Confirm
Automation & Validation

Position Title	Validation Consultant
Location	RTP Area - North Carolina

Confirm is a professional Automation and Computer Systems Validation consultancy firm offering high-quality solutions to manufacturing companies within the pharmaceutical, medical device, and GxP-regulated industries. Whether you are a Confirm client or employee, we want you to feel confident, empowered, and in control. We believe in Quality, Reliability, Integrity, Flexibility, Trust, and Customer Service.

Position Summary & Role:

- Responsible for integrating into an onsite team that deploys, operates, maintains, and supports customer process automation systems, including qualification and validation.
- The Validation Consultant role will support standard activities such as equipment validation when needed and Computer System Validation (CSV).
- Responsible for supporting onsite CSV activities for Automated Equipment or additional activities as required by the client.
- Work on large and small mission-critical projects, site changes and strategies from inception through delivery. This can include major capital projects, change management, qualification and validation of GxP automation systems.
- Deliver solutions that meet high standards for quality, efficiency, stability, extensibility, simplicity, and operational excellence.
- Assist the client as required for investigations, or emergencies as needed.
- Weekends and after hours may be required by client for short periods of time.

Job Responsibilities:

- Perform computer systems validation activities, including risk assessments, validation planning, protocol development, execution, and final reports, in accordance with FDA regulations, GxP guidelines, and industry standards.
- Ensure that computer systems used in GxP manufacturing meet regulatory requirements, including 21 CFR Part 11, Annex 11, and other applicable regulations and guidelines.
- Develop and maintain validation documentation, such as validation plans, test scripts, validation reports, and standard operating procedures (SOPs), to ensure compliance and facilitate efficient system maintenance and change control.
- Evaluate and manage system changes, deviations, and incidents to ensure that appropriate change control procedures are followed and documented.
- Conduct risk assessments to identify and mitigate potential risks associated with computer systems, including data integrity, system security, and compliance risks.
- Perform system testing and execute test scripts to ensure that computer systems are functioning as intended and meeting user requirements.
- Stay up-to-date with industry trends, regulations, and best practices related to computer systems validation and actively contribute to the improvement of validation processes and methodologies

Confirm
Automation & Validation

Preferred Experience, Education & Qualifications:

- Requires a BS/MS in Engineering or equivalent experience.
- Must have 8+ years of experience working in FDA regulated pharmaceutical or biotechnology company.
- Experience as a technical team member.
- Strong understanding of Current Good Manufacturing Practices (cGMPs) and Good Engineering Practices (GEP), including ISA88, Good Automated Manufacturing Practices (GAMP), (ASTM) E2500, International Society of Pharmaceutical Engineers (ISPE) guidance, etc.
- Proficiency in computer systems validation methodologies, including risk-based validation approaches, validation planning, test script development, and execution.
- Validation experience with manufacturing equipment, computer systems validation and software applications.
- Experience with Emerson DCS (DeltaV), ABB or Siemens DCS qualification activities.
- Experience with HMI/SCADA packages such as: Rockwell FactoryTalk or Siemens qualification activities.
- Experience with PLCs such as: Rockwell, Siemens qualification activities.
- Experience in equipment validation and qualification.

Other Ideal Personal Characteristics:

- Good sense of humor is a must!
- Works effectively and productively with others.
- "Customer Service" attitude both internally and externally to always help get things done!
- Fluent English speaking and writing clearly, succinctly, and understandably.
- Able to adapt to change.
- Energetically focusing efforts on meeting goals, missions, and objectives.
- Effective at communicating, building rapport, and relating well to different personality types.
- Anticipating, analyzing, diagnosing, and resolving problems.

A few of the key benefits of working at Confirm:

- 100% Paid Medical Premiums (including Vision and Dental)
- Flextime Hour (PTO) for every hour worked over regular hours.
- 401K benefit is 100% vested first day of work!

Do you want to join this amazing team?

For consideration, please send your resume to: jgu@confirm-automation.com!

Or call us at: +1(910)778-0525