Quality Assurance Auditor

Company Information:
FUJIFILM Irvine Scientific, a member of Fujifilm Holdings Corporation, is a worldwide leader in the innovation and manufacture of cell culture media, reagents, and medical devices for researchers and clinicians. The company provides unrivaled service and quality to scientists working in cell therapy and regenerative medicine, assisted reproductive technology and cytogenetics, and industrial cell culture for the large-scale production of biotherapeutics and vaccines. FUJIFILM Irvine Scientific adheres to both ISO and FDA regulations and operates dual cGMP manufacturing facilities in California, USA, and Tokyo, Japan. The company's consultative philosophy combined with expertise in cell culture and compliance provides customers with unique capabilities and support. For over 45 years, FUJIFILM Irvine Scientific has remained uniquely flexible and focused on media while becoming a strategic global leader in media products and services. Additional information can be found at www.irvinesci.com.

Job Function:
We are seeking an individual to perform and assist with internal, supplier, and customer audits, coordination and completion of supplier qualifications and supplier questionnaires.

Job Duties:

- Perform internal and supplier audits (on-site and paper)
- Coordinate with internal personnel and suppliers to schedule, execute and follow up with audit observations
- Performs supplier qualification
- Complete customer and supplier questionnaires
- Maintain audit documentation and completion of audit observations
- Maintains supplier files
- Assists with customer/regulatory audits as needed
- Collaborates with other departments to meet customer requests

Experience/Education:

- High school diploma or equivalent; basic understanding of mathematics and chemistry necessary.
- Two years of college in a science discipline is preferred.
- A minimum of two (2) years of Quality Assurance in medical device manufacturer or equivalent.
- A minimum of two years in quality auditing for medical device or pharmaceutical companies
- Proficiency in current versions of MS Word, Excel
- Excellent communication and collaboration skills
- Current industry regulations, i.e. Detailed understanding of 21CFR211-cGMP, FDA QSR 820, ISO13485, Canadian Medical Device Regulations, Brazil and inspection and auditing guidelines.
- Ability to speak, read, and write English. Good Oral and communication skills

To Apply: Please apply at: https://uscareers-fujifilm.icims.com/jobs/3751/qa-auditor/job?mode=apply&iis=ISCareers

Principals only. No recruiters please.

FUJIFILM Irvine Scientific is an equal opportunity employer. All qualified candidates will receive consideration for employment without regard to race, color, religion, sex including sexual orientation and gender identity, national origin, disability, protected Veteran status, or any other characteristic protected by applicable federal, state, or local law.