Overview:
Quality In Core (QIC) is a GxP compliance consulting firm offering services and cost-effective solutions in pharmaceutical, healthcare, biotechnology, medical device and medical diagnostics industries. Our experienced team provides leading industry knowledge and proven processes. We offer the excitement of a consistently evolving career and the opportunity to continually learn while working on new and exciting projects in a variety of regions.

Here at Quality In Core (QIC) Group, we offer customizable solutions for various global companies of all sizes and ensure excellence through total lifecycle support. We consider our clients as our partners on this road to sustainable compliance and we ensure this by providing leading industry knowledge, experience, and proven processes, as well as by building site resources. Our goal is to ensure 100% customer satisfaction and quick turnaround time.

Job Title: CSV Consultant

Job Location: USA/India

Job Brief:

- Seeking a CSV Consultant to work on a variety of validation projects including manufacturing systems, lab systems, risk Assessments, etc. Some of the work may be done remotely, some at client sites and other at one of our offices.
- Immediate start date

Job Responsibilities:

- Responsible for the Computer System Validation processes of the company
- Maintain expertise in current and emerging cGMP requirements and quality trends (e.g., 210, 211, 820, and 21 CFR Part 11).
- Work independently on and successfully solve problems and complete/qualify a system within given constraint of scope, time and schedule.
- Lead system qualification efforts and be the primary client contact for coordinating work, reporting status, resolving issues, and addressing change orders as they apply.

Minimum Requirements:

- Minimum degree requirement - Bachelor's degree with atleast 10+ years of experience
- Must be willing to travel regionally and/or nationally throughout India
- Candidates must have excellent verbal communication and technical writing skills.
- Experience in generation and execution of protocols and procedures, related to different areas of qualification and validation
- Candidates must demonstrate expertise in ISPEGAMP5, ICH Q8, ICHQ9, ICH Q10 and 21 CFR part 11, Computerized System Validation, Equipment Qualification and Validation Change Control

- Working knowledge of the development of protocols for the Validation of complex computer systems (e.g., multiple GAMP classes of systems); Protocol development will include ability to develop Installation, Operational and Performance qualification documents.
- Experience in execution of system validation lifecycle deliverables
- Experience in project execution within at least one area of systems validation (e.g.,laboratory equipment, facilities utilities, manufacturing equipment)
- Proficient in Microsoft Word, Excel, Power Point and Project
- Ability to plan and manage own work
- All candidates must be legally eligible to work in India

We are an equal opportunity employer

Thank you for your consideration and application! We review all resumes and submissions, however, due to the sheer volume of requests that we receive, only successful candidates will be contacted.

Quality in Core (QiC) Group does not accept unsolicited resumes from recruiters/third parties. Please, no phone calls or emails to anyone regarding this posting.