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Quality Assurance Manager-Pharma

Hiring organization
BioLink 360

Employment Type
Full-time, Contractor, Temporary

Industry
Pharma/Biotech

Job Location
New Hope, NJ

Base Salary
$ 55 - $ 75

Date posted
April 4, 2025

Description

Location: Southern NJ

Reports To: Senior Director Quality Assurance

Position Type: Hybrid

Pay: $55-75/Hour

Quality Assurance Consultant-Pharma

We are seeking a Quality Assurance GLP Consultant to support Good Laboratory Practice (GLP) compliance activities at a facility in Hopewell, NJ. This contract position requires a strong understanding of 21 CFR Part 58 regulations and hands-on experience conducting phase audits, data audits, and facility audits. The consultant will also be responsible for answering GLP-related inquiries from lab personnel and providing guidance on HPLC-related questions from lab scientists.The person in this role will support and/or conduct internal and external GCP audits of investigator sites, vendors, clinical study reports, investigator brochures, and submission documents, etc. In addition, he/she will assist in inspection readiness activities.

Responsibilities

• Ensure compliance with 21 CFR Part 58 and other applicable GLP regulations.
• Conduct phase audits, data audits, and facility audits to assess compliance and identify areas for improvement.
• Provide guidance and support to laboratory personnel, addressing regulatory and quality-related questions.
• Assist lab scientists with HPLC-related questions, troubleshooting issues, and ensuring compliance with GLP standards.
• Review and assess HPLC-related data and documentation for GLP compliance.
• Support the development and implementation of quality systems and audit procedures to maintain regulatory compliance.
• Collaborate with cross-functional teams to drive quality improvements and adherence to regulatory expectations.

Qualifications

• Extensive experience in GLP QA auditing, with a strong understanding of 21 CFR Part 58.
• Hands-on experience with phase audits, data audits, and facility audits in a GLP environment.
• Proficiency in HPLC, including the ability to assist scientists with HPLC-related questions and troubleshooting.
• Strong analytical skills with the ability to interpret and apply regulatory requirements effectively.
• Excellent communication and interpersonal skills to interact with lab personnel and cross-functional teams.

To be considered, or obtain additional information, reach out to Jackie Cassidy at Jackie@BioLink360.com