Position: QA/VALIDATION ENGINEER

Position Summary

The QA/Validation Engineer works independently to develop Validation Master Plans, oversee all aspects of equipment and process validations, and provide Quality Assurance oversight of technical product and individual component specifications according to current Good Manufacturing Practices (cGMPs) for adherence to regulatory requirements and standards. Regulations and Standards include but are not limited to ISO 13485, FDA Regulations, and encompass warehouse, manufacturing, quality control processes, inspection, labeling and packaging, and new product design control and transfer activities.

FLSA Status: Exempt

Reports to: Director of Quality Systems

Duties and Responsibilities

- Responsible for creating and executing Validation Master Plans (VMPs).
- Responsible for creating and executing Validations (IQ/OQ/PQ).
- Files and maintains quality records listed above.
- Follows established procedures and policies needed to meet the demands of the Quality System in a medical device company.
- Assists in creating and maintaining FMEAs and FTAs.
- Works directly with manufacturing, R&D and other departments to create Purchased Material Specifications for components.
- Works directly with R&D and Manufacturing to create Quality Control testing instructions and processes throughout the manufacturing process and creates other testing protocols as needed.
- Develops equipment specifications, initiates Equipment Evaluation Forms and other quality forms as needed.
- Creates metrics for quality system key performance indicators for management review and Quality Dashboard as required.
- Contributes to strategic direction or initiatives to achieve organizational and quality system effectiveness.
- Assists in performing root cause analysis (RCA) and other problem solving activities to identify effective corrective actions (CAPA) and process improvements.
- Ensures all issues/documentation associated with nonconformities (NCMRs) or process deviations have been resolved and dispositioned appropriately prior to release of equipment for use.
- Works closely with others in the assigned area to recognize opportunities for improvement and drive change through the use of Preventive Actions.
- Provides Quality Assurance support and guidance to key employees.
- Participates in inspection readiness activities.
- Significantly involved in inspections by regulatory agencies and may perform internal and supplier audits as needed.
- Able to react to change productively and handle other essential tasks as assigned.
- Provides feedback to manufacturing, R&D personnel, as appropriate, and supervisor on all issues and concerns with product quality, and equipment performance.
- Must be able to operate in a Bio Safety Level 2 Laboratory with blood-borne pathogens with training provided.

Minimum Requirements and Qualifications

- Bachelor's Degree required (in Engineering or related field).

- Minimum of 3 to 5 years' experience in the Medical Device, Pharma, or similarly-regulated industry.
- Prior Process Validation and Installation/Operation/Performance Qualification (IQ/OQ/PQ) experience.
- Experience using Standard Operating Procedures.
- Knowledge and experience with data management and Quality Assurance.
- Working knowledge and understanding of ISO 13485 and 21 CFR 820 is required.
- Strong independent judgment and decision making abilities required.
- Strong verbal, written, organizational, time management and interpersonal skills required.
- Must possess demonstrated organizational skills that have proven results in the ability to be self-directed while managing multiple projects.
- Manufacturing feasibility knowledge preferred.
- Measurement system analysis/ gauge calibration knowledge preferred.
- Strong computer skills, including working knowledge of MS Word and Excel required, and MS Outlook preferred.
- Ability to work well in a team environment on special projects.
- Strong problem solving skills required.
- Must be detail oriented.
- Ability to work extended hours beyond normal work schedule, sometimes on short notice.
- 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.