

TECH TALK

Data Integrity - A Practical Approach to Assessment and Remediation

Rochestown Park Hotel, Cork
Wednesday, *September 13*, 2017, 19:30pm

There have been recent guidance's to the Food and Drug Administration's stance, as well as other regulatory agencies and advocacy groups like MHRA, PICs, and WHO, regarding Data Integrity (DI) and data compliance for regulated environments. Moreover, there has also been significant activity regarding regulatory notices (483's, Warning Letters and Consent Decrees) on the subject of Data Integrity.

The presentation will take a historical look at the regulations to give a perspective on the progression over time of the expectations and approaches for Computerized Systems. The course will then provide a practical look at how to establish a DI program (Planning, Assessment, Remediation, Maintenance) that embeds, as well as leverages, the new interpretation and approaches for DI within the existing CSV Life Cycle so it can be sustainable.

About Presenter and Company

PACIV is a control system engineering firm specializing in industrial automation solutions for our clients in the life science sector. Founded in 1997, PACIV is a single source provider of industrial automation, validation and instrumentation solutions. PACIV has offices in Ireland, the US and Puerto Rico.

The logo for PACIV, with the word 'PACIV' in a bold, red, serif font.

Company:.

Presenter:

Jorge Luis Rodríguez González

Jorge is the Founder, President and CEO of PACIV, a global leader in industrial automation solutions. 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. He is a licensed Professional Engineer in Control Systems in the State of Indiana and the Commonwealth of Puerto Rico.



All new and existing members welcome

Open to All

Location

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