



NorthEast BioAnalytical Laboratories

925 Sherman Avenue
Hamden, CT 06514

Quality Assurance Manager Position at Northeast Bioanalytical Laboratory, Hamden, CT

Job Description

QA Manager will be responsible for implementing and managing Quality Systems in the laboratory and will perform audits of Preclinical and clinical bioanalytical protocols, in-life phases, raw data and final reports for compliance with Good Laboratory Practice Regulations (GLP) and Standard Operating Procedures (SOP) and maintain written and signed records of auditing activities.

Responsibilities may also include:

- Create, maintain, and revise departmental Standard Operating Procedures, forms, and templates
- Coordinate, conduct, and track Regulatory Training (ICH/GCP, GLP)
- Coordinate, conduct, track, and resolve Corrective Action/Preventative Action (CAPA) investigations
- Review bioanalytical protocols for compliance with all pertinent government and international GLP regulations.
- Perform raw data audits for studies to ensure accuracy and compliance with the GLPs, study protocol and Standard Operating Procedures.
- Audit in-life critical phases of ongoing studies for compliance with the GLPs, study protocol and Standard Operating Procedures.
- Prepare and sign the Quality Assurance Statement to be included with audited final report.
- Prepare and attend Sponsor site visits, review audit reports and work with management to respond to audits.
- Perform additional QA related duties as assigned.

Desired Qualifications and Experience:

Bachelor's degree in life sciences with 2 or more years of experience in a QA department in a GLP bioanalytical laboratory or equivalent

Knowledge of GCP and/or GLP and past supervisory experience is preferred.

Independent thinking and planning ability, excellent written and verbal communication skills, exceptional teamwork skills and Ability to work independently.

Knowledge of Microsoft Office ® applications and spreadsheet programs such as Excel. This position requires the individual to comprehend regulations and guidance documents and apply critical thinking skills to evaluate requirements and effectively communicate (written and oral) findings.

About Company

Northeast Bioanalytical Laboratories LLC (NEBA) is a Contract Research Organization providing multiple drug discovery and development services. NEBA is a young fast growing CRO based in Connecticut. For further details visit us at www.nebiolab.com. We offer competitive salary and benefits including healthcare insurance and 401K.

If interested, please contact Dr. Vipin Agarwal at 203-361-3768.