



IrvineScientific®

Quality Assurance Manager

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 manage the Company's Quality Assurance personnel and activities including incoming QA inspection raw materials, raw material qualification program, change notification, validation, final product release, customer audit management, and various customer and internal support as required.

Job Duties:

- Manage QA Incoming Inspection function and personnel.
- Manage product Final Release function and personnel.
- Manage raw material qualification program including maintenance of data bases and records.
- Assist with customer audit program including scheduling, pre- and post-audit activities.
- Provide customer support in areas such as completion of surveys, providing raw material information, and related QA support.
- Assist in activities related to the preparation for and conduct of FDA and Notified Body inspections and customer audits.
- Manage deviations, CAPA and associated actions and status
- Manage validations planning, coordinating, execution, completion
- Assist and support Quality Systems management in the conduct of daily operations of the department and within the Company as required.
- Trend and Analyze Quality Indicators. Provide input as to appropriate corrective and preventive actions and suggest plans for improvement.

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 ten (10) years of Quality Assurance in medical device manufacturing or equivalent.

- A minimum of four years in a managerial position
- 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/3723/quality-assurance-manager/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.