

TECH TALK

"Harmonization of C&Q and CSV Initiatives"

Rochestown Park Hotel, Cork
Wednesday, 18th February 2015, 19.00

"In many instances there is significant overlap between the computerized system validation and the commissioning and qualification activities specially for computerized control systems utilized in the manufacturing, facilities and/or utility processes (e.g. PLC's, SCADA, DCS). As such, these efforts may be combined under one effort, to ensure proper synchronization and preclude duplication of effort. As a result, a single validation/qualification effort may be performed to produce the required deliverables to achieve compliance while harmonizing work being done even when using different teams. Moreover, the commissioning effort can reduce significantly not only the qualification effort but also the CSV effort, if performed appropriately.

In today's competitive environment, clear and concise policies and procedures that promote such harmonization effort, regardless of the type of regulated manufacturing process and automation platform, will offer significant value by reducing the cost as well as the time it will take to complete such projects while still meeting the required level of compliance.

About Jorge L. Rodriguez and PACIV.

Jorge has over 24 years of experience in the areas of process control systems, instrumentation, commissioning, qualification and computer system validation for the Biotechnology, Pharmaceutical and Medical Devices industry. He is a graduate of Harvard Business School and also holds a Master in Business Administration from the University of Puerto Rico and a Bachelors of Science in Electrical Engineering from Syracuse University. He is a licensed Professional Engineer in Control Systems in the State of Indiana and the Commonwealth of Puerto Rico. Prior to founding PACIV, he worked for over 8 years as a control system engineer in various positions within Westinghouse Electric, Eli Lilly & Co. and J&J Janssen.

Jorge is the Founder, President and CEO of PACIV, a control system engineering firm. PACIV has offices in Puerto Rico, United States and Ireland. PACIV provides operational efficiencies through the automation of manufacturing processes utilizing instrumentation and control systems. PACIV clients include the largest Biotechnology, Pharmaceutical, and Medical Device companies in the world as well as other multinational clients in related industries. PACIV has over 120 associates world-wide and has revenues, in the past 16 years, of over \$135 million.



Jorge L. Rodriguez
CEO of PACIV

PACIV has been recognized as a Harvard Business School case study, 20 Best Employers in Puerto Rico and Eli Lilly & Co. Global Supplier of the Year. Jorge has been recognized as a Most Distinguish Graduate by the University of Puerto Rico, Caribbean Business's "40 under 40" business leaders in Puerto Rico, "Puerto Rico Entrepreneur of the Year" by the Puerto Rico Chamber of Commerce, and "Puerto Rico Young Entrepreneur of the Year" by the Sales & Marketing Executives (SME) of Puerto Rico.

Jorge is the immediate past President of the Board of Sofscape Caribe, Inc. and is also a board member of various non-for-profit organizations including the Supreme Court of Puerto Rico Historical Foundation. He is a member of the Young Presidents Organization (YPO) and the Puerto Rico College of Surveyors and Engineers.

Jorge loves traveling the world to learn about other cultures, reading, and spending time in the outdoors including road biking, surfing, hiking, jogging, and skiing.
