Position: QC TECHNICIAN

Position Summary

A Quality Control Technician works independently to provide quality control support of any area assigned where Sedia Biosciences is responsible for adhering to current Good Manufacturing Practices (cGMPs) for adherence to FDA regulations and applicable ISO standards including warehouse, manufacturing processes, inspection, labeling and packaging, batch record review/disposition, and new product design review and transfer activities. Demonstrates a high level of independent judgment and discretion in the timely identification, investigation and resolution of events impacting the Quality of products and processes.

FLSA Status: Non-Exempt

Reports to: Director of Quality Systems or designate.

Duties and Responsibilities

- Works with manufacturing and other departments as required to inspect, test and approve incoming raw materials (from both suppliers and contract manufacturers), manufactured components, and finished products, as appropriate.
- Ensures all specifications are met and that applicable requirements are completed and acceptable. Ensures all issues/documentation associated with each process in assigned area have been resolved and approved prior to release to the next step and are compliant with cGMPs and SOPs and current manufacturing regulations and site procedures.
- Aids in performing reviews of batch records (includes on-the-floor review of records) to approve and accept for further processing.
- Reports and responds to nonconformances, planned deviations and corrective actions and other quality issues as needed.
- Provides feedback to manufacturing, R&D personnel, as appropriate, and supervisor on all issues and concerns with product
- Reviews temperature monitoring devices daily throughout the facility for compliance with SOP.
- Aids in sending out equipment for calibration and necessary maintenance.
- Aids in maintenance of the equipment calibration and maintenance database
- Performs weekly water sampling to ensure Sedia's water system is continually in compliance with the SOP.
- Supports manufacturing and other departments to keep the workflow moving as needed.
- Aids in creating metrics for quality system key performance indicators for management review and the Quality Dashboard as required and contributes to strategic direction or initiatives to achieve organizational and quality system effectiveness.
- Works closely with others in the assigned area to recognize opportunities for improvement and drive change through the use of Preventive Actions.
- Participates in inspection readiness activities
- Must work operate a Bio Safety Level 2 Laboratory with blood-borne pathogens with training provided.

Minimum Requirements and Qualifications

- Minimum High School diploma or Associates degree (technical field preferred) with a minimum of 3 or 1 year experience, respectively, working in a medical device or similarly-regulated industry.
- Minimum 1 year laboratory experience required.
- Experience with using Standard Operating Procedures preferred

- Knowledge and experience with data management and Quality Control systems preferred
- Good independent judgment and decision making abilities required
- Good ability to effectively communicate verbally and in writing required
- Good organizational, time management and interpersonal skills required
- Possesses demonstrated organizational skills while managing multiple activities under general direction.
- Must be detail oriented
- Strong computer skills, including working knowledge of MS Office, Excel and Outlook preferred
- Strong problem solving skills
- Ability to work well in a team environment on special projects
- Ability to work extended hours beyond normal work schedule to include, but not limited to evenings, weekends, sometimes on short notice
- Able to react to change productively and handle other essential tasks as assigned.
- Ability to work under specific time constraints

Compensation Package dependent on experience. Benefits include paid medical, dental and vision insurance and paid time off.

APPLICATION INSTRUCTIONS

Please read carefully. We consider attention to detail an important qualification for new hires. Improperly prepared or submitted applications may be delayed in routing to the appropriate hiring manager or may not be considered.

Only candidates who apply with a resume and cover letter by email or U.S. mail will be considered. First and Last Name, Mailing Address and Contact Information (email address, phone number or preferably both) must be provided. Be sure your cover letter clearly states the position(s) for which you are applying and any preferences about how to contact you.

Application by Email:

This method is preferred and will receive the fastest consideration. Submit your resume and cover letter as an attachment in either RTF, Word, or PDF format to jobs@sediabio.com. **No other formats including links to other internet addresses will be accepted and emails with such links will be deleted without opening.**

In the Subject Line of your email, enter: "*Your last name, your first name, middle initial (middle initial optional), and Job Title (that you are applying for)".* For example, "**Smith, Mary R, Senior R&D Scientist**". If you are applying for multiple positions, please submit separate emails for each position. If you do not use this format, your application may be delayed in getting to the hiring manager.

Application by U.S. Mail:

Submit your resume and cover letter to the address below. On the mailing address outside, send to the attention of HR indicating the position you are applying for. You may list multiple positions in the attention line. Only one cover letter/resume needs to be sent if you are applying for multiple positions.

Sedia Biosciences Corp.
Attention: HR (*List positions you are applying for, separated by commas, here*).
4900 NE 122nd Ave.
Portland OR 97230

ABOUT SEDIA BIOSCIENCES

Sedia is a privately held medical device and diagnostics company founded in 2009 and based in Portland Oregon. Sedia is committed to the development of novel epidemiological and diagnostic assays and clinical specimen collection products intended to expand access to healthcare worldwide. For additional information, see our website at www.sediabio.com.