



Aderans Research

Job Title & Description: Quality Control Technician/Associate

Hands on development and deployment of product, quality control, label control, and environmental monitoring in the FDA regulated pharmaceutical, biologics and medical device industry. Reports to Manager, Quality Systems.

Responsibilities and Duties

- Creates, reviews and approves Quality System Documents, Protocols, Process and Product Validations, Stability Protocols, and 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.
- Implement and maintain viable and nonviable environmental monitoring program.
- Work with scientists and engineers in development of test parameters, specifications, and validations.
- Tracking and Trending of Quality Indicators
- Raw material, in-process, and finished product quality control testing. Label and controlled inventory support.
- 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

- 2-5 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, GMP and biologic/medical device related ISO work environment required.
- Experience in microbiological and facility environmental monitoring processes.
- Generally, has some independence for unreviewed action or decision.
- Understands basic applied statistics, statistical sampling plans, statistical process control and auditing.
- 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.
- Effectively manage time and multiple task assignments, and interpret Regulations and Company Procedures.

Education

- BS in bioengineering or microbiology or allied health field.

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

10-15% 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

Fax 678-868-1918 or Email gweaver@aderansresearch.com

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