Sr. Process Validation Engineer ID: 13102020

Engineers are the key to success in our organization. We value our engineers and their skills in furthering the cause of helping lives. This opportunity is in the IZiel Healthcare division. IZiel Group is in the business of providing engineering and regulatory services, engineering design and analysis and resource placement services. We work with global medical device manufacturers, automotive, engineering and oil and gas clients. Thorough leadership, robust work planning methodology and exceptional customer service are the key enablers of our success.

POSITION DESCRIPTION:

Provide Engineering Leadership at IZiel for medical device development, product lifecycle from gap assessment, engineering documentation, process validation (IQ, OQ, PQ, TMV, TMD) to acquisition & integration of projects for medical device companies. Project management responsibilities include the coordination and completion of projects on time within budget and within scope. Oversee all aspects of projects, set deadlines, assign responsibilities and monitor and summarize progress of project along with teammates in US & Europe. Present reports tos upper management regarding project status.

POSITION RESPONSIBILITIES:

- Participate in projects to develop engineering documentation and processes for products with emphasis on following quality systems and rigorous documentation to help companies with regulatory non-compliance issues.
- Partner with a Global team lead to collaborate and execute the project with an onshore/ off-shore model.
- Developing Validation plan and Validation summary report, review relevant documents like test plan, requirement traceability matrix, IQ, OQ, PQ, URS, Initial Risk Assessment, Test Method Validation, FAT, SAT etc.
- Provide input in planning for projects, write technical computer system validation protocols, adhering to company procedures and regulatory expectations.
- Create equipment specifications and IQ plans and reports to support equipment installation and qualification process.
- Utilize statistics to analyze data, characterize process and perform process validation activities with support from Global team.
- Create quality system procedures and work with documentation control systems to create, manage and store documents
- Train and teach on concepts related to six sigma and lean manufacturing.
- Complete on time project updates, project hours, development plans, peer/self - assessments, and successful completion of all training requirements.

DESIRED/PREFERRED QUALIFICATIONS:

- Bachelor’s in engineering or any advanced science degree.
- Working understanding of FDA, GMP, and ISO 13485.
- 10+ years of work experience in the Medical Device Industry.
- Willingness to travel, if required
- Strong Communication skills (Written & Oral)
- Team Player
- Technical Writing
- Experience in client co-ordination
- Experience with basic statistics and/or reliability methodologies.