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## Aderans Research Institute, Inc.

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### **Job Title & Description: Quality Engineer**

Hands on development and deployment of product development related quality assurance, metrology, quality control, and validation in the FDA regulated biologics and medical device industry. Reports to Manager, Quality Systems.

### **Responsibilities and Duties**

- Participates on Project Team as Quality Representative. Ensures that principals of Design Control are applied to Product and Process Changes and New Product Development.
- Creates, reviews and approves Quality System Documents
- Creates, reviews and approves Protocols, Process and Product Validations, Stability Protocols
- Creates, reviews and approves documents required for Design History File.
- Creates, reviews and approves Risk Assessments such as FMEA, FMECA or FTA.
- Analyzes process and product non-conformances and implements comprehensive corrective and preventive action plans for internal non-conformances.
- Serves as Independent QA Reviewer for design reviews.
- Develop and deploy Master Validation Plan including but not limited to 1) equipment, 2) processes, and 3) analytical methods.
- Implement microbial environmental monitoring program.
- Work with research scientists in development of test parameters, specifications, and validations.
- Performs Internal or Supplier Quality System Audits. Tracking and Trending of Quality Indicators
- Ensures compliance to Department and Division procedures.
- Participates and has membership in trade and/or professional organizations to ensure that state-of-the-art industry standards are communicated within the company in an efficient, timely, and accurate manner.

### **Work Experience**

- 5 or more years experience required in biologic (tissue/cell technology), implantable medical devices, parenteral pharmaceuticals, or any combination, and aseptic processes.
- Working knowledge of QSR, GLP, GCP, GTP and biologic/medical device related ISO work environment required.
- Experience in taking product through development and into commercialization.
- Experience in microbiological and facility environmental monitoring processes.
- Experience preparing, conducting and analyzing validation of equipment, analytical methods, and processes.
- Generally, has some independence for unreviewed action or decision.
- Understands basic applied statistics, statistical sampling plans, statistical process control and auditing principles.
- Fundamental knowledge of manufacturing processes. Ability to translate quality requirements into product specifications.
- Good communication skills (oral, written, and presentation). Understands how to present information dependent upon the level of the audience.
- Ability to effectively manage time and multiple task assignments.
- Ability to interpret Regulations, and Company Procedures.

### **Education**

- BS (MS preferred) in engineering or allied health field (Microbiology preferred).
- Certified Quality Engineer preferred.

### **Exposure**

- Human materials and laboratory animals (mouse, rat, pig).
- Laboratory use of chemicals and reagents typically used in cell and molecular biology, and polymer/plastic processing.
- Bioprocess equipment, chemical engineering equipment, and component assembly equipment.

### **Travel**

20-30% typically between Philadelphia and Atlanta, and to suppliers and subcontractors.

### **Location**

Marietta, GA

We seek highly creative individuals with excellent written and oral communications skills, able to work in an early stage company in a multidisciplinary team with minimal supervision to achieve project goals under challenging timelines. We offer a competitive salary, incentive plan and an extensive benefits package.

### **Contact**

Human Resources

Aderans Research Institute, Inc.

[gweaver@aderansresearch.com](mailto:gweaver@aderansresearch.com)

Aderans Research Institute, Inc. is an equal opportunity employer. M/F/D/V