

## **Quality Systems Specialist** (Quality Engineer/Compliance)

Contract to Hire position

### Responsibilities:

This position will ensure compliance with the requirements of our client's Quality Management System. As a member of our Quality Systems team you will actively participate in a variety of department functions:

- Represent Quality Systems on design, validation and product/process improvement teams providing support in the areas of cGMP compliance, process mapping, risk assessment, root-cause analysis, experimental design and statistical analysis
- Perform review and approval of validation plans/reports, document and process changes/deviations relative to quality system requirements
- Provide general support and training for company personnel relative to cGMP & QMS requirements
- Contribute to the development of new process workflows including creation and revision of SOPs

### Requirements:

- BS/BA or higher in engineering, physical sciences or equivalent experience
- > 5 years medical device quality systems experience in a quality engineering role
- Working knowledge of 21CFR820 & ISO standards 13485, 9001 and 14971
- Working knowledge of statistics
- Demonstrated data analysis and disciplined problem solving skills resulting in significant process improvement
- ASQ Certification (e.g. CQE) preferred

### Qualifications:

- Conscientious and detail-oriented
- Strong communication skills, both verbal and written
- Ability to prioritize and manage multiple tasks while meeting specified deadlines
- Ability to work independently and in a team environment

### Contact:

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