

# Confirm

Automation & Validation

<b>Position Title</b>	Senior Automation Engineer
<b>Location</b>	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 to an onsite team that deploys, operates, maintains, and supports customer process automation systems, equipment and applications.
- Responsible for supporting onsite Automation Engineering activities are required by the client.
- Lead complex, 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, and simplicity.
- Troubleshoot and support repair of automation systems as needed.
- Assist the client as required for troubleshooting, investigations, or emergency repairs as needed.
- Weekends and after hours may be required by client for short periods of time.
- Working for Confirm you will receive 1 hour of FlexTime for every hour worked over 40 hours! The Flextime hours are used for additional time off as needed.

## Job Responsibilities

- Develop and execute automation systems projects.
- Partner with clients, automation engineers, system service providers, contract resources and project execution resources.
- Support the design, configuration, administration and maintenance activities of manufacturing computer and automation systems, including process control systems, MES and data historians.
- Support site automation systems as required, including hardware/software design specification development, user / functional requirement development, integration, and validation in conjunction with IT Computer Systems Validation & QA Validation leads.
- Support implementations using technical standards, guidelines, and procedures in accordance with industry best practices.
- Stay up to date on the latest trends\ technology for automation systems by committing to continuing education.

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## Preferred Experience, Education & Qualifications

- Requires a BS/MS in Engineering or equivalent experience.
- Must have 12+ years of experience working in FDA regulated pharmaceutical or biotechnology company.
- Experience as a technical team member.
- Strong understanding of cGMPs and Good Engineering Practices (GEP), including ISA88, Good Automated Manufacturing Practices (GAMP), ASTM E2500, ISPE guidance, etc.
- Ability to evaluate automation systems from a compliance perspective and ensure adherence to applicable standards (i.e. 21CFR Part 11, EU Annex 11)
- Troubleshooting experience, both hardware and software, at a 24x7 manufacturing cGMP operation.
- Experienced with Emerson DCS (DeltaV), ABB or Siemens DCS products.
- Experience with HMI/SCADA packages such as: Rockwell FactoryTalk or Siemens products
- Experience with OSI PI Historian or other historians.
- Experience with PLCs such as: Rockwell, Siemens.
- Experience with Manufacturing Networking and IEC-62443 Cyber Security Standards a +!
- Experience in equipment start up, equipment commissioning 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](mailto:jgu@confirm-automation.com)!

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