MedQIA

ROLE: Quality Assurance (QA) Associate

We are looking for experienced Clinical Research Professionals with experience in medical device, pharmaceutical and/or clinical research industry to join our rapidly growing team QA team, with working knowledge of regulations, standards and guidelines related to quality in clinical trials. We currently have a Quality Assurance (QA) Associate position available in our, to assists with assigned QA activities per the company's Quality Management System (QMS).

We offer a competitive salary and benefit package, along with a matching 401k, Flexible Spending Account, a collaborative work environment and an exciting opportunity to work with leaders in the QIA field. Unlike the big pharma companies who scale resources depending on a studies success, MedQIA's solid organic growth encourages long term employment and internal advancement. If you have an entrepreneurial spirit, strong organizational and planning skills, attention to detail, and would like to work with pioneers in the development and use of computer vision technology for QIA.

DEPARTMENT

QA & Regulatory Compliance

DESCRIPTION

Performs document control and training coordination activities, as well as participated in assigned QA activities per the Quality Management System (QMS).

REPORTS TO

Director of Quality

RESPONSIBILITIES & ACCOUNTABILITIES

- Performs document control activities, including quality record maintenance
- Performs activities related to personnel training and maintenance of training documentation
- Involved in administration and overall maintenance of the company's eQMS
- Participates in QA activities that include, but not limited to:
  - Audit activities, including planning, conduct, response, and documentation
  - Quality issues, complaints, nonconformities and Corrective and Preventive Actions (CAPA)
  - Vendor/ supplier qualifications
  - Quality management review
  - QA and regulatory compliance reviews of documentation
  - Periodic review of controlled documentation, and assessments of internal files
- Assists with development, review and revision of procedures in accordance with the QMS
- Communicates cross-departmentally for quality-related items for improvement
- Assists with various departmental administrative tasks, such as meeting set up and record filing
- Performs other departmental activities as needed and upon request

EDUCATION & EXPERIENCE

- Requires undergraduate degree and at least 1 to 2 years of experience in activities related to quality assurance, or an acceptable combination of education and experience
- Experience in medical device, pharmaceutical and/or biotech clinical research industry preferred
- Knowledge on eQMS a plus
- Excellent written and oral communication, attention to detail, organizational and planning skills
- Ability to perform and maintain quality work while prioritizing and managing multiple deadlines
- Ability to work with different departmental designees on quality-related activities