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: Laboratory Quality Control Expert

Job Location: USA

Job Responsibilities

1. Support and implement new laboratory systems, testing, management, troubleshooting, and administration of new and existing systems within a Pharmaceutical lab environment which include but not limited to Chromatography Data Systems such as Empower, UV-Vis, GCMS, FTIR, LIMS, Mastersizer and other standalone equipment.
2. Support the development, revision, and review of written procedures for system administration of GxP systems in both Laboratory and manufacturing areas.
3. The candidate must have the ability to independently perform evaluation of applications, instruments and equipment for 21 CFR Part 11 compliance and to create a gap analysis, suggest and implement corrective actions.
4. The candidate must be able to author compliant (Administration and Usage) SOPs and other documents as per the company's standards and processes.
5. Strong computer, scientific, and organizational skills
6. Proficient in MS Project and other planning / scheduling tools.
7. Knowledge of 21 CFR Part 11 and data integrity requirements
8. Knowledge of risk-based Change Management and Quality Management systems like EDMS &TrackWise preferred.
9. Laboratory systems usage experience. Understanding of what the above systems perform (analysis), how they are configured and connected to instruments and servers.
10. Strong understanding of Data Integrity principles.
11. Strong in:
    a. Computer System Validation
    b. Equipment Qualification
    c. Spreadsheet Validation
    d. Facility Validation
    e. Utility Validation
12. Validation Lifecycle management
13. Risk Management lifecycle understanding

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.