURS.**™



“The tax incentives program for R&D is really good and this is also available for services and manufacturing”

Dante Castillo, Haemonetics

As a result, we have supported the construction of innovation centers bringing together academia and the private sector for Phase II development. If we formulate and develop the product here, it is also very likely that its manufacturing and launch will also take place on the island.”

“Puerto Rico offers plenty of opportunities for both R&D and manufacturing, however it is important to identify how it can better capitalize corporations’ needs for net low cost,” says Dante Castillo, managing director of Boston-based blood management company Haemonetics’ Puerto Rican affiliate. “Puerto Rico holds an extensive combination of talent, knowledge and maturity in the manufacturing environment.” But it also needs R&D talents as well, he says. Additionally, “the tax incentives program for R&D is really good and this is also available for services and manufacturing.”

Where some see optimism, others exercise a degree of caution. Ireland and Singapore, Puerto Rico’s two biggest competitors for life sciences manufacturing may have gained the upper hand in terms of R&D. Verónica Cruz, executive vice president and COO of local consulting firm ReComS Group, notes that R&D is very different to manufacturing and while Singapore has a strong pipeline of scientists, Puerto Rico has a strong pipeline of manufacturers. “However, I strongly believe that Puerto Rico needs to think about what it really wants to do,” warns Cruz. “Just because Ireland is really successful in R&D, is that a reason to try and compete with them

in that area? We have a tremendous footprint here of idle capacity and globally approved sites; we ought to put that to work and bring in other kinds of products. There is no reason why we cannot start building other skills in the long-term, but in the meantime Puerto Rico should be exploiting its fortés rather than trying to be good at what someone else is already great at.”

But staying up-to-date in the manufacturing arena may also pose a problem. “Ireland and Singapore began in the following generation of pharmaceutical development which was less labor-intensive and more automation-driven,” recalls Cruz. “In comparison, we have not moved quickly enough to reach that technological level. The challenge we face is that retrofitting halts production and is more difficult than building from the ground up.”



**Siempre pensando en ti y los tuyos**  
con el mayor menú de pruebas y más laboratorios para estar cerquita de ti...

- Se aceptan la mayoría de los planes médicos
- Te atendemos enseguida con cita previa
- Abierto domingos\*



Hacemos pruebas de Chikungunya, Dengue, Influenza, BRCA

Tel. 787.300-2990



Barceloneta • Bayamón • Caguas • Fajardo • Guaynabo  
Gurabo • Río Piedras • Toa Baja • Vega Alta



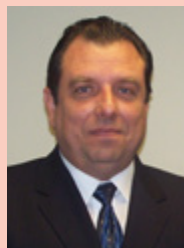
An artist's rendition of San Juan's future "Science City"

## EVOLVING THE MANUFACTURING MODEL: LESS IS MORE

The frantic rush to create an automation-driven manufacturing environment, coupled with the impact of global consolidation is being felt throughout the island. "In terms of technology, everything is moving towards being more automated," says Tom Forrester, president of engineering and architectural design firm CRB Caribe. "We are seeing a move in Puerto Rico towards biopharmaceutical products and processes in the oral solid dosage area finishing and packaging and less in the APIs."

Ricardo Zayas, senior vice president of global pharmaceutical manufacturing at Bristol-Myers Squibb (BMS), says that product volume and technology trends have become an increasingly important part in the future of pharmaceutical manufacturing networks and individual facilities. "Consolidation has created a significant amount of excess capacity in small molecule manufacturing around the

world, prompting companies to repurpose, close or sell their facilities," emphasizes Zayas. "Companies focused on innovative science are moving towards lower volume, higher value products. The challenge is that many plants were not designed for this model and will have to redefine their mission, strategy and operating model. Smaller plants that optimize space utilization are better equipped to handle changing



**TOM FORRESTER**

President,  
CRB Caribe



**RICARDO ZAYAS**

Senior vice  
president global  
manufacturing, BMS



**LOURDES DE CÁRDENAS**

Vice-president of  
operations Latin  
America, Stryker



demands of the industry. This is especially true in Puerto Rico where energy costs are relatively high.”

In addition to the “smaller is better” mantra, according to Zayas the convergence of development with production makes great sense. “First launching in market, then a rapid deployment to target markets around the world can help get medications to the patients who need them,” he stresses. “The primary focus during the development to launch process in terms of lead time has typically been the clinical and regulatory processes, but in today’s world, any time the manufacturing and development teams can work together to reduce the development-to-launch cycle time provides a significant opportunity to accelerate timelines.”

Lourdes de Cárdenas, vice president of operations Latin America for Stryker, notes that the intellectual value that Puerto Rican engineers adds makes the island particularly productive: “An increase in production volumes does not necessarily require the addition of many people because processes

are highly technological and automated; thus you can absorb increases or decreases in demand easily,” she says. One of Stryker Puerto Rico’s goals is to continue integrating automation into its processes. “This poses a certain degree of difficulty because of the variety of products we manufacture but moreover our approach to automation is not necessarily automating a process completely,” explains de Cárdenas. “It is automating unit operations that repeat themselves among different processes. Once those technologies are perfected you can reproduce them across many different lines. Consequently, demand can be easily managed.

Merck is no stranger to these trends. In the last two years, the company sold two of its three plants in Puerto Rico and is redefining its strategy at the remaining plant in Las Piedras. This plant has undergone a USD 100 million investment since 2011 focused on transforming the site from a basic supply site to a commercialization site, which CRB Caribe played a significant role in designing.

## SOLVING YOUR NEEDS!

- Visual Inspection process development (vials, syringes, cartridges, plastic containers)
- Standards preparation for visual inspection
- Visual inspection training center (vials, syringes, cartridges)
- Manual inspection holding tools (vials, syringes, cartridges)
- Commissioning, Validation, Regulatory, Quality Assurance
- Media-fills and airflow pattern visualization recording
- Project management

W. [www.biopharma-pr.com](http://www.biopharma-pr.com)

M. [info@biopharma-pr.com](mailto:info@biopharma-pr.com)

P. + 1 (787) 917-8780



**Biopharma**  
CONSULTING SERVICES

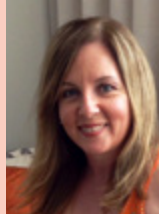


## Industrial Spotlight: Medical Technology



**MICKEY CENTENO**

General manager,  
Roche Diabetes  
Care Puerto Rico



**ANA MYRIAM IRIZARRY**

Plant manager,  
Lifescan Puerto  
Rico



**ROBERTO TOUS**

President, Techno  
Plastics Industries

While the majority of Puerto Rico's life sciences activity is generated from pharmaceuticals, medical devices and diagnostics (MD&D) companies also play a sizable role in the country's economy. "MD&D has been present in Puerto Rico for 40 years, and is currently growing faster than the local pharmaceutical industry," says Mickey Centeno, general manager of Roche Diabetes Care in Puerto Rico. "They are not as big as pharmaceutical companies because the business is smaller here. But we do see investment coming to Puerto Rico, which as a country has demonstrated the capability and quality to continue growing."

This undivided attention to quality among Puerto Rican medical device manufacturers has not gone unnoticed. Centeno points out that the nearest Roche Diabetes Care facility to Ponce costs 15 percent more to run their operations. That cost differential is another incentive for the corporation to consistently invest in Puerto Rico. Farther east in the city of Arroyo, Stryker hosts a site that produces over 800 different products for the medical device giant.

Ana Myriam Irizarry, a J&J veteran in Puerto Rico, became plant manager of medical device manufacturer Lifescan in early 2015 having worked in a similar position at other J&J campuses on the island. She was immediately impressed by the company's technical capability. "I was struck by the fact that much of the automation and manufacturing electronic systems were designed, built and installed here by our own engineers," recalls Irizarry. "Our employees support the design and installation of equipment when we need it. Once equipment is transferred to this site, the workforce has the knowledge required to manage the day-to-day operations."

This expertise is not just limited to the big players on the island. Techno Plastics Industries (TPI) is a local injection molding company that services the medical

device industry in Puerto Rico. Founded by a group of ex-Baxter employees, the company now competes with similar multinational companies to make parts for the medical device industry. "We started TPI with \$36,000, six associates and three machines in April 1992, running a one shift operation," explains Roberto Tous, president of TPI. "Today we have 25 machines as part of a 24/7 operation, and we have a workforce of 140 people." The Añasco-based company now supplies parts for a number of medical device and medical component companies based in Puerto Rico, Dominican Republic, the US and the UK.





“A commercialization site has the responsibility of shepherding new chemical entities (NCEs) from proof-of-concept to commercialization in the marketplace - which is a far more dynamic objective,” remarks Andrew Wirths, associate vice president and general manager of Merck’s Puerto Rico pharmaceutical operations. “Taking a plant site with five products producing one billion tablets for many years and adding several more products with new launches means an increase in capability, speed, cadence and cost competitiveness. We get really involved at the Phase IIb level, in terms of scaling it up, supplying clinical, and going full-scale commercial depending on the forecast.”

Merck’s facility in Las Piedras obtained a commercialization certification in part because the facility itself

was suited to the change in mission. “With non-sterile oral dosage, powders are blended and granulated and pressed into tablets,” explains Wirths. “It is simpler in some ways to the large molecule space, but we have consolidated commercialization activities here, de-risking the business by putting all the MKs in Puerto Rico from a cost perspective. I do not have to recapitalize because I have a very flexible facility where I can make different drugs with different technology platforms embedded here. If a new product does not succeed, I do not lose that much.”



**ANDREW WIRTHS**  
Associate vice president & general manager, Merck Puerto Rico Pharmaceutical Operations

**invision**  
*engineering corp.*

Empowering the industries with  
Insightful and Visionary Engineering

[invisioneng.com](http://invisioneng.com)

**Systems Integration**

**Automation and Control Systems**

**Instrumentation and Calibration Services**

**Electrical and Instrumentation Installations**

**PROVIDING SUPPORT TO INDUSTRIAL CONTROL SYSTEMS IN THE LIFE SCIENCES INDUSTRIES FOR MORE THAN 13 YEARS**

**MAYAGÜEZ OFFICE**  
B Street #4040  
Guanajibo Industrial Zone  
Mayagüez, PR 00680  
787-831-0070  
787-831-0071

**CAGUAS OFFICE**  
Borgoña Street 3B6,  
Villa del Rey 4,  
Caguas PR 00725  
787-653-4800  
787-653-4800





## Pharma-Bio Serv: A Model to Follow

“Puerto Rico has developed a very strong ecosystem to support this industry, of which we are part,” say Elizabeth Plaza and Victor Sanchez, founder & chairwoman of the board and CEO of local service provider Pharma-Bio Serv.



### ELIZABETH PLAZA

Founder & chairwoman of the board,  
Pharma-Bio Serv

### VICTOR SÁNCHEZ

President & CEO, Pharma-Bio Serv

“Every necessary component that might be part of what any company needs is easily accessible here. That makes Puerto Rico a very strong place to come, establish operations and be successful for many years.”

As a company, Pharma-Bio Serv

is the perhaps the most well-known example of the Puerto Rican success story. Founded in 1993, Plaza established the company in Puerto Rico following a career in the pharmaceutical industry. “The opportunities in manufacturing were so huge at the time that founding a company was the best option, and Pharma-Bio Serv has expanded exponentially ever since,” she says. The company’s evolution parallels many dynamic changes that have occurred in the industry as a whole, and today Pharma-Bio Serv offers a wide variety of services, including technology transfer, process validation, quality systems, regulatory compliance, and management of projects from engineering through commissioning and

qualification. The company now has offices in the US, Spain, Ireland, and most recently Brazil, and is increasingly recognized as a key consultant on a variety of issues.

But Pharma-Bio Serv is not the only company to have undergone a rapid international expansion. “When I visit other countries and I speak about regulation requirements, I realize how much we can contribute,” says Plaza. “Regulations are a learning process that Puerto Rico has already undergone. That knowledge for manufacturing is our major asset and competitive advantage. The Puerto Rican pharmaceutical, biotech and medical device industry professionals are well-versed in what it takes to produce quality products.”

## A GENERATION OF FDA EXPERIENCE

Puerto Rico has many features that make it an attractive place to invest in manufacturing – a US jurisdiction, an FDA regulated environment, and competitive tax breaks. But ask any Puerto Rican and they will tell you that what really sets them apart is their 50+ years of experience in the

life science sector. Many pharmaceutical and medical device companies have been operating in Puerto Rico for decades. At first most facilities were run by American plant managers repatriated to the island, but nowadays they are more likely to be managed by Puerto Ricans who have been in the game for years.

“Puerto Rico is more competitive as a consequence of learning to

transform itself from a US supplier to a global supplier, especially given the importance of the rise of emerging markets,” explains Ileana Quiñones, president and general manager at iPR-Astra-Zeneca. As these emerging markets tend to offer cheaper high-quality labor, the name of the game in Puerto Rico has been learning to demonstrate that the quality



**ILEANA QUIÑONES**

President and general manager, IPR-AstraZeneca



**YANIRA TORRELLAS**

President, Quality Consulting Group

of manufacturers located on the island truly is one of the best worldwide, as a US jurisdiction following FDA regulations. Consequently, Puerto Rico has become a manufacturing hub for global exports, rather than simply focused on the US as it had in past decades.

“Companies in other regions know how to manufacture, but doing it according to the FDA is markedly different”

**Yanira Torrellas, President of Quality Consulting Group.**

“Here at iPR-AstraZeneca,” Quiñones remarks, “we have been developing expertise to work with different regulatory agencies, markets, and other stakeholders throughout the globe.”

“We have a top notch labor force—hard workers, dedicated, committed and intelligent—and that is Puerto Rico’s number one asset in the manufacturing sector.

It continues to be one of the main reasons companies continue operating locally and are drawn to the island,” says Yanira Torrellas, president of Quality Consulting Group. The industry relies on the knowledge and experience of its people, and with our geographic location and US territory status, Puerto Rico becomes very important. Puerto Rico’s life science



Our Customers.



Our People.



Our Passion for Quality.



Our Community.



Our Caring for the World, One Person at a Time.



industry is governed by the FDA, so you can manage products in Ireland and Singapore but cannot necessarily export them to all US territories like this country can. That differentiation allows us to continue being competitive.”

Torrellas says that while other parts of the world offer competitive manufacturing of pharmaceuticals and medical devices, Puerto Rico does it better. “Companies in other regions know how to manufacture, but doing it according to the FDA is markedly different. Puerto Rico has investigators that came from local plants who know and are used to working in manufacturing. Those investigators may

have higher expectations compared to investigators in other parts of the world. They have probably not been exposed to that experience even though the regulations are the same. We know that in this kind of industry there are some practices, while not written down, that are the expectations of the FDA (cGMP). This attention to detail is part of many Puerto Ricans’ DNA in terms of expertise.”

.....  
**NO CHOICE BUT TO  
BE THE BEST**

“Due to the concentration of life science companies in Puerto

Rico, the office of the FDA is very aggressive in their enforcement here,” says Osvaldo Carlo, president of ReComS. “Compared with other jurisdictions with a limited number of pharmaceutical and medical device companies, in terms of geographical area and population, Puerto Rico has substantial presence from the federal government. The government engages in monthly enforcement actions, inspections or auditing of many companies in Puerto Rico. This makes sense given that Puerto Rico produces such a large amount of drugs and devices that are shipped to the US and other jurisdictions.”

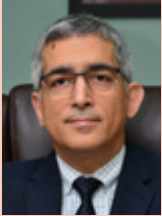
The true recipe of  
**OUR SUCCESS.**



Gurabo | Manatí | Guaynabo



## Back to School



**AGUSTÍN RULLÁN**

—  
Dean of the College of Engineering, UPR Mayagüez



**JOHN FERNÁNDEZ VAN CLEVE**

—  
Chancellor, UPR Mayagüez



**CARLOS VELAZQUEZ**

—  
Director, CPEDaL

By square mile, Puerto Rico has more post-secondary institutions than anywhere in the world. This concentration has led to the development of a number of college and university programs which produce world-class talent for the territory's life sciences industry.

From the manufacturing perspective, one of the leading institutes in Puerto Rico is the College of Engineering at the University of Puerto Rico (UPR) in Mayagüez. "We are consistently the number one producer of Hispanic engineers in the US, according to the American Society for Engineering Education," says Agustín Rullán, the College's dean. "Every year around 600 engineers from different levels graduate. And with our research projects, we have also increased the number of collaborations with other universities." Among the College's many programs, the institution has created a multi-disciplinary graduate program in bio-engineering involving all engineering departments that impact the pharmaceutical, medical device and healthcare industries in Puerto Rico. Rullán aims to have 20 students within the next couple of years.

"We have a lot of top-notch projects across various disciplines which have the potential to be patented and go global," notes John Fernández van Cleve, chancellor of UPR Mayagüez. "For example,

we developed new technology to quickly test for several diseases which will have significant impact worldwide. Software engineering is another good example; there are a lot of patentable ideas that can be developed in relation to applications and programs. At UPR Mayagüez we have the CRD (Research and Development Center) and we receive USD 20 million a year from various sources for numerous research projects. We believe that if we get those marketable patents it will be of high-impact nationally and internationally and we may also be able to sell the patent.

The Center for Pharmaceutical Engineering and Learning (CPEDaL), a training and research center established in 2006 at UPR Mayagüez, is also supporting. "We have projects with Janssen, BMS and Lilly, among others," says director Carlos Velazquez. "The success stories are the interactions with these companies. Furthermore, we have established a continuous manufacturing room here which can be used by those companies for experiments or projects. CPEDaL has managed to integrate research, education and services for the industry and facilitate intercommunication and collaboration between the three. This has driven us to focus on process control. This research could be a great asset not just for the pharmaceutical industry but many others as well."

Beyond that, Puerto Rico serves as a convenient gateway for Latin American healthcare companies looking to bring their products to the US, for which ReComS provides ample expertise.

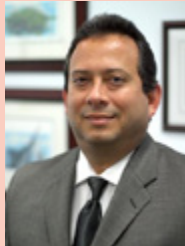
Carlo recognizes that there's no such thing as a small investigation in Puerto Rico. "Comparing Puerto Rico with other US jurisdictions, we have to be at the top in terms of compliance. Locally, Puerto Rico

has developed much expertise. When you have a large concentration of companies as is the case in Puerto Rico, even a couple of cases have national impact. An investigation initiated by the FDA would



**OSVALDO CARLO**

President,  
ReComS



**ENRIQUE ALEJANDRO**

Director/team  
leader finance,  
Pfizer Puerto Rico

impact a product that is distributed all around the US.”

“Puerto Rico has been one of the biggest hubs of pharmaceutical manufacturing for the last 40 years,” says Enrique Alejandro, director and team leader finance at Pfizer Puerto Rico. “Therefore there is a strong culture of compliance spanning two generations. Through training and development, we have worked that culture into our facilities, so everyone understands why quality and compliance are so important to our patients. We need to keep building on this to maintain it as one of our strengths.”

Alejandro articulates that many facilities have many second generation colleagues. “They are the children of employees who worked in the industry in the early nineties and saw economic growth and social development in their communities as a result of their jobs,” he remarks.

“The pharmaceutical industry has a significant impact on the economy of Puerto Rico in terms of export and employment,” continues Alejandro.

“Major consolidations bring with them network rationalizations, and that has impact on the number of jobs in the island. However, if the consolidations provide stability for the plants that remain and these maintain strategic roles that are bigger than before, that is good for Puerto Rico.”

### SUPPORT FOR LIFE SCIENCE IS BROUGHT TO YOU BY...

It’s not just the Puerto Rican multinational life science companies

that impress. “We carry this enormous sense of pride,” explains José Rullán, president of local automation solutions provider Invision Engineering, which specializes in efficacy and productivity. “We want to keep the pharmaceutical industry alive in Puerto Rico. We still want to be competitive worldwide. While Ireland and Singapore used our model to develop their own very successful models, we still pride ourselves on having most of the key medicines and pharmaceuticals in the world manufactured here.”

**escalate** [www.escalatesciences.com](http://www.escalatesciences.com)

**Customized Science-Based Consulting Solutions**

**PROCESS DESIGN**  
Provide consulting to reduce and control process variability, optimized-designs space to yield consistent result of critical to quality attributes.

**QUALITY SYSTEMS & TRAINING**  
We provide consulting services to keep your product & process in compliance based on integrated quality systems approach throughout their life cycle.

**QUALIFICATION & PROCESS VALIDATIONS**  
We are proud of our track record and hands-on expertise in process, cleaning validation and equipment qualifications.

**JOB OPPORTUNITY**  
We listen, understand and mentor our staff so that they can have the assurance that their ideas and contributions are always considered, challenged and pursued.

**Take The Right Decisions**

“We have a capability to serve many different aspects of the manufacturing industry including validation and qualification compliance with quality standards and regulations, as well as design and process improvement.”

Edgar Torres, Ph.D.  
President

**Contact Us**  
Dorado, Puerto Rico  
Toll Free 1(877) 213-7740 | Fax: 1 (800) 614-8329  
Email: [info@escalatesciences.info](mailto:info@escalatesciences.info)



## Circumnavigation of the Caribbean Nucleus

Edgar Rodriguez serves as DHL's area operations manager for Puerto Rico and the US Virgin Islands. When it comes to logistics and transportation, he explains why Puerto Rico is an important regional hub not only for the life sciences but for industrial sectors in general.



**EDGAR RODRIGUEZ**

Area operations manager Puerto Rico & US Virgin Islands, DHL

### What do you perceive to be the main focuses for DHL in the region?

My area of focus is Puerto Rico, the US Virgin Islands and being a gateway for the Caribbean. I need to make sure everyone receives their packages on time to offload and continue logistics until the final destination for our customers. Puerto Rico is closely

positioned to manage other islands in the region like the Dominican Republic, St Maarten, or Dominica; but Puerto Rico and the Virgin Islands remain as the first station for Caribbean connections.

### What characteristics of Puerto Rico make it a convenient hub for the Caribbean?

"Puerto Rico is the main island that controls distribution around the entire region. We have better resources and services in terms of distributing on-time based on geography. Other than the Caribbean, I can say that some parts of Central and South

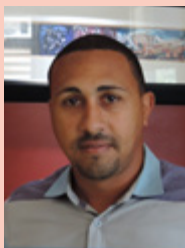
America are also important. But our main bridge from the US into the smaller islands is Puerto Rico. It has the best airports, resources, infrastructure, and it is right in the center of the Caribbean, which makes it easier to build distribution for northbound and southbound deliveries. With Puerto Rico centralized as a gateway for the entire Caribbean, you can move the local business to the next level because you can expand services that contribute to employment in Puerto Rico. By building a strong strategy for local service, we can look at Puerto Rico servicing other countries outside of the Caribbean."

The reliance of the industry on this ecosystem of service providers is paramount. Gustavo Hermida, president of local construction company CIC Construction Group explains:



**JOSÉ RULLÁN**

President, Invision Engineering



**MANUEL DE LA CRUZ**

President, M&N Electronics

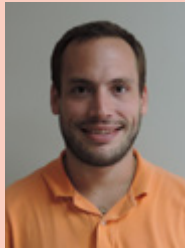
"As a general contractor, CIC provides the infrastructure for the life science sectors in the construction industry. Life science companies need the infrastructure built so they can produce their pharmaceuticals, biotechnology or medical devices products," he says. "As a service provider of infrastructure, it is critical to gain the confidence of the industry, to show that you can provide the quality, performance and safety that they are looking for, at a competitive price." The company is the largest of its kind in Puerto Rico servicing the pharmaceutical,

biotechnology, manufacturing and medical devices industry, and is the third largest general contractor in Puerto Rico. It is precisely this attention to the relationship between manufacturers and their service providers that has allowed companies like CIC to thrive.

M&N Electronics, for example, which distributes industrial doors for the life sciences industry such as cleanroom and stainless steel doors, distributes worldwide while controlling 60 percent of the Puerto Rican market share. Their clients include many



**GUSTAVO HERMIDA**  
President, CIC Construction Group



**ANDY VIVONI**  
Business development manager, Steri-Tech

familiar names, including Pfizer, BMS, Amgen, J&J, Medtronic, Novartis, Actavis/Allergan and Baxter.

“Door installations are very critical here because of the nature of pharmaceutical production in Puerto Rico. Not everyone has access to such hi-tech doors,” says Manuel De La Cruz, the company’s president. M&N Electronics has grown organically: “We started in my father’s house with two technicians and now have 45 employees in our facility and service Puerto Rico, the Dominican Republic, St. Thomas and St. Croix.”

## TO THE CARIBBEAN AND BEYOND

Countless service providers to the life sciences industry of Puerto Rico are expanding their services to nearby countries in the Caribbean, Latin America and the US.

“To continue growing we must expand outside Puerto Rico, particularly to the mainland US, which is a major point for us right now,” says CIC Construction Group’s Hermida. “We are in the process of obtaining the license to operate in North Carolina, and we are planning to open an office there early in 2016.”

“Companies have to be able to appeal to multinationals’ investments by strengthening their core competencies and outshining their competition on a global scale,” explains Andy Vivoni,

business development manager for local contract sterilization company Steri-Tech. “In today’s game, the geographic barriers that existed in the past which restricted companies from transferring their operations are not present. Companies are now working on a multinational scale, outsourcing their operations to obtain the best cost-savings without sacrificing quality. Specialization has helped accelerate this trend, but the key element for us is differentiation. We have the basic infrastructure the industry needs but we have to



## THE SOURCE FOR CONTRACT STERILIZATION, DISPOSABLE GOWNING & CLEAN ROOM SUPPLIES

**STI**  
STERI-TECH INC  
Contract Sterilization & Disposable Apparel MFG, CO.

**HEADQUARTERS**  
Salinas Industrial Park, Road 701  
Km 0.7, PO Box 1145, Salinas, PR 00751  
T +1 (787) 824-4040

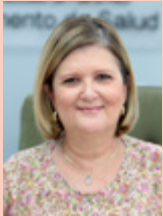
[www.steri-tech.com](http://www.steri-tech.com)

PARTNERS:





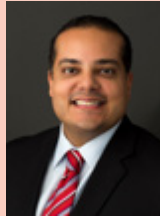
## Healthcare Spotlight



**ANA RÍUS**  
—  
Secretary  
of Health of  
Puerto Rico



**JIM  
O'DROBINAK**  
—  
CEO, MCS



**HARI SABNANI**  
—  
Managing director  
Puerto Rico and  
Caribbean region,  
Quest Diagnostics



**RICARDO  
RIVERA**  
—  
Executive  
director, ASES

"There is a cap on our Medicare funds which, in 2018, may amount to USD 500 million because although Puerto Ricans contribute the same amount to the system as Americans, they do not pay federal taxes. A coalition of the key stakeholders such as hospital associations, insurance companies, doctors' associations and the government have to lobby intensely for the cap to be withdrawn and so that there are no cuts to the Medicare funds. On the one hand, we will have to negotiate with the US Department of Health and Congress to have the cap eliminated. On the other hand, we must strive to create a better health system which has a greater focus on prevention through health education whilst also being more financially efficient."

— **ANA RÍUS, SECRETARY OF HEALTH OF PUERTO RICO**

"In 2011, we used to receive about USD 6 billion a year in MA funding. We are now down to USD 5 billion, and that funding is

also for a larger population base. ACA mandated that 85 cents on the dollar has to go to patient medical costs. However, when Puerto Rico loses a billion dollars in funding a year, this equates to USD 850 million less that has to be paid to the medical community, in addition to the health plans having to cut USD 150 million to offset the USD 1 billion in revenue cuts. These cuts put tremendous pressure on the health care system. Half of the money in the Puerto Rican healthcare system is funded through this USD 5 billion MA figure, but there is only so much you can cut back on."

— **JIM O'DROBINAK, CEO OF MCS**

"With USD 1 billion cut, MA plans will reduce their free schedules. There is no way they will be able to sustain their businesses paying the same as they are paying now for their providers," he says. "I foresee a lot of consolidation and preferred providers. Quest must continue being competitive and careful about how we manage the

operation from a cost perspective. We have to do more with less money and our clients will be even more sensitive to price increases. One of our biggest segments of business is reference to local labs. The affiliate provides services to over 600 mom-and-pop labs twice daily across Puerto Rico. In order for them to be able to survive in the business with a reduced free schedule, they will need better pricing from us. For that to happen, we need to economize what we do as an operation. We will also need to do better in procurement with suppliers, so that we obtain the best deals possible, which will also have an effect on the economy. Like a domino effect, we will ask for better deals and volume consolidation will also happen."

— **HARI SABNANI, MANAGING DIRECTOR PUERTO RICO & CARIBBEAN REGION, QUEST DIAGNOSTICS**

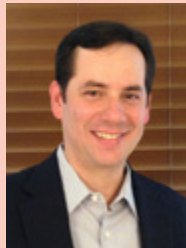
"Governor García Padilla has created a Healthcare Coalition to appeal to the federal government for a fairer allocation of the Medicaid and Medicare funds. The coalition represents a group of patient advocates, doctors, hospitals, insurers, activists, labor unions and business leaders who have joined forces to call on Washington to end the appalling injustice of healthcare funding in Puerto Rico."

— **RICARDO RIVERA, EXECUTIVE DIRECTOR OF THE PUERTO RICO HEALTH INSURANCE ADMINISTRATION (ASES)**





**YOEL RIVERA**  
President, Ultimate  
Solutions Corp



**OMAR MUÑIZ**  
President, ShareTech  
Group

offer the added value these companies desire.”

Steri-Tech is no stranger to working on this multinational scale. The company intends to outsource some of the products it currently resells from Asia and Latin America; “this would bring significant cost savings, compared to buying from second-hand suppliers in the US,” comments Vivoni. “Eventually we can start branding our own products like our competitors do. The goal is to increase sales by penetrating new markets, both stateside and Latin America, where we see an increase in pharmaceutical and biotechnology activity, while decreasing purchasing costs, which translates into income.”

“Exporting services to other life science hubs will encourage our service sector to grow while creating new markets for Puerto Rico. Working with academia to develop future professionals is also a great way of promoting growth,” says Omar Muñiz, president of ShareTech Group, a local

“Exporting services to other life science hubs will encourage our service sector to grow while creating new markets for Puerto Rico”

**Omar Muñiz, President, ShareTech Group.**

engineering, architecture, environmental consulting, and construction program management firm. The company also aims to target Puerto Rico’s compet-

itors in Ireland and Singapore. “It is fascinating to see how modern day information technology and globalization can facilitate and connect us, service providers,



Health is to live intensely. **Dancing** is excellent for flexibility and improves your circulation. A **walk** in the park helps you workout. **Having lunch with your friends** is perfect for relieving stress. **Laughing** is wonderful for your lungs, and **chatting** with your friends is an unflinching therapy. Enjoy every moment of your life because, to live intensely, is the best prescription for your **health**.



[mcs.com.pr](http://mcs.com.pr) • 787.758.2500

Group • Individual • Medicare • Life  
COM\_E\_1508227



**EDGAR TORRES**

President, Escalate Sciences



**FRANKIE CHÉVERE**

Executive director,  
Puerto Rico Trade  
& Export Company

to our multinational clients' worldwide networks," remarks Muñiz.

International expansion offers sizable opportunities for Puerto Rican companies. However, this must not be done in isolation. "Puerto Ricans should not think of their business as just part of an island; that is small thinking. We can broaden our collective mindsets," remarks Yoel Rivera, president of local packaging company Ultimate Solutions Corp. "But for some reason, we have been taught to work for other people and make their processes better rather than bringing our own systems and make them globally scalable. It is a mindset that must change in Puerto Rico." Rivera points out that some companies are trying to adopt this mindset, but that it must be developed much more in order to succeed. "We have great universities and key opinion leaders making great investigations, but for some reason we are just thinking about staying

here locally," Rivera continues. "That is not how we can create a global business. I would like others to realize that they can dream about being more global; we have been doing this for 60 years. R&D in global companies brings us their processes and we improve them. The change needs to be that we create those processes or be part of them to make sure we are owners of that technology and those patents."

"Every company has its own strategic plan but we in Puerto Rico should be seen as a world-class exporter of these services," says Edgar Torres, president of Escalate Sciences, a Puerto Rican specialized science-based consulting firm focused on R&D, tech transfer, process design & improvement, analytical development and characterization. "Most people know that consulting companies export qualification and validation, but with resources specialized in packaging, R&D, and many other areas in Puerto Rico, there will continue to be room for international growth. We have adapted to many needs in R&D; we can bring the right consulting resources with the right expertise to service different regions' specific needs."

"Companies have learned that they need to be very selective in their supply chain about who is supplying services and products," continues García. "Companies today have a lot more evaluation

in their processes. That is an opportunity because many companies here have operations in other parts of the world so they are recommending suppliers here outside of Puerto Rico. Those companies can start exporting their services. That is a win-win situation; the clusters and their supply chains become very meaningful. The stronger the cluster, the stronger the interactions of the supply chain, the more experience you have internationally, and the better service you can get here."

Frankie Chévere, executive director of the Puerto Rico Trade and Export Company (CCE), has been working to help merchants and small businesses become more competitive and foster an export culture.

The first law that Governor Alejandro García Padilla's signed in 2013 was the "Jobs Now Act" (Law 1), in which CCE played a pivotal role. "This law created a scheme of short-term incentives for companies to create jobs in Puerto Rico through tax exemptions, salary subsidies, and energy credits," Chévere says. "It aimed to give preferential treatment through those incentives to SMEs. Big companies, both local and foreign, also benefited. The new jobs in the health industry were in new diagnostic centers, services for the elderly, small pharmacies, and medical offices, all of which benefited from these incentives."



“Entrepreneurship is being taught not only at the high school level but also at universities, making students aware that there is an opportunity to start your own company”

**Francisco García, Executive Director of the Puerto Rico Manufacturers Association.**



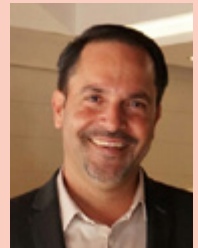
**FRANCISCO GARCÍA**

Executive director, PRMA



**JOHN TABOAS**

President, Biopharma Consulting Services



**NÉSTOR CARDONA**

President, N&CS Consulting Group

## NEW BEGINNINGS

SMEs are making leaps and bounds, and new startups are still emerging in Puerto Rico. “We are starting to see a wave of new entrepreneurs and there are many entities in the ecosystem that are supporting entrepreneurship,” remarks Francisco García, the newly appointed executive director of PRMA. “It is being taught not only at the high school level but also at universities, making students aware that there is an opportunity to start your own company and that there is learning required for entrepreneurship.”

García acknowledges that Puerto Rico is becoming more sophisticated in that regard, and industry professionals are applying their experience to the life sciences cluster inside and outside Puerto Rico. “There is a large ecosystem trying to help people learn how to export, work outside Puerto Rico and how to manage that work,” he says.

Take Biopharma Consulting Services (BCS) for example, which was founded in 2010 by John Taboas, an entrepreneur with expertise in validation. “A couple of years ago, we identified visual inspection as a sector in which other competitors were not paying attention,” Taboas remarks.

## Did you know?

According to the Battelle Memorial Institute, the bioscience industry is well distributed across the US and plays a major role as an economic driver, with many states maintaining niche strengths in specialized areas across major industry subsectors. Puerto Rico is specialized in four out of five bioscience industry subsectors in the US, a feat shared only with New Jersey.

- Bioscience-related distribution
- Medical devices and equipment
- Drugs and pharmaceuticals
- Research, testing and medical labs

*(Source: Battelle/BIO State Bioscience Jobs, Investments and Innovation 2014 Report)*



**DAVID LENIHAN**  
CEO, PHSU

“BCS has managed to create expertise in that area. We have been working in projects on vision inspection in the US and Puerto Rico, including manual, semi-auto, and automated. We have FDA commitments related to vision inspections, new processes for new facilities that are already Pre-Approval Inspection (PAI)-approved.”

“Through our years of experience on highly regulated environments such as Consent Decrees and constantly being watched by agencies, we have the expertise to provide excellent results in implementing and sustaining appropriate quality systems,” Taboas says. “This is important

both for keeping a high standard of manufacturing on the island and for emerging markets such as Latin America.”

Also founded in 2010, N&CS Consulting Group, headed by president Néstor Cardona, specializes in performing validation GAP assessments to determine if life science companies’ current processes and equipment are GMP-compliant. Cardona, an expert in computer systems validation, started the company as its sole employee. “We are now celebrating our fifth anniversary in 2015 and we are handling projects of about USD 5-6 million per year,” he says. “We perform GAP assessments and recommend feasible solutions to the industry to improve their manufacturing processes. Our reputation has quickly grown throughout the country.”

# Driven by Quality!

- PHARMACEUTICAL ENGINEERING
- VALIDATIONS
- REGULATORY COMPLIANCE CONSULTING
- GXP DOCUMENTATION

T +1(787) 685-3708  
+1(787) 402-5252  
M orders@nandcsgroup.com  
W www.nandcsgroup.com



## GLOBAL LEADER IN BLOOD MANAGEMENT SOLUTIONS



[www.haemonetics.com](http://www.haemonetics.com)

Carr 194, Pall Boulevard #98  
Fajardo, Puerto Rico 00738  
TEL +1 787-355-4100





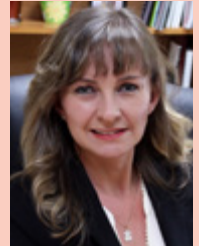
## BI-CULTURAL SKILL SETS

At first glance, with only 800 students, Ponce Health Sciences University (PHSU) may seem like just another medical school in Puerto Rico. But upon closer inspection, one realizes that this university is a breeding ground for a new type of doctor altogether, one that is ready to cope with the changing dynamics of the US healthcare system.

Leading the charge is David Lenihan, CEO of PHSU. “North America is facing a cultural deficit in healthcare, and our unique health disparity research is a real asset for the US,” he says. “Despite the rapid increase in the Latino population, there is actually a decline per hundred thousand of Latino doctors. Such a decline affects not only the patient–doctor clinical reality but

how a given disorder or disease is investigated.” Given that many diseases can be specific to certain genotypes and cultures, the research being done at PHSU is truly groundbreaking.

Take cancer for example. According to Kenira Thompson, president of the Ponce Research Institute, genetic ancestry studies have identified that breast cancer predisposition for Puerto Rican women is different from that of North American women of other ancestries. “Our Cancer Biology Division has spent many years identifying the genetic markers specific to Puerto Rican breast and skin cancer predisposition compared



**KENIRA THOMPSON**  
President, Ponce Research Institute

**10 años**  
Ultimate Solutions Corp.

Integrated Packaging Services  
FOR THE HEALTHCARE INDUSTRY

www.usolutionspr.com

Bay II, Inteco | Inova Building  
PR 34 Regimiento 65 Infantería  
Caguas PR 00725  
Tel 787.961.2019

FTIS MSF UA AE SI VIS V RC

**M&N ELECTRONICS**

**YOUR PARTNER FOR HIGH-QUALITY INDUSTRIAL DOORS**

M & N Electronics, Inc is a reputable company with over 24 years experience in servicing and installing all types of commercial, industrial doors, and loading dock equipment. We are the number one authorized distributors for such companies as Rite Hite, Chase Doors, Gyro Tech Nabco Doors, Berner Air Curtains, Overhead Rolling Doors, and Wayne Dalton.

**FIND OUT MORE IN**  
[www.mnelectronic.com](http://www.mnelectronic.com)

**m&n Electronics**  
G.O.O.D Enterprises

PO Box 51648  
Toa Baja, PR 00950

TEL +1 787-798-1261  
FAX +1 787-798-7826



to other Hispanic and global populations,” Thompson remarks. “We have also identified low DNA repair capacity as an important risk for breast cancer in Puerto Rican women. Our current research sits at the forefront of Precision medicine, which requires epidemiological, demographic, and genetic information to make the best therapeutic decision for each individual patient. These targeted treatments for specific populations are extremely important for patient outcomes and for reducing costs.”

PHSU’s groundbreaking work goes far beyond the research, however. The school is actively dedicating its curriculum to what Lenihan describes as “bicultural skill sets”, which are particularly important in Puerto Rico, the number one supplier of Latino doctors to the US. “Medical treatment for most patients tends to be the same, but the cultural handling of the patient – whom you talk to, physical contact with the patient, etc. – can be very different based on the patient’s background,” explains Lenihan. “PHSU produces doctors in Puerto Rico with the necessary levels of cultural competency to effectively manage this kind of situation, whereas the majority of US-trained doctors lack this skill.” These skills, which Lenihan views as a unique value proposition, will become necessary as the demographics of many states in the center of the US start to see an influx of Latinos, while the number of actual Latino doctors in these states remains negligible.

Lenihan, Thompson and the PHSU team hope to replicate this method of teaching in the US. “I hope to quadruple our research and to have interacted with at least ten health systems across the US during my tenure here,” says Lenihan. “These interactions with non-Puerto Rican health systems will contribute to a database on patients, in turn allowing us to apply for more basic science and clinical research grants that will provide a significant number of ROIs for Puerto Rico. I want medical students from other schools to come here to receive training that they would not receive in their home states.”



Inside iPR-AstraZeneca’s facility in Canóvanas

“The US needs this, and we can be number one in this niche,” he concludes. “Puerto Rico is the answer to many healthcare problems in the US. If managed correctly, this could bring Puerto Rico out of its economic crisis.”

---

## BEYOND REGULAR TOURISM

As healthcare costs are on average 40 percent cheaper in Puerto Rico compared to the mainland US, the island offers plenty of opportunities for treating patients from the US as well as patients in the Caribbean. Puerto Rico’s healthcare infrastructure is the best among its neighbors. Between 15,000 and 20,000 patients visit Puerto Rico every year and spend on average USD 10,000 in medical costs. Puerto Rico’s newly established Medical Tourism Corporation aims to increase that figure in the coming years.

“Many people come to Puerto Rico for complex surgeries, such as open heart, orthopedics, dental, or plastic surgeries,” says José Luis Rodríguez, CEO of Hospital Pavia’s Santurce division. “We believe we can attract patients because we speak their language and have the same judiciary system, and these characteristics can give peace of mind for the patients. It is much better than going to another country.” Metro Pavia, which has been operating one of the largest hospital networks in Puerto Rico and the Virgin Islands for 20 years, runs 12 different hospitals, each with its own specialty; such as the Santurce branch, which has expertise in cardiovascular treatments. “Besides medical tourism we are also providing emergency services for those



in need in other countries,” continues Rodríguez. “The government of Puerto Rico is betting on that and building more facilities for these patients.”

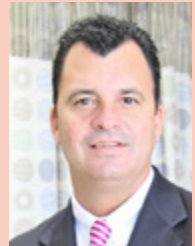
## MADE IN PUERTO RICO

**“Industry is not a collection of machines and tools and buildings. It is a social entity that has the responsibility of realizing the happiness of those who work in it.”**

(Luis A. Ferré, Third Governor of Puerto Rico, May 1962)

Despite the economic situation, the strength of Puerto Rico’s manufacturing sector in life sciences and beyond will play a critical role at this point

of the island’s development. “This country has realized that it cannot continue to depend on others,” declares PRMA’s Carlos Rivera. “It is our charter to grow our country, and therefore we must be present in every aspect of promoting Puerto Rico. Only Puerto Ricans can turn this country around. People have become conscious of this and everybody is fighting for it. Puerto Rico has been in a recession for seven years, with negative growth. We need to do something about it on as many fronts as possible: working with Washington, working on exports, generating new jobs, government buying in Puerto Rico, and generating more domestic capital.” ❁



**JOSÉ LUIS RODRÍGUEZ**

CEO, Hospital Pavia Santurce



Techno Plastics Industries™

NEW  
MICRO  
MOLDING

## We offer custom solutions for Medical Device & Electronics Markets

### Services

- High Precision Injection Molding
- TPI enters now in the 1-1000 mg range.
- In House Mold Maintenance & Repair Inventory Management

### Other Services

- Consulting, Mold Construction
- Project Management, Inventory Control Kan Ban Services
- On-Time Delivery
- Validations
- Contract Manufacturing
- Tool Manufacturing

Techno Plastic Industries, Inc. • Tel.(787) 826-6000  
Road 402 Km. 0.6 • Añasco, PR P.O. Box 1544 - 00610 - 1544  
[sales@technoplastics.com](mailto:sales@technoplastics.com) • [www.technoplastics.com](http://www.technoplastics.com)



# LOCAL INDUSTRY; GLOBAL REACH

**Preface:** Juan Sénquiz, President and CEO of JC Automation, weighs in on the capacity of Puerto Rico's local service industry for pharma to grow globally and how the company's computerized systems services have helped some of the biggest names in the industry to automate more effectively.

---

**HCLS:** JC Automation offers many services to the life sciences industry. What is particularly competitive about your offering?

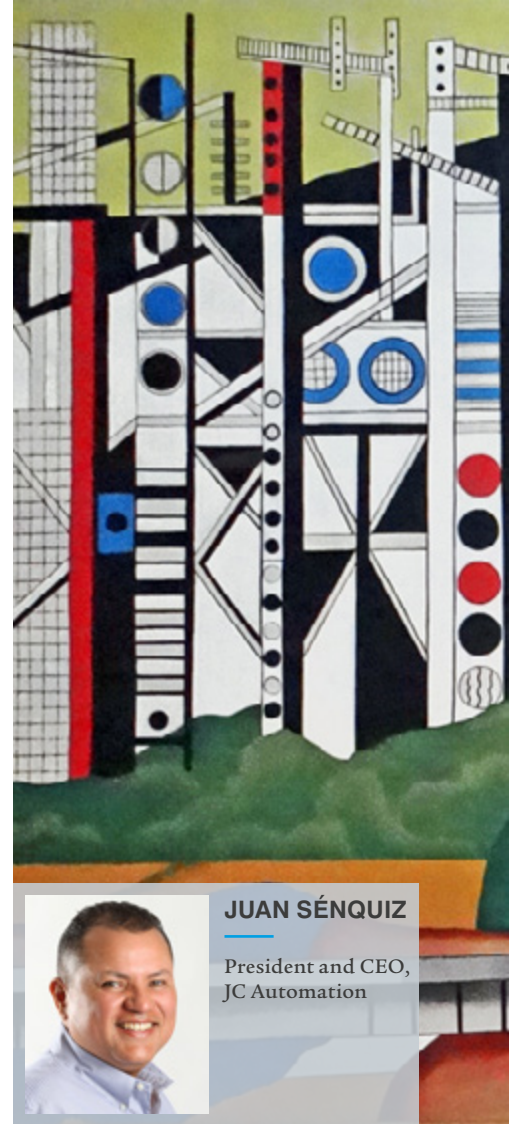
**JUAN SÉNQUIZ:** JC Automation focuses on computerized systems. All our services revolve around automation or technology that enables automation. We provide a single source for design, implementation, validation, and management services associated to computerized systems. Managing the whole cycle allows for easier project implementation, as knowledge and expertise is leveraged across one functional team among the various phases.

For example, we have partnered with VMware to accelerate the deployment of server infrastructure required for Automation projects. In the old days, obtaining new hardware took three months; now it is done in two days. In addition, we are helping customers to know more about their processes by allowing them complete visibility to their critical process parameters using OSISoft. This allows the customer

to really understand what is going on with their processes. It also allows the customer to compare the product batch running now to a batch from a year ago, and determine if there is any variation and why; that helps our clients greatly.

**HCLS:** How did this partnership with OSISoft come about?

**JS:** We learned about OSISoft from one of our customers. At the time we did not had the expertise but we saw the opportunity and went for it preparing our people and the infrastructure to make it part of our service suite. The partnership OSISoft is part of this preparation. OSISoft is one of the few companies that can interconnect with any piece of equipment regardless of which brand it is. Typically, certain parts require dealing with specific companies but OSISoft can get information from practically any source. Customers can see all their plant information in one single database regardless of which brand of equipment you are using, great value.



**JUAN SÉNQUIZ**

President and CEO,  
JC Automation

**HCLS:** JC Automation has been very active in promoting its brand overseas in the mainland US, Dominican Republic and Brazil to name a few. What is your overall internationalization strategy?

**JS:** We are taking advantage of multinational plants with sites in Puerto Rico. The strategy is simple; people do business with people they trust. It is easier for us to obtain business with companies using feedback from a previous customer than to simply cold call them. We are following the sites of the companies that are based here in Puerto Rico setting up proper infrastructure at each country





and leveraging local Puerto Rico talent with the talent found at the countries we are serving. All administration services are kept at our headquarters in Humacao and regional work centers are habilitated for sales and execution logistics at the remote locations near our customers.

**HCLS:** The regulatory mindset of these other countries is sometimes not as stringent. How challenging is it for you to get customers in other countries to adhere to that mentality?

**JS:** It has its challenges. Some people are more challenging than others. As a consultant, you have

to give the best advice possible and help the customer balance business needs with regulatory requirements. Certainly, other places in Latin America do not have the same level of awareness of compliance than here. Even more, for those that have had the opportunity to execute projects in Puerto Rico and mainland US are witnesses that local companies have a higher sense of compliance than in the mainland, as the FDA regulators are more demanding. This makes us very prepared for audits and boosts our positioning compared to the rest of the world, including many clients in the mainland US.

**HCLS:** What is the next step for internationalization?

**JS:** Maintain our focus on leveraging customer referrals that are obtained by delivering high quality services. Our workforce, the key to our success, knows that our company is as good as the delivered services, so attention to details and discipline are key elements of our culture. We have come a long way since 2006 when decided to export our services but there is much more to do yet. Our pipeline has very exciting new places for us including Spain, Ireland, China, and Germany. However, we have no hurry; we have to follow our own bit and



making sure that the results of our execution wherever we go help us move up.

**HCLS:** What makes JC Automation the computer systems partner of choice for the life science industry?

**JS:** We have the experience, the technology and an outstanding project track record. Our workforce and our partners' network allow us access to world class resources that are focused and committed to deliver value for our customers.

We always deliver what we promise, and always make sure that the system we implement fit our customers' needs.

**HCLS:** What is the potential of the Puerto Rican service provider industry to become global?

**JS:** We transitioned from a worker to an entrepreneurial culture. The talent that we have in Puerto Rico, the universities and what we have learned from working on these multinationals for so many years has prepared us to compete at any level. Furthermore,

we have worked in the key foundations to acquire capital needed for entrepreneurial growth with local forums like the one provided by Grupo Guayacán, and others.

If you want to decide where to put your manufacturing site, you should take a close look at Puerto Rico and its capabilities. Local people in the manufacturing and pharmaceutical industries are dedicated and hard workers, and there is no process or technology in life sciences that we cannot get to work on efficiently. Trust in Puerto Rico!!! 🌟

**UNLEASH THE POWER...**

**JCA**  
since 1997

**INTELLIGENT OFFERINGS...**

REGULATORY COMPLIANCE | **CSV**

INFORMATION TECHNOLOGY

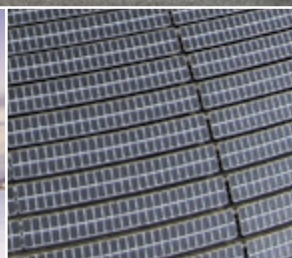
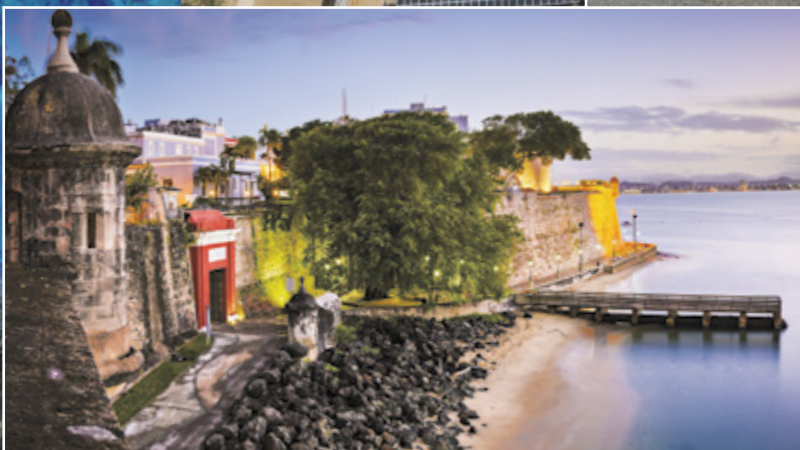
AUTOMATION

**CONTACT US:**

T: 787-716-4872 | [JCAPR.COM](http://JCAPR.COM)

Twitter Facebook LinkedIn

# Pfizer and Puerto Rico: Working together for a healthier world



For more than four decades, Pfizer has been part of Puerto Rico's pharmaceutical industry; employing more than 2,700 in the manufacturing of medicines that improve the quality of life of people around the world.





# INDIGENOUS INNOVATION

**Preface:** Ana Myriam Irizarry, plant manager for LifeScan in Puerto Rico, discusses the competitive nature of the facility's production of diabetes test strips and the immense talent that Puerto Rico has to offer in terms of manufacturing talent.

## **HCLS:** How was LifeScan established in Puerto Rico?

**ANA MYRIAM IRIZARRY:** LifeScan is the diabetes care segment of the Johnson and Johnson (J&J) family of companies. Our key decisions are always based on the J&J Credo and this impacts how we interact with our patients, customers, stockholders, nurses and doctors. LifeScan aims to take care of and provide the best quality of life for diabetes patients.

LifeScan Puerto Rico started in 1989 in a very small, second-floor space in San German with a limited number of people working as a packaging operation. As the company grew, we moved to Cabo Rojo into a facility and expanded the operation beyond packaging and into some steps of the conversion process. As LifeScan continued to grow, we moved into the current Aguadilla facility in 2008. Puerto Rico was one of 25 potential sites that competed for the entire manufacturing process of our OneTouch Ultra test strips, and the final decision was to move here to Aguadilla. This visibly demonstrates what the corporation saw in our people, infrastructure and environment. The move to Aguadilla further expanded the operation; we were not only doing just packaging and conversion processes, but an end-to-end process of the One Touch Ultra Plus strips. The Aguadilla facility does everything from receiving and manufacturing to packaging and shipping, with approximately 270 employees working here supplying the US market.



**ANA MYRIAM  
IRIZARRY**

Plant Manager,  
LifeScan Puerto  
Rico

## **HCLS:** What are some of the competitive characteristics of this facility?

**AMI:** This building was designed to be a lean facility. It has a uni-directional flow, which means we begin our process with receiving until the product is taken from the facility at the other end. This single flow movement has greatly reduced our waste. The design of this facility is critical because it does not matter if we bring new products in; we would still be able to keep the design without disrupting that flow.

Talent is also a key component of our competitiveness. This is the third plant I have led in Puerto Rico, the others being J&J's facilities in San German and Manatí. Each of these plants has impressed me in different ways due to their capabilities and core competencies. However, when I arrived to LifeScan, I was very impressed by its talent. The technical capability of the workforce is outstanding. I was struck by the fact that much of the automation and manufacturing

“I was struck by the fact that much of the automation and manufacturing electronic systems were designed, built and installed here by our own engineers”



electronic systems were designed, built and installed here by our own engineers. Our employees support the design and installation of equipment when we need it. Once equipment is transferred to this site, the workforce has the knowledge required to manage the day-to-day operations.

Execution is also fundamental in terms of ensuring we make products with the right quality, caring about employee safety, and being cost-competitive. You have to meet or exceed targets in those three areas to be competitive within the site and the business. The mindset of continuous improvement is very much engrained here. We have many Kaizen events throughout the year, belt certification, and FPX (flawless project execution) certification, a J&J methodology used to ensure success during the project execution. This makes the facility a place of choice in diabetes care.

**HCLS:** Does this added knowledge help drive costs down in any way?

**AMI:** Building and maintaining those capabilities definitely helps us to be more cost-competitive. For example, manufacturing execution systems may cost about three times more by doing it with our own engineers. This expertise will be key selling point for a product that LifeScan headquarters is considering to bring to Aguadilla. The platform for this product is totally different but requires knowledge and expertise in automation and injection molding. LifeScan Puerto Rico as this expertise and will represent a key element in the decision-making process of the site selected to make that new product.

**HCLS:** The added value of having several other J&J sites nearby must also factor into this decision-making process.

**AMI:** Indeed, it is not only about what we have in-house, but what we have in the J&J Puerto Rico campus as we work collaboratively, supporting each other. For example, Ethicon has expertise in clean rooms and Janssen has expertise in injectables, which we can





freely use. In terms of project management, we can tap into any strength in the J&J Puerto Rico campus for anything required in a manufacturing facility, which we call “The Strength of One”. Furthermore, our plants in the diabetes segment, have a collaboration forum where we share best practices and we benefit from learnings in Scotland or here in Puerto Rico. This keeps our sites competitive.

**HCLS:** What makes LifeScan’s test strips so innovative?

**AMI:** It is the quality of our product that makes it a choice for diabetes patients, both type-1 and type-2. There is also a product being made in LifeScan’s sister company right now, which not only measures the

glucose level in the blood but hematocrit. In this business you have to think about being innovative and cost competitive all the time.

**HCLS:** How is that being focused in terms of personalized medicine?

**AMI:** From the glucose monitoring perspective, it would be much harder to personalize. Our strips do have a certain range of accuracy for readings, using a standardized calculation code that customers use when monitoring their glucose levels. We have tried to make it easier for the patient, but the strip and measuring the glucose level can be made more or less accurate, which differentiates our products over other companies’ products. ❁





# Beyond Sustainable Compliance to Groundbreaking Results

“The advanced remediation methodologies that we offer at **Quality Consulting Group** result in a sustained compliance that guarantees the high level of efficiency you demand. Our improvements are based on the Quality Risk Management approach to ensure the validated state of regulated industries’ controls. By engaging in a partnership with you—and making your goals ours—we commit to attain the realization of our mission: to make your business exceed performance expectations, and go beyond compliance to achieve groundbreaking results.”

  
Yanira Torrellas  
President & CEO

 **Quality**  
CONSULTING  
GROUP

SINCE 2002

*Sustainable Planning,  
Implementation & Support Services  
for highly Technical Industries*

Contact us at:

**(787) 418-0240**

[WWW.QUALITYCONSULTINGGROUPPR.COM](http://WWW.QUALITYCONSULTINGGROUPPR.COM)





# DOMESTIC TALENT FINDING SOLUTIONS

**Preface:** Pedro Tejada of Right Way Environmental introduces the environmental and life science markets in Puerto Rico and elaborates on the challenges that the company faces.

---

**HCLS:** What were the main reasons for the establishment of Right Way Environmental?

**PEDRO TEJADA:** I have worked in the environmental field since 1983. In 1995, my wife and I decided to establish our own company to provide quality environmental and construction services to Puerto Rico. We started out offering our services to consulting groups that were doing business in the pharmaceutical and life science industry with projects for Pfizer, BMS and MSD. In addition, we also worked for the state and government. Over time, we became a prime contractor for various divisions for the Department of Defense, such as the U.S. Navy, U.S. Airforce and U.S. Army Corps of Engineers. Currently, the public sector is our main market and our clients hire us on a recurring basis because our business is in our name. We like to do things the right way, the first time around. We complete projects on a timely basis, cost efficiently and safely. Indeed, safety first is a main goal in our company.

**HCLS:** What are some of the daily challenges you face?

**PT:** Environmental remediation is very diverse and can be quite complicated because there are many options to any issue our clients may have. Finding the right solutions is therefore key to resolving any challenges in a cost-efficient manner. One problem that we come across frequently is the generation of hazardous waste. This is a problem that pharmaceutical companies face in particular. As Puerto Rico is an island, we need to take into account this waste when planning a new project as hazardous waste is a major cost factor in any project.

Usually, when we start new projects, the damage has already happened in terms of hazardous waste generation and we mostly attend already closed facilities. However, occasionally we also install control systems in order to prevent contamination. When engaging in these construction projects, environmental protection and waste reduction are always key priorities.



**PEDRO TEJADA**

Co-Founder and Vice President, Right Way Environmental Contractors Inc.

As time has passed, both public and private organizations have become more conscious of their environmental responsibility, which means that they usually have taken measures on their own. However, they still bring in service providers like Right Way to provide them with specific solutions to their issues. This awareness of environmental responsibility was started in the 1970s but a lot of the problems





we attend to originate from before that time.

**HCLS:** We have recently seen a considerable amount of new investments in the healthcare and life science sector in Puerto Rico. Might those investments offer an opportunity for you to return to the life sciences sector?

**PT:** Yes, we have been exploring this opportunity for the last two years. Even though the pharma-

ceutical and medical device industry is smaller than it used to be in the 1980s and 1990s, it is making a comeback due to the availability of human asset. Puerto Rico has an immense pool of talented people with a high capacity to work in a very controlled and regulated environment. You don't get this kind of quality control and quality assurance in any other nearby countries and pharmaceutical companies know that. Therefore, there is a marketplace

for these manufacturers to expand their operations here. The fact that seven out of ten of the world's top selling drugs are manufactured here shows that there is still a thriving industry in Puerto Rico. However, it is a very demanding market that is difficult to get into. First, most of the life science companies already have service providers and we need to prove that we can perform better than they do and second, pharmaceutical manufacturers nowadays have environmental control systems in place to prevent spills or reduce waste. Despite these limitations, we are optimistic and expect to engage in new pharmaceutical projects in the near future.

**HCLS:** How do you stay up-to-date with the internal developments of life science companies in order to provide continual service and maintenance?

**PT:** We don't have any issues keeping up with these developments. A majority of our work is for the federal government and their procurement and requirements do not change that much or that often. When we work for federal contractors the end client is the federal government. This means that not only do we have the same client but the same set of rules apply to everyone equally. For example, since 1995 we have serviced the U.S. Corps of Engineers annually because we not only attend to their needs but we



“Even though the pharmaceutical and medical device industry is smaller than it used to be in the 1980s and 1990s, it is making a comeback due to the availability of human assets”

also provide good service and are very professional in our conduct.

**HCLS:** What makes Right Way Environmental Contractors the right way?

**PT:** We conduct business within the law and environmental

regulations. We have a significant human asset within our company. A lot of employees have been with us for 20 years, since the beginning of our company. Moreover, the trust of our clients in the quality of services we provide is a big asset for us as well. This is how we have

attracted recurring business from the same clients. We believe that this is the only way to do it and therefore have been looking at expanding into other markets beyond the federal government. While the pharmaceutical industry in Puerto Rico is experience growth and investment right now, business in the government sector is shrinking because of the current economic situation. This opens the market for us but it also means that at a local level it will be more competitive. 🌱

# QUALITY ENVIRONMENTAL REMEDIATION & CONSTRUCTION SERVICES

Problem solving by integrating forward thinking, new technologies and logistics with common sense to achieve successful, safe and cost effective projects.



[www.rightwaypr.com](http://www.rightwaypr.com)

RIGHT WAY ENVIRONMENTAL  
HC 72 Box 3744  
Naranjito, Puerto Rico 00719

TEL +1 787-857-8832  
FAX +1 787-857-6068  
EMAIL [ptejada@rightwaypr.com](mailto:ptejada@rightwaypr.com)





# *Excellence beyond expectations*

For over 32 years CIC Construction Group, S.E. has been serving our clients with the determination to deliver excellence beyond expectations. It's reflective in the way we deliver quality professional construction services to the commercial / retail, hospitality, pharmaceutical, biotechnology, medical devices and industrial projects in Puerto Rico. Our services go beyond time, budget and quality work expectations.



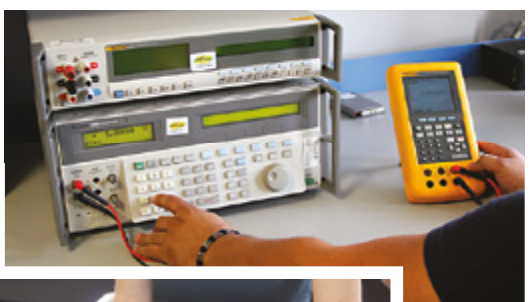
For more information visit our website, [www.cicconstruction.com](http://www.cicconstruction.com), or call us at 787-287-3540

Advertisers

COMPANY NAME	PAGE #
Abbvie	4, 7, 8, 22
<b>BioPharma Consulting Services</b>	<b>28, 41</b>
Bristol-Myers Squibb (BMS)	7, 8, 18, 19, 27, 34, 37, 54
<b>CIC Construction Group</b>	<b>13, 36, 37</b>
<b>CRB Caribe</b>	<b>27, 28</b>
<b>DHL</b>	<b>36</b>
<b>Escalate Sciences</b>	<b>35, 40</b>
Fiddler, González, & Rodríguez	24
<b>Haemonetics</b>	<b>7, 26, 42</b>
Hospital Pavia Santurce	45
Industry University Research Center Inc. (INDUNIV)	16, 17, 25
<b>Invision Engineering</b>	<b>30, 35, 36</b>
<b>iPR-AstraZeneca</b>	<b>7, 23, 31, 32, 44</b>
<b>Janssen</b>	<b>7, 8, 22, 34, 52</b>
<b>JC Automation</b>	<b>46, 47, 48</b>
Johnson & Johnson	22, 29, 37, 50, 51, 52
LifeScan Puerto Rico	7, 29, 50, 51, 52
Lilly	4, 7, 8, 34
<b>M&amp;N Electronics</b>	<b>36, 37, 43</b>
<b>MCS</b>	<b>38, 39</b>
Merck	5, 8, 11, 28, 30
<b>N&amp;CS Consulting Group</b>	<b>41, 42</b>
<b>Pfizer</b>	<b>7, 17, 35, 37, 49, 54</b>
<b>Pharma-Bio Serv</b>	<b>7, 31, 57</b>
Ponce Health Sciences University (PHSU)	42, 43, 44
Ponce Research Institute	43
Puerto Rico Health Insurance Administration (PRHIA / ASES)	14, 15, 38
<b>Puerto Rico Industrial Development Company (PRIDCO)</b>	<b>4, 6, 7, 8, 9, 10, 11, 12, 21</b>
Puerto Rico Manufacturing Association (PRMA)	21, 23, 41, 45
Puerto Rico Pharmaceutical Industry Association (PIA)	24
Puerto Rico Science, Technology & Research Trust	25
Puerto Rico Trade & Export Company (CCE)	40
<b>Quality Consulting Group</b>	<b>32, 33, 53</b>
<b>Quest Diagnostics</b>	<b>38</b>
<b>ReComS</b>	<b>25, 26, 33, 34, 35, 59</b>
<b>Right Way Environmental Contractors</b>	<b>54, 55, 56</b>
<b>Roche Diabetes Care</b>	<b>31</b>
<b>ShareTech</b>	<b>8, 39</b>
<b>Steri-Tech</b>	<b>37</b>
Stryker	5, 7, 27, 28, 29
<b>Techno Plastics Industries (TPI)</b>	<b>5, 29, 45</b>
<b>Ultimate Solutions</b>	<b>39, 40</b>
University of Puerto Rico (UPR) in Mayagüez	8, 34



*We are the Company of choice  
for the pharmaceutical, medical  
device and healthcare industries.*



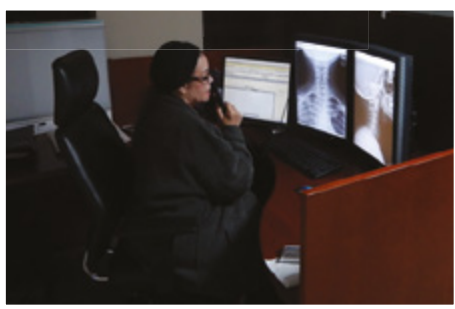
- **Regulatory Legal Services**

Conduct your Regulatory & Compliance assessment activities under attorney-client privilege.



- **Quality & Compliance Services**

Conduct your strategic Quality assessments with experienced Quality Executive professionals; outsource your temporary staffing of Quality professionals.



- **Calibration, Validation & Research**

Outsource your instrumentation & metrology activities with customized solutions.

- **MEDSCI Radiology Diagnostics**

Outsource your radiology diagnostics to an automated, rapid, robust, confidential and high quality workflow; 24/7 service.

*ReComS Group is a certified minority business by the Puerto Rico Minority Supplier Development Council.*

Phone: **787-300-6483** • Fax: **787-300-6491** • Website: **[www.recomspr.com](http://www.recomspr.com)**



# PharmaBoardroom.com

Local Conversations, Global Connections

20,000 members and counting...

Over 1,500 exclusive interviews  
with C-level executives worldwide

Reports from over 40 countries  
available for free download

Articles and analysis from  
around the world



**PHARMA**  
BOARDROOM



---

[www.pharmaboardroom.com](http://www.pharmaboardroom.com)

Photo © cover: *Flora de Puerto Rico*, Ángel Botello Barros (1946). Oil and gold leaves on masonite. Courtesy of Museo de Arte de Puerto Rico.

Photo © page 2 : Flickr: RasMarley. Leger, Fernand - 1950 The Builders (Solomon R. Guggenheim Museum, New York City).

Photo © page 4-5 : Flickr: Tom Ipri. Fernand Léger: The City.

Photo © page 12-13 : Courtesy of PRIDCO.

Photo © page 18-19 : *La Guancha Recreational and Cultural Complex*, Ponce. Courtesy of PRIDCO.

Photo © page 20-21 : Flickr: Ricymar Photography. Puerto Rico (San Juan).

Photo © page 22 : Flickr: Breezy Baldwin. Virgin Islands.

Photo © page 26 : *Tahitian Women Under Plants*, Paul Gauguin. Public domain.

Photo © page 31 : Flickr: Breve Storia del Cinema. *Machine Element 1st State*, Fernand Léger. Public domain.

Photo © page 46 : Courtesy of IPR-AstraZeneca.

Photo © 48-49: Flickr: Jean-Pierre Dalbéra. Oeuvre de Fernand Léger sur les murs du Palais de la Découverte à Paris.

Photo © 52: Flickr: nathanmac87. Blue Cobblestones of San Juan.

Photo © 53: Old San Juan. Courtesy of PRIDCO.

Photo © 56-57: Courtesy of PRIDCO.