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Can PACIV (Puerto Rico) Serve European Customers?

Since I founded PACIV in 1997, I have had it in mind to be a global company by serving a few multinational pharmaceutical companies at all their sites around the world, rather than to capture all of the business in Puerto Rico. The real question is how to provide such excellent customer service abroad so that we will maintain our reputation and client trust...People do business with people they like and trust.

—Jorge L. Rodriguez-Gonzalez, Founder and CEO of PACIV

Jorge L. Rodriguez-Gonzalez (age 39), founding CEO of PACIV—Process Automation—Controls Instruments Validations, Inc. (“PACIV”) of San Juan, Puerto Rico, had had his eye on going global since founding PACIV ten years ago. After Rodriguez-Gonzalez learned that two of PACIV’s customers—Amgen and Eli Lilly—were planning to build plants in Ireland, Rodriguez-Gonzalez wondered if the time was right to cross the Atlantic. As of October 27, 2006, PACIV had 89 employees in Puerto Rico and 33 employees in PACIV-USA. But in 1999, when PACIV was much smaller, Rodriguez-Gonzalez had tried to expand his business in Ireland, only to abandon the effort within a year because he felt PACIV’s resources had been overextended and thus made it difficult to guarantee the required level of service to his customers. Years later, Rodriguez-Gonzalez was now wiser and more realistic about the issues that he would encounter setting up an overseas operation from Puerto Rico, and he knew that he could not afford another false start. Rodriguez-Gonzalez was feeling the pressure to make a final decision as to whether he should expand PACIV’s operations to Ireland, the U.K. and Europe.

PACIV – A Star Is Born

Although in the context of the U.S., PACIV is one of thousands of small enterprises; in the context of Puerto Rico, I am a mini-celebrity, which I find surprising. I am stopped on the street, gossip columns mention me, and I am sought out for interviews and of course, donations, like a baseball player, boxer, or salsa musician from the tiny Caribbean island, who has made it in the big world. - Jorge L. Rodriguez-Gonzalez

Rodriguez-Gonzalez was born in San Juan in 1967, one of four sons and a daughter of Spanish immigrants. Rodriguez-Gonzalez’s father himself was born in Cuba, moved as a child to Spain and returned to Cuba to earn his law degree. The rise of Castro forced him to return to Spain where, unable to use his law degree, he studied accounting. In the early 1960s, the senior Rodriguez married and moved to Puerto Rico, where he became involved in the textile industry, as did many Spanish immigrants, eventually owning two small plants that made the ubiquitous *Guayabera* shirts and other

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garments for the masses. Since most of the family's cash was tied up in working capital or saved for private education and college, the Rodriguez-Gonzalez children lacked all but the basic staples, and from the age of 10, Rodriguez-Gonzalez delivered newspapers, worked on shoe polishing stands, and sold *quenepas* fruit at traffic lights, all the while helping out in the clothing warehouse, where the family also lived. The senior Rodriguez-Gonzalez sent the family every second summer to Spain to live and work with the extended family on their farm. Recalled Rodriguez-Gonzalez:

Our days were highly structured in our deeply religious family: swim before school, gymnastics after school, home at 3 p.m., nap, do homework together with my mother helping, and then out into the streets to play. I was good at math, horrible at English, and although the native Puerto Ricans saw us as "Spaniards" and I was very self-conscious, I made many friends through league basketball. I went to Syracuse University to study engineering where my elder brother was a senior and the Puerto Rican student population relatively large. But I realized that rough times were ahead when I went to freshman registration and the hall was empty: the lady told me, "The computers are down," so I went "down" to the basement to look for them. When my dorm mates first asked, "What's up?" I went to the mirror to see if there was something in my hair. I cried a lot from embarrassment and homesickness. But my family would not hear of me leaving, and although I had the toughest four years of my life, I worked to overcome my deficiencies: I would borrow lecture notes and read them many times to understand. I took the entire English as a Second Language program, getting to the freshman level when I was a senior. When I graduated, I felt that if I could make it through Syracuse, I could conquer the world. I was ready to kick ass.

Choosing among job offers, Rodriguez-Gonzalez joined the two-year Westinghouse training program in manufacturing engineering, returning to Puerto Rico to work in a Westinghouse plant. Later, Rodriguez-Gonzalez landed a position with Eli Lilly and Company ("Lilly"). Responsible for the plant's instrumentation and manufacturing control systems, Rodriguez-Gonzalez spent four years gaining experience in pharmaceutical manufacturing and compliance with U.S. Food and Drug Administration ("FDA") manufacturing regulations (see below). It was while at Lilly that Rodriguez-Gonzalez learned first-hand about the issues that, in the future, PACIV would address.

FDA Compliance

Excerpts from Sections 210.1, 201.2, and 211.68 of the FDA's Current Good Manufacturing Practice (cGMP) Regulations:¹

[Sec. 210.1, 210.2 excerpts:] The regulations set forth [herein] . . . contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture . . . of a drug . . . The failure to comply with any regulation set forth . . . shall render such drug to be adulterated . . . and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action . . . [emphases added].

[Sec. 211.68 excerpts:] Automatic, mechanical, or electronic equipment or other types of equipment, including computers . . . may be used in the manufacture . . . of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained. . . . Appropriate controls shall be exercised over computer . . .

¹U.S. Food and Drug Administration, www.fda.gov, accessed October 16, 2007.

systems. . . . Input to and output from the computer or related system of formulas or other records or data shall be checked for accuracy [emphases added].

The implication of the FDA cGMP regulations was that computer systems (as well as any aspect of the drug production process) used in making drugs were required to be conceived, designed, commissioned, validated, maintained, and, eventually, retired from use, all in accordance with strict procedures consistent with the cGMP as specified in the extensive FDA requirements. A non-compliant or non-validated computer or software application could render a drug manufactured at that facility to be adulterated and banned from the market. This created a powerful incentive for manufacturers to ensure that manufacturing facilities at different locations, for example in New Jersey, Puerto Rico, and Singapore, were identical in every respect, including automation processes.

With little advanced notice, the FDA could send uniformed inspectors to audit any aspect of a manufacturer's facility, including its computer systems, a process that might take days or weeks. The resulting "Form FDA 483," dreaded by every pharmaceutical company,² consisted of the auditor's inspectional observations and could result in penalties of varying degree, including a demand for corrective action, or a consent decree that could shut down part or all of the facility. At its most extreme, the FDA could send a U.S. Marshall to seal the plant and serve criminal indictments to the company's executives. "As a result," explained Rodriguez-Gonzalez, "the CEO of even the largest pharmaceutical company would be personally aware of every Form 483."

Compliance Experiences at Lilly del Caribe

The FDA began regulating computerized process controls when the drug makers began to adopt such controls in the late 1980s, and in the early 1990s, when Rodriguez-Gonzalez started working at Lilly in Puerto Rico³, the FDA issued the first computer-related Form 483 warnings. Rodriguez-Gonzalez experienced first-hand the difficulty of regulatory compliance when he was in charge of installing, configuring, validating and maintaining the process control systems and instrumentation for one of Lilly's Puerto Rican manufacturing facilities, when he needed to hire several different outside firms in order to implement and validate the system. Rodriguez-Gonzalez explained:

The problem was that computer system validation (CSV) really sits at the intersection of three disparate fields: *validation processes*, which are written protocols developed and implemented by consultants, that are extensive checklists for commissioning and validating new controls and instruments; *process controls*, which are specialized computers that are typically installed, configured, and maintained by engineers; and *instruments*, which are the myriad sensors, valves, and other mechanical or electronic devices which are connected to the process control system and which are typically installed and maintained by instrument engineers and technicians. Effective CSV requires an understanding of all three disciplines, but the process control engineers did not talk to the instrumentation technicians, and neither of them talked to the validation companies, whom they viewed as "pencil pushers." Furthermore, at the time, the validation companies in the pharmaceutical industry knew little about process controls and instruments, thus, little about their validation. In short, there was a lot of confusion about interpreting and complying with the FDA regulations.

During my four years at Lilly, I assisted with the development of the company's first computer validation guidelines and wrote our manufacturing site's first computer validation protocols, and we handled the first FDA computer system audit ever conducted in Puerto Rico:

² Use of the term "pharmaceutical" in this case implies "pharmaceutical, biotechnology product, and medical device."

³ Or "Lilly del Caribe." Lilly and Lilly del Caribe are used interchangeably in the case unless otherwise noted.

we passed with minimal Form 483 observations, and my exposure to corporate was great. In 1997 a different FDA inspector came down, uniform and all—she had a drill sergeant reputation, and we were worried. She walked into a meeting with plant management and demanded, “Is Rodriguez-Gonzalez still working here? I want to talk to him.” I got word of that and thought, “Oh shit, I am finished.” I responded to her subsequent “interrogations” firmly, and when she stopped the week-long audit on the third day and called together the entire management team, including corporate executives; I was nervous. She said she was done: There were no observations at all, and “Jorge is excellent.” I became a rock star, becoming known in Lilly del Caribe as well as headquarters as an expert, and the word spread to other companies—everyone in the industry knows when someone is undergoing an audit.

In 1997, after completing his MBA and a brief stint in an administrative role in another pharmaceutical company (“boring”), Lilly asked Rodriguez-Gonzalez to assist them with CSV as an outside consultant.

PACIV Gets Started in Puerto Rico

With contracts from Lilly, Johnson & Johnson, and Pfizer (then Upjohn) in Puerto Rico, PACIV remained a small operation for several years, achieving almost \$1 million in revenues in 1999 (see **Exhibit 1a**) before even hiring a secretary. From 1999–2002, PACIV grew to almost 40 employees. As Rodriguez-Gonzalez recalled:

Because I could do everything from the instrument wiring and calibration to the computer programming to writing the validation protocols, I went to customer installations with a hard hat and safety-shoes—clients respected that, and later, employees as well. In 1999 Lilly said that the FDA was coming in three weeks to an Ireland facility, which had an identical control system as the one I had worked on in Puerto Rico. I was there in three days, staying for a month. They were satisfied, and we landed our second contract with them and decided to set up an Ireland office. The problem was that all of the relevant validation professionals in Ireland worked as independent contractors who would opportunistically jump to the higher paying job. I realized that to provide the extremely high level of service I aspired to, people would have to be permanent PACIV associates, and customers would value that. So I turned down potential business in Ireland, instead helping out with Lilly in Indianapolis.

Rodriguez-Gonzalez Starts PACIV-USA

By mid-2002 Rodriguez-Gonzalez had leveraged PACIV’s growing expertise in providing CSV services⁴ (see **Exhibits 2a** and **2b** for a description of PAVIV services) to the Puerto Rican facilities of U.S. drug makers to win and fulfill several small contracts in Indianapolis, where Lilly, Roche, Abbott, and Pfizer—all major pharmaceutical manufacturers—had plants, sending engineers from Puerto Rico for extended periods in order to service the contracts. To further maintain a competitive cost structure by reducing travel expenses, Rodriguez-Gonzalez decided it would be advantageous to have staff situated permanently in the U.S. PACIV’s major competitors had set up offices in New Jersey, Philadelphia, and California, where most pharmaceutical companies had their headquarters and/or clusters of plants. Rodriguez-Gonzalez wanted to avoid head-to-head competition with

⁴ PACIV also provided control system integration and instrumentation services as well as commissioning and qualification (C&Q); its competitive advantage was that these services were provided in ways that were explicitly FDA-compliant and “validation-friendly.” For the sake of convenience in this case, these are collectively referred to as “CSV.”

companies many times PACIV's size and decided that Indianapolis offered the optimal mix of proximity to enough customers (including Lilly headquarters) and obscurity from competitors.

In 2002 Rodriguez-Gonzalez received a call from Rick Straw, an engineer responsible for senior process control and CSV at Lilly Indianapolis with whom he had worked closely on several projects. Going through a difficult period in his personal life, the highly regarded engineer told Rodriguez-Gonzalez, "I want a change and want to be your partner in the U.S.." Rodriguez-Gonzalez recalled:

I was a bit nervous because Lilly was a key customer, and I would never solicit a client employee. We agreed that we need to get Lilly's approval, and I explained to Lilly that having Rick with PACIV in Indianapolis would allow PACIV to serve them even better. Rick also explained to his superiors that he needed a personal change, and they agreed. In order to not pay taxes twice, once as a U.S. C-corporation and again as a Puerto Rican resident receiving a dividend, PACIV-USA LLC was established, owned directly by Rick (10%) and myself (90%). There was no vesting of stock: I knew Rick well and trusted him.

PACIV-USA hired its own local staff, bringing experts from PACIV Inc. for extended periods of time to train staff (Rodriguez-Gonzalez: "We call this PACIVation") and help when needed, and both affiliates grew rapidly, reaching \$16 million in consolidated revenues in 2005.

The Market for CSV

CSV and related services were required (a) when any manufacturing investment was made (which could range from the installation of one piece of equipment to an entire factory), and (b) as part of the facility's ongoing, periodic validation that fell within the operational maintenance budget. When a new plant was built, CSV services were required to a limited extent during the concept and design phases in the first two years, and intensively in the third and fourth years when the facility was constructed, commissioned, and qualified to become operational, and periodically thereafter. (See **Exhibit 3** for a description of the system development life cycle.) CSV services during plant or equipment installation tended to be capital expenses, and periodic validation was part of the operating budget.

In late 2006, Rodriguez-Gonzalez forecasted 2006 ethical drug sales worldwide to be \$555 billion, with health-care equipment and non-prescription drug sales generating an additional \$200-\$300 billion of revenues. For pharmaceutical companies alone, there would be \$30 billion in new capital investments made by the end of 2006, and plant, property, and equipment assets of about \$200 billion. Generally speaking, a third of the sales of pharmaceuticals and medical devices were in North America; a third in Europe; and a third in Asia and the rest of the world.

Rodriguez-Gonzalez used two methods to estimate market size, one derived from the size of the capital investment, and the second derived from the number of data input and output connections between the process controllers and the instruments, called I/O points. Between 7%-10% of the capital investment was budgeted for operational maintenance, 10% of which was budgeted for CSV. Using the I/O method, \$1,000 was spent about every four years for each I/O point for configuration and CSV when the equipment was operational.⁵ However, during the initial three-to-four year concept-to-commissioning stages, each I/O point was worth \$4,000. The \$4,000 total included \$1,000 for hardware and software licenses, and \$3,000 for configuration (system integration), instrumentation, CSV, and related services.

⁵ A small amount was budgeted for hardware, but one can assume that 100% of the \$1,000 was available to PACIV.

Biosciences Manufacturing in Puerto Rico and Ireland

U.S. pharmaceutical companies had begun establishing manufacturing capacity in Puerto Rico in the 1960s. (See **Exhibit 4** for an overview of Puerto Rico and its biosciences activities.) By 2006, there were 79 FDA-regulated facilities, which accounted for one third of Puerto Rico's GDP, that manufactured 13 of the top 20 drugs sold in the U.S. and provided 38,500 jobs.

Rodriguez-Gonzalez estimated that there were 641,000 I/O points installed in Puerto Rico. (See **Exhibit 5** for PACIV's estimates of I/O points in various regions.) This reflected a capital investment of \$16-\$18 billion, with an additional 38,000 I/O points being brought online as part of \$4 billion in investments from 2003-2007, and about 10,000 I/O points added yearly as part of smaller capital investments. "In general," commented Rodriguez-Gonzalez, "20% of the cost of a drug is R&D, 20% marketing, 20% is overhead, and 40% is manufacturing costs, which is up from about 20%." Profit margins were about 20%.

Since the 1980s, Ireland—similar in some ways to Puerto Rico—had become a destination for pharmaceutical companies' manufacturing for sales in Europe as well as globally, with 83 manufacturing facilities, 17,000 jobs created, and several research and development centers. Rodriguez-Gonzalez estimated:

Each manufacturing site in Ireland has an average of 5,000 I/O points, and I estimate the United Kingdom market outside of Ireland to have 680,000 I/O points, compared to just over two million in continental Europe, and almost three million in the continental U.S..

Competition

Several types of players competed, directly and indirectly, to provide CSV and related services to pharmaceutical customers. In Puerto Rico alone there were many engineering firms that offered validation services, 20 of which had 30 or more employees, not all of whom were devoted to validation. In domestic revenues, PACIV ranked third in revenues in 2005, up from sixth the previous year. Rodriguez-Gonzalez believed that none of these competitors was active outside of Puerto Rico, and in terms of consolidated revenues, PACIV was the largest. Furthermore, Rodriguez-Gonzalez observed that these other Puerto Rico-based firms offered validation for a broad range of functions, whereas PACIV specialized in process control and instrumentation validation.

There were four additional sources of competition from large players, many of which had offices throughout the world: (1) suppliers of factory automation systems, such as Rockwell Automation and Emerson; (2) manufacturers of process controllers and instrumentation, such as Allen-Bradley/Rockwell Automation, Emerson or Invensys; (3) packaged equipment manufacturers (OEMs), such as Glatt, FETTE, and Thomas Engineering; and (4) architect and engineering (A&E) firms that sometimes built the pharmaceutical facilities as contractors. Among the largest of these were Fluor Daniel, Jacobs, Skanska, and Washington Group International, which had the following on its web site:

Washington Group International pioneered the concept of validation in 1986. We are one of the largest and most diverse compliance consultants in the biotech and pharmaceuticals industries, with more than 150 employees dedicated full-time to commissioning and qualification (C&Q) validation and . . . GMP . . . compliance.⁶

⁶ Washington Division of URS Corporation web site, <http://www.wgint.com>, accessed October 22, 2007.

Fluor Daniel, the multinational engineering and construction firm with \$12 billion in revenues in 2005, listed validation as one of ten services it offered customers in a broad variety of industries.

Rodriguez-Gonzalez explained how PACIV differentiated itself in such a diverse market:

We have the following four key elements that comprise our comparative advantage: (1) a leadership team that has profound expertise in each of the services that we provide, (2) a blend of (still limited) global reach for our multinational customers and local presence by employing local experts, (3) our associates' technical expertise in control systems and instrumentation from the perspective of regulatory compliance, and probably the most important, (4) our commitment culture. Hence, we have become a global automation, commissioning and CSV partner for our large customers. By taking advantage of global replication, we can reduce time to market by 20%-30%, reduce costs by 40% through scale economies, and meet deadlines reliably, at the same time achieving global consistency and compliance.

We are without a doubt more agile and flexible in serving our customers, which is enabled by 120 PACIV associates who display a "commitment culture" [see below] and form unusually close relationships with the customers. The fact that we are privately held allows us to dedicate ourselves to our customers and our associates and not just to our own bottom line because we don't need to report quarterly to a board or shareholders. In fact, some of our projects come from the A&E firms that subcontract various services to us, because for them these services are often a nuisance. Three of them have asked if we were willing to be acquired.

Business Model

Rodriguez-Gonzalez explained that PACIV generated revenues primarily from "time and materials" contracts, with overhead allocations and a profit margin included in the hourly rates quoted to customers. "Materials," which included equipment purchases, international travel and other direct expenses, were subject to a 10% administrative fee. All budgeted and actual expenses were open to customers; one customer who conducted an audit of PACIV's books from a \$15 million multi-year project issued a report indicating that no discrepancies were found. This became known to senior management and even other customers as a first. "In the past, we had found a billing error in our favor and returned the money to the customer," commented Rodriguez-Gonzalez.

The single biggest line item was the direct cost of the engineers who were sent to client sites, accounting for about 50% of revenues which, together with related expenses (travel, insurance, benefits, etc.), were included in the hourly engineering costs quoted to customers. When combined, about 65% of PACIV's revenues were direct costs (see **Exhibit 1f** for an itemization of expenses).

Customer Relations

Rodriguez-Gonzalez reflected on the importance of customer relations for PACIV (see **Exhibit 6** for a list of customers and a breakdown of sales to each customer):

The key to our success is our associates' commitment and our relationships with our customers, whom I call our business partners, which is founded upon world class professional service, complete trust, and transparency. Our project billing is transparent, and we routinely submit the company's financial statements, as well as my personal tax return. Some customers

say, "We don't need your statements; they are confidential." I reply, "Our relationship is like a marriage, we tell each other everything."⁷

Even our human resources are transparent: we do not prevent customers from soliciting our staff, and I deleted a standard non-solicitation clause from a contract which offered to pay us \$25,000 for any staff member hired. The customer called me in and asked, "Do you realize what you are doing? What is this out-of-the-box stuff?" I replied, "You should not have to pay us anything. We are partners, like a marriage, and need to trust each other. I don't think you will do anything to hurt me because if I am weaker, it will hurt you." Our competitors were pissed at us because customers subsequently deleted the non-solicitation warrantee from all of their contracts and started requiring financial statements.

We found out that one client announced salary freezes, and I sent a letter to the client stating that PACIV will also freeze its hourly rate, even though we had internally announced a salary increase. Another client's multimillion dollar project was over budget and late, so I sent a letter saying that contrary to our contractual rate of 150% for overtime hours, we will charge overtime at 100%, and we will double overtime hours. Again, other contractors were pissed at us because the plant manager then asked all other contractors to follow suit.

We don't have any sales people or business developers, as do our competitors. Our leads come from several sources. Our leadership team has extensive industry contacts, and we are constantly attending and presenting at industry forums, and I personally spend about 40% of my time meeting customers. Our reputation is so crucial: From the beginning, we have let competitors take business if we thought we could not do a great job. A second source is word of mouth: We are constantly surprised how much our customers will go out of their ways to help us succeed. Whenever our contact people, many of whom become friends, move to another company, it helps spread our name. But our biggest generators of business are our associates, who are our on-site ambassadors and who leave a lasting impression.

Organization and People

By the last quarter of 2006, PACIV Inc. had 89 full-time employees, and PACIV-USA had 33 full-time employees (see **Exhibit 1e** for historical headcount, and **Exhibit 7** for the organizational chart). The two vice presidents of regional operations (Rodriguez-Gonzalez: "They know more about the business today than I do."), the directors of finance and human resources, and several engineering experts were based in PACIV's modest San Juan office. All associates, from vice president down, were typically in the field at client sites. Rodriguez-Gonzalez recalled:

Until 2004 our organization was a mess, everyone reported to me. In the first years, I worked seven days a week all year, and I would do all the administrative work from 5 p.m. until late at night. But in 2005 I got a shock: I did not need to travel all the time to Indianapolis. PACIV-USA did not need me much anymore. With over 25 people, Rick was really running the show well. If I could manage that in two years in the U.S., why couldn't I do that in Puerto Rico in seven years? I began to work on a formal organization, dividing Puerto Rico into two regions, and promoting people from inside: one became regional vice president; our first administrative assistant had really grown, and she became director of finance. I also promoted a 12-year veteran to be director of validation services and promoted a director of human

⁷ As of the time of the case, Rodriguez-Gonzalez had never been married.

resources. Finally, I hired one of the most experienced CSV engineers in Puerto Rico to the other vice president slot.

All PACIV employees were called “associates,” most of whom were professional engineers with bachelors of engineering or science degrees, the majority from the highly regarded University of Puerto Rico’s School of Engineering and equivalent schools in the U.S., such as Purdue University and the acclaimed Rose-Hulman Institute of Technology. Most of the engineers had the title of senior validation engineer, with the second most common being instrument or automation engineer. In customer contracts each level of expertise had a range of hourly billable rates—from approximately \$50 to \$150 per hour—and a description of the minimal qualifications (e.g., minimum of five years’ experience) of resources in that category.

In order to maintain a consistently high level of customer service expertise, PACIV had a policy of not using subcontractors, despite the fact that this practice was common in the industry. PACIV had extensive selection criteria and invested heavily in formal and informal training, as well as “culture-building” (see below). “As a result,” commented Rodriguez-Gonzalez, “we have only lost 12 people in undesired turnover, and 4 of those came back to us later.”

Rodriguez-Gonzalez believed that, compared to competitors, PACIV had the highest concentrations of engineers who were factory certified on the largest number of process control systems. In addition to system-specific certification, PACIV associates were trained in Good Automated Manufacturing Practices, C&Q, and CSV by the International Society of Pharmaceutical Engineers and underwent training in project management. Finally, all levels of associates attended management training programs in leadership, customer service, and the like.

PACIV did not have a stock option plan, but, in addition to a benefits scheme that was liberal for similar companies, PACIV’s bonus scheme distributed up to 10% of the project’s profit to billable associates, weighted by the relative number of hours they contributed. An associate’s entitlement to the performance bonus was directly related to attendance, quality, and customer satisfaction. Good performers could realistically add 10%–15% to their salary with bonuses. Vice presidents, who were not billable, received up to 5% of their region’s profits, and all associates including administrative staff were eligible for an annual bonus in addition to any project-related bonuses.

Culture and Style

Rodriguez-Gonzalez frequently used the term “commitment culture” in his communications with customers and associates, and the first article of every proposal contained a written warrantee of “complete customer satisfaction.” Over the years Rodriguez-Gonzalez had developed an interlocking series of “feed back” and “feed forward” meetings involving all associates to make sure that information cascaded up and down the organization. In addition to those informational meetings, Rodriguez-Gonzalez held half-day semi-annual vice president-level meetings, a day-long annual meeting with all associates, and monthly “Breakfast with the CEO” meetings with small groups of associates. Explained Rodriguez-Gonzalez:

I try to promote a family spirit, a sense of belonging and mission. One of my senior associates left PACIV to work for a consulting firm, and after a few months, he had a personal crisis and wanted to come back. We welcomed him. Another associate left to work for a customer and asked to come back after a few months because he was so bored. I have helped some associates who wanted to leave to find a new job. One of our senior people went through a messy divorce, I went to meet with him and told him to take some time off to sort things out;

the business can wait. I treat Rick Straw like my brother, and if he ever needs help, I will fly to meet him in an instant. An associate was unhappy with his performance bonus, so I asked to meet with him. We opened up our books, showed him all the calculations, and what others made on the project. He said, "Okay, okay." I said, "I want you to stay here and ask any questions, and make sure you have the whole picture." The word spread internally that we are fair and transparent. We get total and surprising commitment from our associates. I have heard from customers, "I saw one of your engineers from another project leaving our plant at 2 a.m." He had gone over to help one of his colleagues, even though it was not his project.

Rodriguez-Gonzalez's style was described as follows by several of his associates:

"Passion: that is the one word that characterizes Jorge. He lives, breathes, and eats PACIV."

"His commitment to customer service is 'take no prisoners': Jorge has taught us that the customer gets what they want, and proposals are received in 48 hours, not two weeks like our competitors. At the same time, he is clear with customers about what they can expect."

"I [vice president level] was surprised when I joined: I thought he would be more hands on, but he empowers me and has let me and Adrienne [director of finance] make major decisions and set strategy. But if we need him, he is there, either by phone, or he hops on a plane."

Europe Heats Up

ProsCon (Ireland)

In the late 1990s Rodriguez-Gonzalez had become aware of an Irish firm, ProsCon, which was an established factory automation system integrator and the leader in Ireland in FDA-compliant commissioning of manufacturing process controls. ProsCon had about \$25 million in revenues,⁸ 230 full-time professionals (45 of whom were validation engineers); and offices in the U.K. and Singapore. Five percent of ProsCon's cumulative 10-year revenues had come from validation services, although Rodriguez-Gonzalez believed that percentage was higher in recent years. Rodriguez-Gonzalez had considered partnering with ProsCon in 1999 when he first worked in Ireland, but despite the good communication between the companies, he was concerned that PACIV's validation-related know-how would be exploited by ProsCon to compete with PACIV. (Rodriguez-Gonzalez recalled, "I was paranoid due to inexperience.") In early January 2006, the media reported Amgen's intention to invest \$1 billion in plants and other facilities in Cork, Ireland,⁹ and it was about that time ProsCon's CEO contacted Rodriguez-Gonzalez to again explore cooperation between the two companies. Communication between the two companies continued, and in April 2006, Rodriguez-Gonzalez and Straw made a formal proposal to ProsCon to jointly submit a proposal to Amgen. Before Amgen made a decision on the proposal, Rodriguez-Gonzalez emailed his Amgen contacts about the proposed alliance, and the reaction was favorable. (See **Exhibit 8** for an excerpt of the email.) In mid-2006, amidst rumors of a \$500 million investment by Lilly in Ireland, the alliance discussions between ProsCon and PACIV intensified, with meetings in both Ireland and the U.S.

⁸ Based on PACIV estimates.

⁹ Biotechnology Ireland web site, <http://www.biotechnologyireland.com>, accessed October 21, 2007.

Snelgrove (U.K.) Appears on the Scene

Around the same time, Wayne Snelgrove, a senior process control engineer at a Lilly facility outside of London and a good friend of Straw's sent an email expressing interest in setting up PACIV in the U.K. Although Rodriguez-Gonzalez had worked with Snelgrove and when Snelgrove was posted to Indianapolis for a period of time, and had a high opinion of him, Rodriguez-Gonzalez immediately rejected the idea of recruiting another senior Lilly engineer. The plot thickened in June 2006, however, when Straw learned that Lilly would close Snelgrove's Basingstoke U.K. facility, and Rodriguez-Gonzalez, Snelgrove, and Straw began to exchange emails about the strategy and structure of a possible PACIV-UK office and the appropriate timing of Snelgrove's departure from Lilly. With Snelgrove's permission, Rodriguez-Gonzalez discussed the situation with Lilly executives, who felt that this would be a good out-placement solution for Snelgrove. Snelgrove proposed that he would leave Lilly and join PACIV by the end of 2006, and he requested that his territory cover all of Europe. **Exhibit 9** contains email excerpts of exchanges between Rodriguez-Gonzalez and Snelgrove; **Exhibit 10** contains Snelgrove's resume.

Decisions

On Friday evening, October 27, 2006, Rodriguez-Gonzalez drove the short distance from PACIV headquarters to his home. His anticipation of the weekend salsa party was displaced by the realization that he could no longer postpone several important decisions. If PACIV were to open an office in the U.K., he believed that Snelgrove would be an excellent partner to have: He had the right customer contacts, Straw knew him well and trusted him, and most importantly, Snelgrove knew where to find excellent engineers. But should he grant the 34-year-old Snelgrove all of Europe? Snelgrove had been quietly adamant about this, but would this be a deal breaker? Furthermore, Cork, Ireland, where most of Ireland's pharmaceutical facilities were concentrated, was about a three-hour trip from Heathrow Airport, and Rodriguez-Gonzalez wondered if it made more sense for Snelgrove to oversee the potential Ireland operations of PACIV from London.

The decision about Snelgrove was intimately related to the question as to the form of cooperation the ProsCon alliance should take. How much oversight would be required? Would PACIV need to hire its own engineers in Ireland, or would it be enough to rely on ProsCon?

One of the complicating factors was that the contracts with Lilly and Amgen, which were worth \$500,000 and \$700,000, respectively to PACIV in the first year, potentially reaching \$7 million and \$15 million over a three-year period, would only be awarded in Q1, 2007. Rodriguez-Gonzalez estimated that the first six months of operating a U.K. office would require out-of-pocket financing of about \$200,000. He then recalled what his wise and experienced entrepreneurship professor at UPR used to say: "Starting a venture will cost twice as much and take twice as long as you plan."

Exhibit 1a PACIV Inc. – Profit & Loss Statement (in \$\$)

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006 (est.)
Revenue	112,033	414,099	911,794	1,683,386	1,908,426	2,616,995	4,351,585	8,343,539	12,171,455	6,361,938
Labor Expenses	19,284	139,819	340,594	735,444	00),	1,260,466	2,225,348	4,196,199	5,671,516	4,509,085
Other Expenses	30,286	164,396	309,562	456,125	615,446	723,106	1,162,842	1,636,471	3,842,030	1,563,076
Other Income	-	-	590	15,148	303,703	9,405	(105,422)	247,943	893,624	6,650
*Net Income	62,463	109,884	262,228	506,947	761,681	642,828	857,973	2,758,812	3,551,534	296,427
Retained Earnings, (beginning of year)	62,463	62,463	48,792	290,141	168,863	365,240	403,264	526,636	1,845,752	1,116,223
Retained Earnings Dist. (dividends)	-	(123,554)	(20,879)	(628,225)	(565,304)	(604,804)	(734,601)	(1,439,696)	(4,281,063)	(1,019,037)
Retained Earnings (end of year)	62,463	48,793	290,141	168,863	365,240	403,264	526,636	1,845,752	1,116,223	393,613

Source: Company documents.

*PACIV as a company does not pay dividends to the partners; instead, it uses the dividends to pay its taxes.

Exhibit 1b PACIV Inc. – Balance Sheet Statement (in \$\$)

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006 (est.)
Assets										
Current Assets	52,647	135,204	224,707	204,498	463,526	439,054	760,378	2,281,860	2,446,375	997,966
Property & Equipment	25,400	21,203	37,745	109,638	100,455	91,406	62,438	39,662	38,331	56,297
Other Assets	-	-	137,700	24,155	6,552	905	1,255	1,855	8,623	57,165
Total Assts	78,047	156,407	400,152	338,291	570,533	531,365	824,071	2,323,377	2,493,329	1,111,428
Liabilities & Stockholder's Equity										
Current Liabilities	10,584	9,061	105,011	122,546	10,584	92,319	195,641	392,972	1,266,761	715,392
Long-term Liabilities	-	-	-	50,300	-	49,628	99,248	82,094	107,337	-
Total Liabilities	10,584	9,061	105,011	172,846	10,584	141,947	294,889	475,066	1,374,098	715,932
Equity	67,463	147,346	295,141	165,445	-	389,418	529,182	1,848,311	1,119,231	396,036
Total Liabilities & Stockholders' Equity	78,047	156,407	400,152	338,291	10,584	531,365	824,071	2,323,377	2,493,329	1,111,428

Source: Company documents.

Exhibit 1c PACIV-USA, LLC – P&L Statement (in \$)

	2003	2004	2005	2006
Revenues	1,157,700	2,844,296	4,267,530	3,842,939
Labor Expenses	330,133	1,743,905	2,663,997	2,619,394
Other Expenses	763,298	460,506	466,079	560,816
Other Income	-	-	-	-
*Net Income	64,269	639,885	1,137,454	662,729
Retained Earnings, beginning of year	21,200	85,469	455,024	480,197
Retained Earnings Distribution (dividends)	-	(270,330)	(1,112,281)	(576,250)
Retained Earnings, end of year	85,469	455,024	480,197	566,676

Source: Company documents.

*PACIV as a company pays dividends to the partners, who in turn pay their own taxes.

Exhibit 1d PACIV-USA, LLC – Balance Sheet Statement (in \$)

	2003	2004	2005	2006
Assets				
Current Assets	310,586	703,962	695,874	850,764
Property & Equipment	16,873	10,530	7,880	20,048
Other Assets	2,903	2,603	2,303	2,003
Total Assets	330,362	717,095	706,057	872,815
Liabilities & Stockholder's Equity				
Current Liabilities	244,893	262,071	225,860	306,139
Long Term Liabilities	-	-	-	-
Total Liabilities	244,893	262,071	225,860	306,139
Equity	85,469	455,024	480,197	566,676
Total Liabilities & Stockholder's Equity	330,362	717,095	706,057	872,815

Source: Company documents.

Exhibit 1e Headcount – Number of Employees at Year End

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
PACIV, Inc. (San Juan)	2	7	19	22	23	39	66	108	124	89
PACIV-USA Office							13	27	36	33

Source: Company documents.

Exhibit 1f PACIV Income Statement for the Nine Months Ending September 30, 2006

	YTD 2006
Income from Contracts	\$4,819,932
Misc.	4,629
Total Revenues	4,824,563
Labor and Materials Admin	2,525,428
Equipment	4,860
Travel & Lodging	121,534
Subcontracting	82,192
Rental	271
Salary Expenses	(13,402)
Allowance	356,625
Professional Services	79,721
Cost of Goods	3,157,229
Net Revenues	1,667,333
Admin Salaries	197,251
Allowance	31,884
Auto Expenses	17,967
Insurance	46,260
Legal	18,435
Accounting	6,997
Computer Services M&R	3,625
Administrative Services	4,987
Office Supplies and Maintenance	26,511
Advertising & Promotion	55,701
Bank Charges	3,924
Interest	1,940
Licenses & Permits	384
Postage & Freight	6,073
Depreciation Expenses	9,634
Rent—Equipment	152
Rent—Office	45,000
Phone and Utilities	36,254
Training, Seminars	55,295
Travel & Lodging-Admin	24,353
Uniforms	6,166
Furniture	318
Meals	20,430
Medical Insurance	890
Donations/Charitable	18,393
Employer Taxes	240,922
401K ER	61,914
401K Other Expenses	(1,562)
Medical Insurance	188,354
Municipality and Property Tax	47,867
Maintenance	2,529
Misc. Expenses	4,248
Total Expenses	\$1,201,831
Net Income (Loss)	\$465,502

Source: Company documents.

Exhibit 2a PACIV Services



**PROJECT MGMT
TEAM**

- Automation Project Management
- Resident Contractors such as Process Engineers, Project Engineers, Project Coordinators

Instrumentation

**INSTRUMENTATION
TEAM**

- Instrumentation Specification and Procurement
- Instrument Calibration, Installation, and Maintenance (NIST Traceable)
- On-Site Support of Instrumentation (Troubleshooting, emergency calls)
- Hands-on Assistance to C&Q and Validation Personnel
- Computer Maintenance Mgmt. System (CMMS) (e.g. MAXIMO)
- QC Labs Fume Hoods Certification

Control Systems Integration

**AUTOMATION
TEAM**

- Automation Project Management
- Control System Design, Configuration, Installation and Start-up
- System Integration including Batch Applications as per SP88
 - ✓ Foxboro I/A and DeltaV DCS
 - ✓ PLC Programming (SLC's, PLC's, ControlLogix)
- Data Acquisition using SCADA (iFIX, RSVIEW/RS Batch, Wonderware)
- Alarm Management Systems configuration and maintenance (e.g. TIPS)
- Instrumentation Networks such as FOUNDATION Fieldbus, DeviceNet
- On-Site Support of Control Systems (Troubleshooting, Emergency Calls)
- Control Panel Engineering Design, Construction, Installation and Start-Up

Commissioning & Qualification (C&Q) and CSV

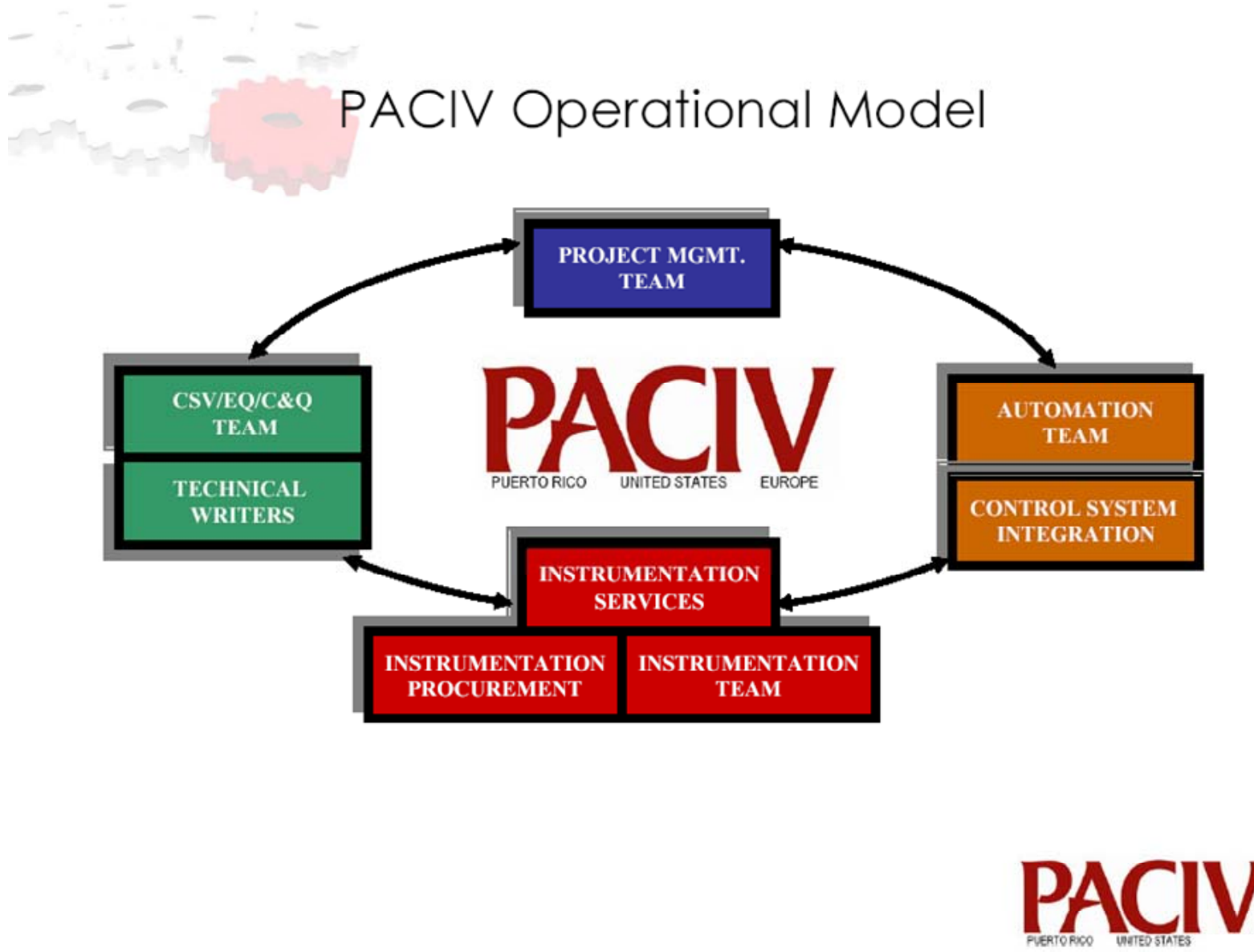
**C&Q and CSV
TEAM**

- C&Q and CSV Consulting and Training
- C&Q and CSV Development and Execution as per full SDLC (GAMP, C&Q Guidelines)
- Risk Based Approach Consulting, Training, Development and Execution ("right sized validation services") including Part 11
- Commissioning, Equipment Qualification and Platform Qualification
- Development of Validation deliverables such as Requirements, Design, and Testing Protocols (FAT, SAT, DQ, Soft. ULT/ILT/SLT, IQ, OQ, PQ)
- SOP Development and Implementation (Change Control, Backup, Security, Disaster Recovery, and Periodic System Review)
- Hands-on Execution of Commissioning and Testing Protocols for Equipment, Control System Platforms, Application Software, IT Systems, and Analytical Laboratory Systems.



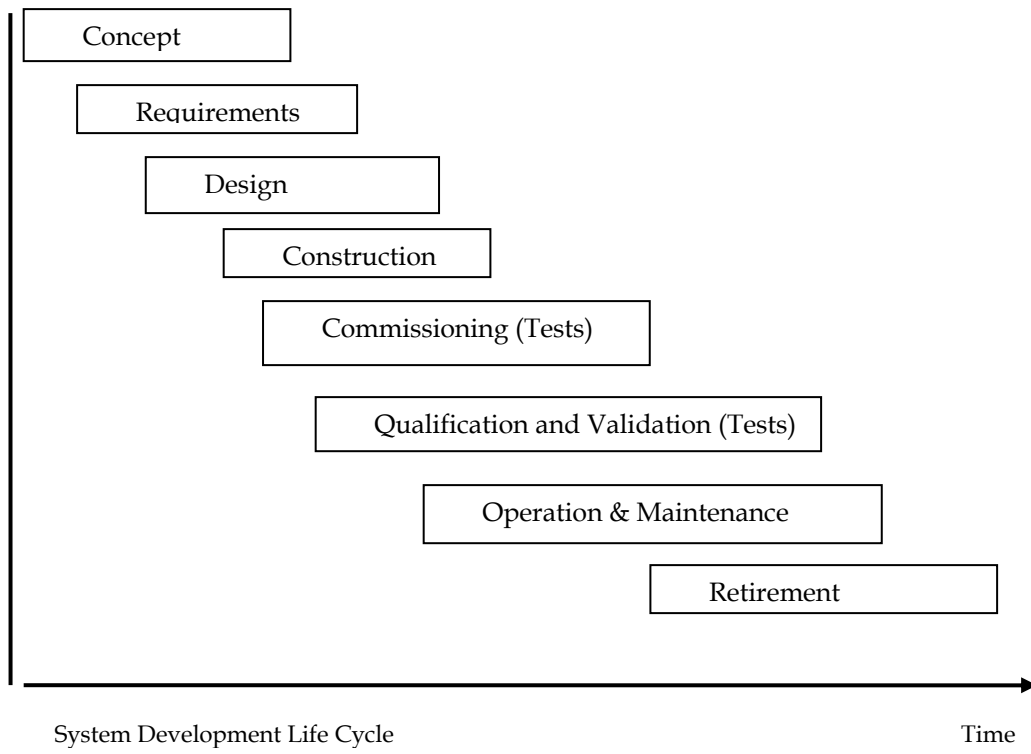
Source: Company documents.

Exhibit 2b Paciv Operational Model



Source: Company documents.

Exhibit 3 System Development Life Cycle Graph



Source: Company documents.

Exhibit 4 Puerto Rico—A Brief Overview

History. The foundations of the Commonwealth of Puerto Rico were laid in 1898 after 400 years of colonial rule, when Spain and the U.S. ended the Spanish-American War and signed the Treaty of Paris, under which Puerto Rico was granted to the U.S.. In 1917, Puerto Ricans were granted U.S. citizenship, and immediately following World War II the first governor was appointed by U.S. President Harry Truman, following which subsequent governors were determined through democratic elections. In 1952, Puerto Rico established its own constitution, and in several public referenda, voters have retained Puerto Rico's status as an independent Commonwealth of the U.S..

Economy and Society. In 2006 the 14,000-square-mile Caribbean island had an estimated population of 4,000,000 people, with an estimated 6,000,000 Puerto Ricans living in the U.S., primarily in the major urban centers. As a Latin American territory, Caribbean island, and U.S. Commonwealth, Puerto Rican economy and society were often compared (favorably) to other Caribbean and Latin American countries, and (unfavorably) to the U.S. on economic, health, and educational indicators, such as GDP per capita, employment rates, literacy, and life expectancy (see the table below). For example, Puerto Rico had about ½ of the GDP per capita of the U.S., and over twice that of its closest neighbor, the Dominican Republic, about 100 miles to the west.¹⁰ Puerto Rico had also evolved into a regional commercial hub, serving as a link between Latin America and North America in trade and finance.

	Dominican Republic	Puerto Rico	U.S.
GDP per capita (PPP)	\$8,400	\$19,300	\$43,500
Life expectancy (years)	73	78.5	78.5
Literacy	87%	94%	99%
Unemployment	16%	12%	5%

Biosciences. Although the Puerto Rican economy had experienced both ups and downs in recent years, one of the bright aspects of the economy was the pharmaceutical and medical device (sometimes referred to as biosciences) sector. Due to the proximity to the U.S., the high quality/low cost labor, and tax incentives for manufacturing in Puerto Rico, most of the U.S.-based biosciences companies had established manufacturing facilities in Puerto Rico.¹¹ This sector alone accounted for about approximately one third of Puerto Rico's GDP in 2006, creating employment and investment. Since 2003, Amgen, Eli Lilly, Abbott, and Becton Dickinson had collectively invested approximately \$4 billion dollars in manufacturing plants, creating 3,000 new jobs, which represented a 7% growth on the 38,500 base of pharmaceutical manufacturing jobs. Fourteen of the world's 20 largest pharmaceutical companies had manufacturing facilities in Puerto Rico, with 79 U.S.-FDA approved manufacturing facilities exporting approximately \$100 billion of pharmaceuticals. (These facilities manufactured 13 of the 20 top-selling pharmaceuticals in the

¹⁰ CIA, "The World Factbook," <https://www.cia.gov/library/publications/the-world-factbook/index.html>, accessed October 11, 2007.

¹¹ Much of the information in this section is adapted from: *Puerto Rico: Bioscience Destination*. INDUNIV Research Consortium, San Juan, Puerto Rico, 2007.

U.S.) In addition, 7 of the top 10 medical devices manufacturers and 25% of the world's share of biologics manufacturing were located in Puerto Rico.¹²

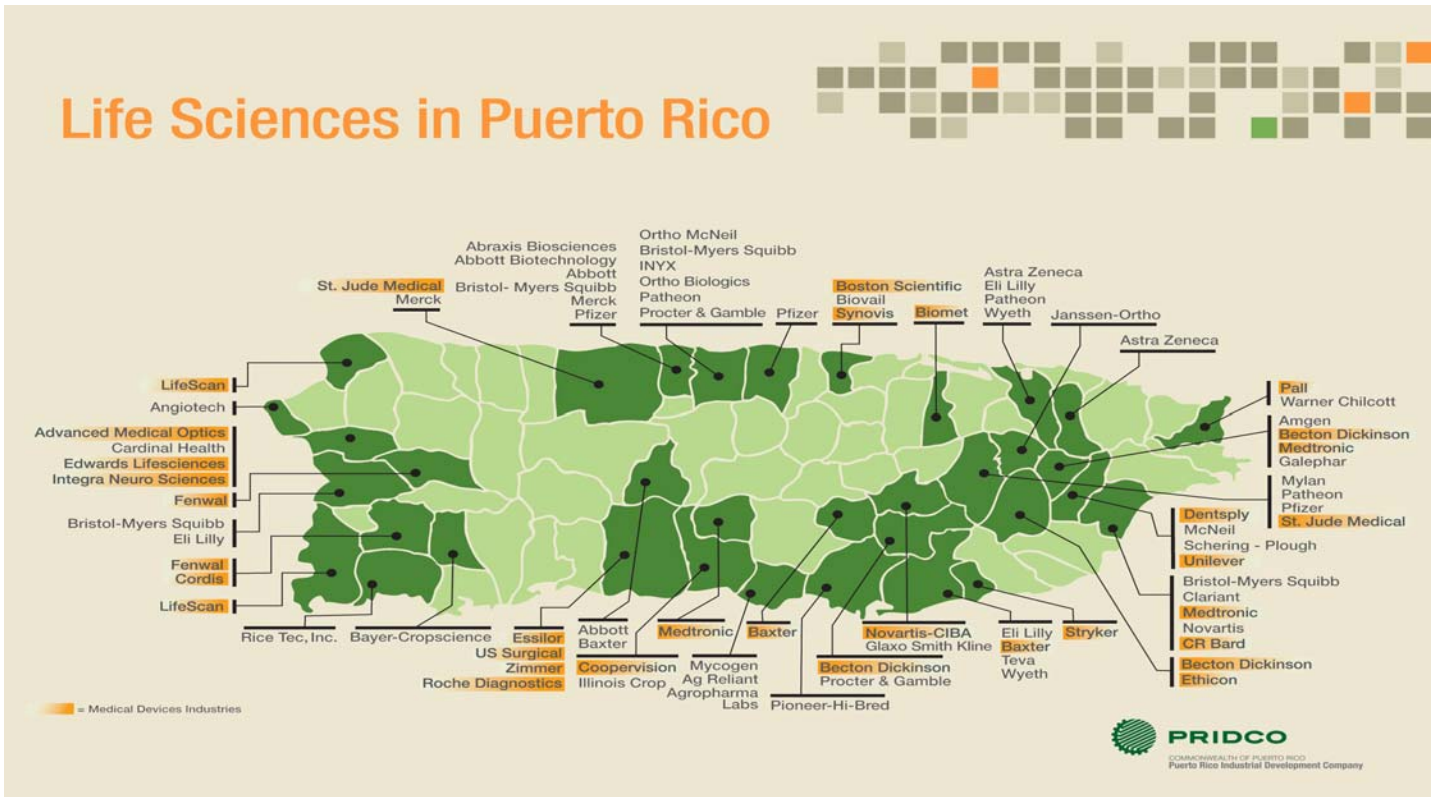
Biosciences infrastructure. One of the reasons biosciences companies started investing in Puerto Rico in the 1960s was the attractive tax structure. Exports to the U.S. were duty free, and manufacturers had effective tax rates ranging from 0 to 7%. Furthermore, 200% of expenditures on clinical research and R&D were tax deductible, and many capital investments in plant, equipment, and buildings had accelerated deduction schedules.

Nevertheless, although some of the specific tax incentives were being phased out, a unique biosciences "eco-system" had evolved by 2006, which included modern transportation, communications, and financial infrastructures, as well as a network of 139 industrial parks, including facilities for pharmaceutical R&D and manufacturing. A central element of Puerto Rico's biosciences eco-system was the island's human capital created by the higher education system:

- 40% of the 25,700 bachelor's and 5,090 post-graduate degrees awarded annually were in science and engineering.
- The University of Puerto Rico (UPR) ranked first among all U.S. institutions in graduating chemical engineers and Hispanic engineers; second in women engineers; and eleventh in undergraduate enrollment among engineering schools in the U.S.. The UPR and the Polytechnic University of Puerto Rico were in the top 20 of undergraduate engineering enrollment. UPR also had had for over a decade a special bachelor's program in industrial biotechnology.¹³
- Puerto Rico had fostered the establishment of several special programs and institutions related to biosciences, such as the Biotechnology Learning Center, the Center of Excellence for Advanced Technology, and the Puerto Rican Industrial Development Corporation, and INDUNIV, which facilitated academia-government-private cooperation.

¹² Biologics were "... all viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals." (UC Sustainable Agriculture Research and Education Program, <http://www.sarep.ucdavis.edu>, accessed October 22, 2007.)

¹³ American Society for Engineering Education, <http://www.asee.org> and Pridco, www.pridco.com.



Source: Puerto Rico Industrial Development Company (PRIDCO), <http://www.pridco.org>.

Exhibit 5 I/O Estimates for the Top 20 Pharmaceutical Companies

Top 20 Companies By Revenue	2006 Estimated Revenues (\$mil)	Market Share (%)	Growth (2005-06) (%)	Estimated I/O points per Company					
				U.S. (excl PR)	Puerto Rico	Ireland	Great Britain	Rest of Europe	Asia
Rank Name									
1 Pfizer	\$45,083	8.6	1.8	275,000	30,000	50,000	8,000	175,000	75,000
2 GlaxoSmithKline	36,947	7.1	8.9	200,000	25,000	20,000	100,000	150,000	100,000
3 Sanofi-Aventis	35,605	6.8	4.9	170,000	0	10,000	24,000	250,000	50,000
4 Novartis	28,868	5.5	17.9	75,000	8,000	15,000	8,000	200,000	50,000
5 Hoffman-LaRoche	26,560	5.1	21.4	100,000	7,000	0	8,000	175,000	100,000
6 AstraZeneca	25,741	4.9	10.5	120,000	15,000	0	45,000	150,000	100,000
7 Johnson & Johnson	23,267	4.4	4.2	150,000	70,000	25,000	32,000	100,000	50,000
8 Merck & Co.	22,636	4.3	2.8	150,000	30,000	15,000	16,000	75,000	35,000
9 Wyeth	15,683	3.0	9.8	89,000	25,000	15,000	16,000	40,000	25,000
10 Eli Lilly & Company	14,816	2.8	7.5	83,000	40,000	20,000	16,000	30,000	15,000
11 Bristol-Myers Squibb	13,861	2.6	(9.1)	120,000	30,000	0	8,000	14,000	59,000
12 Amgen	13,858	2.6	15.3	77,000	40,000	0	500	0	0
13 Abbott	12,395	2.4	(6.8)	72,000	40,000	20,000	8,000	45,000	35,000
14 Boehringer Ingelheim	10,401	2.0	15.2	40,000	0	10,000	5,000	60,000	15,000
15 Takeda	9,429	1.8	4.8	0	0	10,000	0	0	100,000
16 Bayer Schering Pharma	8,681	1.7	85.3	60,000	0	10,000	10,000	60,000	50,000
17 Schering-Plough	8,561	1.6	13.2	65,000	10,000	5,000	18,000	100,000	50,000
18 Astellas Pharma	7,723	1.5	3.1	20,000	0	0	0	20,000	100,000
19 Daiichi-Sankyo	6,859	1.3	2.6	10,000	0	0	0	10,000	80,000
20 Novo Nordisk	6,518	1.2	15.8	20,000	0	0	8,000	20,000	50,000
21 Others				855,000	261,000*	200,000	350,000	500,000	250,000
Total	373,492	71.2		2,751,000	641,000	425,000	680,500	2,174,000	1,389,000

* Following is the breakdown of I/O points for "Others" in Puerto Rico. Estimated I/O points are in ().

PR Medical Devices: Boston Scientific (10,000), Baxter (15,000), Medtronic (8,000), Becton Dickinson (10,000), U.S. Surgical (7,000), St. Jude Medical (9,000), Synovis (6,000), Biomet (5,000), Pall (10,000), Dentsply (5,000), Unilever (5,000), CR Bard (6,000), Stryker (5,000), Coopervision (7,000), Zimmer (5,000), Essilor (5,000), Fenwall (5,000), Integra Neurosciences (5,000), Edwards (5,000), Advance Medical Optics (6,000)
Total = 139,000

Pharmaceutical: Abraxis Biosciences (5,000), YNIX (5,000), Warner-Chilcott (8,000), Galephar (5,000), Becton Dickinson (6,000), BioVail (5,000), Clariant (5,000), Teva (5,000), Pioneer-Hi-Breed (5,000), Mycoge (4,000), Ag Reliant (4,000), Agropharma Labs (4,000), Illinois Crop (4,000), Paytheon (10,000), Baxter (8,000), Rice Tec (5,000), Cardinal Health (8,000), Angiotech (4,000), Mylan (5,000), Ivax (6,000), Procter & Gamble (5,000)
Total = 116,000

Biotech: Becton & Dickinson (4,000)
Total = 6,000

Grand Total of "Others" in PR: 261,000

PACIV assumed that all of the above facilities were FDA-regulated, with the exception of Rest of Europe and Asia; 40% of the European and 30% of the Asian facilities were assumed to be FDA-regulated.

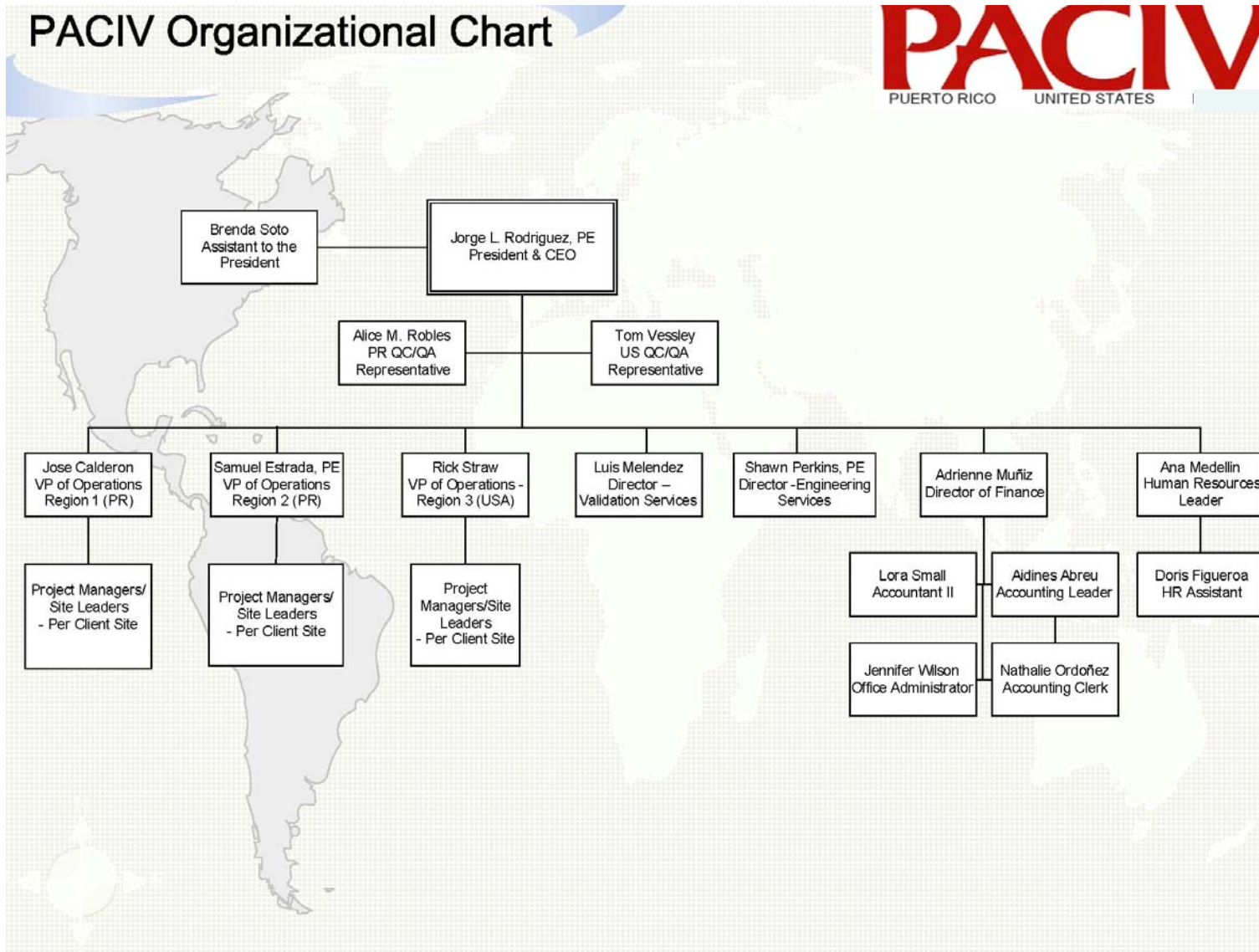
Source: Company documents.

Exhibit 6 PACIV Customers

Clients	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
Abbot Pharmaceutical									0.05%	
AES Puerto Rico, LP										0.22%
Aireko										0.06%
AMGEN Pharmaceutical								0.32%	3.65%	4.29%
AMS/Gilbane										0.44%
Astrazenca - iPR Pharmaceuticals						0.86%	3.57%	5.85%	2.67%	6.22%
Becton & Dickinson					0.38%		22.00%			
Boston Scientific										
Bristol Myers Squibb								0.07%	0.12%	0.04%
Ceph International Corp.							0.00%			
Constructora Hato Rey, Inc.				0.15%						
Cornerstone Controls, Inc.				12.36%	14.56%	7.08%	95.00%	0.03%		
Day & Zimmerman									0.03%	
Eli Lilly & Company				1.87%	14.86%	19.00%	16.92%	0.94%		
Eli Lilly, SA - Irish Branch					7.53%		7.21%			
Eli Lilly, SA - Spain Branch						0.98%	2.79%			
Empresas Barsán							0.03%		0.00%	
GAP								0.02%		
Global Turn Key										1.79%
Janssen-Ortho					0.54%	1.05%	0.28%			0.54%
Johnson & Johnson	24.00%	18.00%	6.00%	19.55%		0.14%	1.01%	0.50%	0.16%	0.04%
Honeywell International, Inc.								0.30%	0.66%	0.56%
Isopharm Services, Inc.			1.00%							
Lily del Caribe, Inc.	76.00%	82.00%	89.00%	51.46%	39.21%	31.72%	24.27%	21.35%	15.70%	27.93%
Lily del Caribe, Inc. - PR04			4.00%	9.51%	7.38%	9.24%	7.70%	3.92%	0.67%	
Lily del Caribe, Inc. - PR05						5.86%	34.71%	66.56%	71.86%	42.40%
Lily del Caribe, Inc. - PR06									3.68%	6.36%
Merck Sharp & Dohme										
Mentor Technical Group										0.20%
MOVA Pharmaceuticals				2.33%		0.05%	4.88%	0.02%		
PEC Technologies Caribbean, Inc.						0.61%				
Pfizer Pharmaceuticals					5.25%	12.32%	2.01%	0.09%	0.07%	0.19%
Pharma Serv										
Pharmacia - Barceloneta						1.79%	0.64%			
Pharmacia - Upjohn				2.78%	10.26%	2.11%				
Pharmak Group Corporation									0.10%	
Roche Diagnostics										5.79%
Schering-Plough Products										
Siemens PR								0.02%	0.00%	0.03%
VIACI Engineering & Consulting					0.07%					0.01%
Wyeth-Ayerst Lederle, Inc.									0.48%	2.34%
Master Agreement & Preferred Vendors Status:										
Astrazenca - iPR Pharmaceuticals										
Lily del Caribe, Inc - MI&CS (Master agreement is in process)										
Preferred Vendors Status:										
Merck Sharp & Dohme										
Affiliated Engineers, Inc.										
PACIV-USA, LLC, List of Clients										
Affiliated Engineers, Inc.							2.00%	0.65%	0.48%	
BMW Constructors, Inc.									1.38%	
Cook Pharmica, LLC										1.27%
Eli Lilly & Company							97.98%	99.35%	69.67%	65.94%
Pharma Automation, Ltd, LLC							0.02%			
Pharma Tech, Inc.										2.74%
Roche Diagnostics Operations, Inc.									28.47%	30.04%
Master Agreement & Preferred Vendors Status:										
Eli Lilly & Company										
Roche Diagnostics Operations, Inc.										

Source: Company documents.

Exhibit 7 PACIV Organizational Chart



Source: Company documents.

Exhibit 8 Excerpt from Email from Rodriguez to Amgen, April, 18, 2006

ProsCon and PACIV have been talking about providing Amgen with a “truly global solution” for automation, commissioning, and CSV in where we can seriously replicate methodologies, conceptual efforts, best practices, and development and execution of documentation and at the same time utilize “learning curves” of resources in order to maximize “time to market” and “compliance consistency” while achieving serious economies of scale to reduce cost and be on schedule. . . .

We have successfully done this for the past 9 years with other clients and the testimonials are very impressive. We have been able to save approx. 40% in development cost, reduce delivery schedule by 20-30% and achieve an unprecedented consistency in regulatory compliance interpretation among sites of the same company. . . .

Through this “replicability model” we also provide other great benefits such as consistency in project delivery and minimize disruption and misunderstandings since best practices within the System Life Cycle Delivery model of the capital project are very similar and only accommodate those differences originally identified or that may arise due to the idiosyncrasies of each particular project. Moreover, the client receives a “consistent” sound beat as to the methodologies and practices to follow.

Source: Company documents.

Exhibit 9 Exerpts from Emails from Rodriguez to Snelgrove (with cc: to Muniz and Straw, Sept.-Oct. 2006)

BEFORE WE DISCUSS THIS FURTHER, PLEASE THINK AGAIN, THIS IS TOUGH BLOODY SHIT, I WANT TO MAKE SURE YOU UNDERSTAND THE LONG HOURS, THE FOCUS, DEDICATION AND COMMITMENT THAT IS NEEDED, IT IS AT THE BEGINNING SICKENING AND YOU NEED TO BE PREPARED MENTALLY, PHYSICALLY AND EMOTIONALLY. . . .[capitals in the original].

Trust me, although salary we are proposing is good, the other benefits you will get are key, company car, fuel expenses and meals, and others, which will all run through the company, now they run through your own pocket after tax, a killer, not to mention the best part the 10% ownership that gives you dividends of the company plus ownership, if we ever sell, you have a 10% of the value of the company for the UK office. . . .

You will own 10% of the PACIV UK company which will be legally a separate entity registered in the UK. At the end of the year, we will have profits, those profits are then turned into dividends to its owners which they will get through the operations the next year, I get \$40,000, you get \$5,000 and Rick gets \$5,000. We will only pay dividends to ourselves once we have paid taxes on that profit not before—that is a must. And, none of us can get the dividends if the other is not getting them. For example, if there is \$10,000 available to pay the dividends from the previous year as surplus, we will divide that in 3 parts and I get \$8,000, Rick gets \$1,000 and you get \$1,000 . . . all provided that we are profitable and we have the cash to do it. . . .

Your homework is to identify how much an office lease costs, how much using a payroll accounting and legal firm will cost, estimate all these needed costs and let us know. We will make a deposit to cover all that and put a buffer of probably 6 months your salary assuming you are not billed one cent—which will not happen but to be cover. Something like that; however, to determine that final amount we need to do an estimate on all the To Do’s and we will need you to do that, we can give you the many To Do’s that we know need to happen and you can also identify others, use an excel spreadsheet and there you start your entrepreneurship career. Once you have the estimated number, you present to me and Rick, we discuss it, agree upon it, and money is in the bank.

Source: Company documents.

Exhibit 10 Wayne Snelgroves's Resume**Wayne Andrew Snelgrove****Eli Lilly and Company - UK Operations****Project Engineer**

- Responsibility for the Environmental Health and Safety (EHS) deliverables and EHS project commitments for the manufacturing engineering group. I developed an EHS vision to meet site EHS expectations. This vision was delivered using my management and leadership skills.
- During January 2005 I was selected to be part of a Site Operational Review Team. In an intensive five-week program I applied Lean Six Sigma techniques to analyze business operations and identify future operational improvements.

Ely Lilly and Company - USA Operations**Senior Process Engineer**

- Recognized as an expert within my field of equipment installation, qualification and validation, I took the lead Process Engineering role with IndyDry Operations to support the development of the Process Engineering group. I used my extensive knowledge of engineering group structures and customer support requirements to develop models for a world-class engineering department.
- During my assignment I also took the lead process engineering role for the IndyDRy forming project where I used my organizational skills to keep Process Engineering efforts to plan and used my influencing skills to help coach and develop labor from key sub-contractor groups. The main activities included equipment installation, commissioning and validation of coating equipment and technical review and oversight of all new equipment purchases. (Project value: \$65MM.)
- I also took responsibility for coaching the Staff, Project and Process Engineers within the engineering group.

Eli Lilly and Company - UK Operations**Equipment Engineer**

- Responsible for the reliability and availability of the tablet compression, tablet printing capsule filling and tablet coating suites within the Dry Products facility of Eli Lilly and Company. I also took lead roles in all major capital equipment purchases, installations and supplier quality development, with key focus on Equipment qualification and validation.
- I developed many skills including influencing of peers, coordination and facilitation of investigation teams. Communication and interpersonal skills were developed through teamwork with other groups and departments within Manufacturing.

EDUCATION: BS Mechanical Engineering, Brunel University - West London (UK)

PROFESSIONAL DEVELOPMENT/TRAININGS/CERTIFICATIONS

- Eli Lilly & Co. CSQ Policies and Procedures
- NEBOSH - General Certificate in Environment, Health and Safety
- Target Selection Recruitment Course
- Participation in ISPE, GAMP and IMechE conferences
- Six Sigma Advocate Course

Source: Company documents.