



Puerto Rico • United States • UK • Ireland

total instrumentation and control systems engineering solution provider

Date: **January 24,2012**

Positions: **Automation/Validation Engineers**

Location: **North & South Region, Puerto Rico**

PACIV, a global instrumentation, control systems integration and regulatory compliance engineering firm with offices in Puerto Rico, United States, UK and Ireland, servicing BioPharmaceutical, Medical Device, F&B and Utilities clients, is looking for **Automation/Validation Engineers** in its Puerto Rico office (South region and North region). The Automation/Validation Engineer will be responsible for the development and execution of for automated control systems as well as work within automation teams to develop and execute control system deliverables.

Job Description:

The **Automation/Validation Engineers** will be responsible for the various tasks executed within Automation Systems Development Life Cycle (ASDLC) for industrial systems within the BioPharmaceutical and/or Medical Device regulated industry. This consists on the requirements, design, configuration/programming, testing, start-up, commissioning, qualification and validation of process control systems (PLCs/DCS's platforms). It also includes development and execution of Commissioning & Qualification (C&Q) and Computer System Validation (CSV) efforts for computer control systems.

Position Responsibilities/Essential Functions

- Develop and execute Commissioning & Qualification (C&Q) documents as well as Computer System Validation (CSV) deliverables such as Planning, User/Functional Requirements, Design Specifications, Design Qualification (DQ), testing (Loop Checks, ULT, ILT, SLT) and Final Reporting.
- Prepare and/or review system related procedures such as: Operational, Security, Backup and Restore and Disaster Recovery.
- Support automation systems and teams working on the design, development and implementation of such systems (e.g. Foxboro, DeltaV, Siemens, CLx), programmable logic controllers (e.g. SLC 500, Micrologix, Logix 5000) and HMI/SCADA systems (e.g. iFix, RSView/Batch, Wonderware).

Requirements

- Education: Bachelor's Degree in Engineering (preferably Electrical or Chemical).
 - Minimum three (3) years of related experience in control systems with strong knowledge and hands-on experience of control system commissioning, qualification (C&Q) and validation (CSV) in the regulated industries (Biopharma and/or medical device).
 - Knowledge and experience of API, Bulk Chemicals, Fill Finish, Parenterals, Dry Products, and Medical Device Industry.
- Desired Hard Skill Sets:
 - Proficient knowledge of computer system life cycle concepts and FDA regulatory requirements, including 21 CFR Part 11.
 - Experience with development of FRS's, DDS, DQ, Validation and Test Planning, Development and Execution (C&Q/CSV, Installation Commissioning (ICO) and Automation Commissioning (ACO), Loop Checks, Final Reports, SOP's).
- Desired Soft Skills:

- Strong analytical and problem-solving skills.
- Deals well with uncertainty and pressure.
- Works well with others, within a team and takes accountability.
- Results driven and self-motivated.
- Strong interpersonal and communication skills (verbal and presentation).
- Organized, with strong computer literacy such as MS Project, Excel.

Other Requirements

- Location: One for the North Region, one for the South Region, Puerto Rico

Please send your resume to

Via email to:

pacivpr_autovaliengineer@paciv.com

RE: Automation/Validation Engineer PACIV-PR

Via mail to:

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