POSITION: Quality Control Manager

Job Description:
The Quality Control Manager is responsible for managing all daily activities of a QC team. The primary responsibility is to ensure that Quality Control personnel perform all testing accurately and as specified by the appropriate quality documentation while maintaining the lab instrumentation in accordance with approved procedures

Key Responsibilities:
The QC Manager is responsible for leadership of the QC team and the effective implementation of quality control procedures and plans to effectively o, key responsibilities include:

- Manage the QC team to test all raw materials in process samples and finished products utilizing Empower
- Participate in Method development and validation
- Review and approve new methods for inspection, and testing of raw, in-process and finished products
- Establish and maintain QC related policies and procedures in compliance with regulatory requirements,
- Coordinate all QC activities in accordance with the requirements of standard operating procedures (SOPs), protocols and product development specification documents
- Review data for compliance to specifications; document and investigate nonconformities
- Lead investigations, and/or provide expertise for resolution of laboratory deviations and OOS/OOT results related to reagents and consumables
- Ensure Good Documentation Practices for relevant QC testing procedures, and that documents are current and accurately and clearly describe processes, reagents, and acceptance criteria
- Work with Laboratory personnel to ensure all routine QC testing occurs and is documented in a timely manner
- Provide oversight and guidance for interpretation of QC test results, identify deviations, and make appropriate recommendations, as needed

Qualifications:

- BS/MS/PhD in Chemistry, Pharmaceutical Sciences, Analytical Sciences or closely related scientific discipline is required, advanced degree preferred
- Proficient in Empower
- 5+ years of demonstrated quality control experience
- Strong working knowledge of ICH, cGMP, FDA and USP guidance
- Recent experience with method development, qualification/validation and transfer preferred
- Laboratory experience with a variety of analytical techniques including, but not limited to, GC,UV,HPLC, IR
- Proficient in general and non-routine laboratory skills
- Excellent computer, documentation, communication and organizational skills required
- Must have strong attention to detail, strong problem-solving skills, as well as the ability to work in a cross-functional team environment
- Exercises judgment within well-defined and established procedures and practices to determine appropriate action
- Strong interpersonal and verbal/written communication skills required
- Able to respond quickly to shifting priorities and to meet deadlines

Located in Bergen County, Northvale, New Jersey. We offer a competitive salary and benefits package.

Contact Information: Email: careers@elitepharma.com