Chemistry Instrumentation Manager/Trainer

Corporate Statement

Nephron Pharmaceuticals Corporation is a privately owned global leader in the manufacturing of generic drug products, over-the-counter (OTC) drug products and medical devices. Nephron's products are sterile, preservative and additive free and proudly made in the USA! We are headquartered in West Columbia, South Carolina, with additional distribution centers in Kentucky and Arizona. Our location provides the ability to develop new devices and medications including respiratory therapies, ophthalmics, and injectables, for in-house or contract manufacturing opportunities. The facility utilizes completely automated manufacturing, packaging, and distribution systems, in addition to high volume and redundant utility systems, to ensure production system availability. Nephron specializes in Blow-Fill-Seal (BFS) manufacturing, a niche technology that allows a vial of medication to be formed, filled and sealed in a continuous process, in a sterile, enclosed environment and without human intervention.

As an industry leader in product safety and quality, Nephron produces a variety of inhalation solutions, and has distributed over 1 billion doses of respiratory medication per year since 2009. Nephron is currently working on research and development projects that include over 50 new products. The company's longstanding relationships with major drug wholesalers allow us to distribute our products to retail pharmacies, mail order pharmacies, hospitals, home care companies, and long term care facilities. Nephron has a sales force that covers all fifty states and Puerto Rico, with additional sales channels throughout South America, the Middle East, and Europe. **Nephron exists to provide top-quality, affordable medications to everyone.**

Position Summary:

Oversees all aspects of the laboratory instrumentation in the chemistry laboratory

- Plan and follow through of equipment routine maintenance, calibration and qualifications per internal procedures and cGMP
- Repair, troubleshoot and maintain the qualified state of the laboratory instrumentation under cGMP requirements.
- Coordinate the evaluation, purchase and installation of new instrumentation and associated software.
- Perform all administrative duties including documenting qualifications and validations to comply with regulatory requirements, cGMPs and internal SOPs.
- Performs other duties as assigned or apparent.

Primary Accountabilities:

NOTE: The Primary Accountabilities below are intended to describe the general content of and requirements of this position and are not intended to be an exhaustive statement of duties. Incumbents may perform all or most of the primary accountabilities listed below. Specific tasks or responsibilities will be documented in the incumbents' performance objectives as outlined by the incumbents' immediate supervisor or manager.

- Act as a single point of contact for instrument related issues for internal staff and vendors.
- Plan, initiate, setup and perform routine maintenance, including installation qualifications (IQ), operational qualifications (OQ), performance qualifications (PQ), and preventive maintenance (PM) per internal procedures.
- Work with QA to ensure compliance with cGMPs and internal SOPs for validation/qualification activities.
- Provide or facilitate training to laboratory staff on existing and/or new equipment.
- Create or modify SOP's, forms, logbooks, etc. as necessary to facilitate the instrumentation program and operating procedures related to instrumentation and laboratory equipment.
- Ensure that supplies are on hand to perform routine instrument maintenance and that supplies for non-routine maintenance or troubleshooting are ordered promptly as needed.
- Focus on cost savings and value delivery, ensuring that instrument maintenance is of higher quality and lower cost than vendor maintenance contracts.
- Perform all administrative duties including documenting qualifications and validations to comply with regulatory requirements, cGMPs and internal SOPs and maintenance of logbooks.
- Facilitate with IT for any laboratory support as needed including 21 CFR compliance.

Knowledge, Skills & Abilities:

Minimum Bachelor's degree or 7 years of experience working in Quality Control Chemistry and/or laboratory analytical instrumentation.

- Experience with cGMP documentation systems and with implementation of quality systems.
- Strong knowledge of FDA, USP, and industry requirements for analytical instrumentation qualification and maintenance
- Must have strong project management skills and be able to provide technical support and direction with compliance to standards in order to meet business initiatives.
- Must possess direct experience with maintaining HPLC, GC, and other common laboratory instrumentation.
- Must possess strong IT skills and a strong understanding of hardware and software troubleshooting of laboratory instrumentation.

- Must be detail oriented and have excellent organizational skills.
- Must possess effective written and oral communication skills and be able to handle multiple projects within limited time frames.
- The ability and willingness to change direction and focus to meet shifting organizational and business demands.
- The ability to effectively manage one self, demonstrates integrity, be productive under pressure, and achieve developmental goals.
- The ability to manage a multitude of resources and to be accurate and current with data and information
- The ability to create new products and processes that add value to the Business, by generating new ideas and applying creative and analytical approaches.
- Position requires standing (40%), sitting (25%), talking, hearing, typing and walking (35%).
- Position encounters the following environmental factors: hazardous materials including HPLC solvents, chemical reagents, acids and other non-specified hazardous materials that are project specific.
- Position requires safety glasses, respiratory and other non-specified protective equipment to be worn as necessary.
- Salary range: Based on experience

EEO Statement:

Nephron is an equal employment opportunity employer and does not discriminate against employees or job applicants on the basis of race, religion, color, sex, sexual orientation, age, national origin, mental or physical disability of a qualified individual, veteran or military status, pregnancy, marital status, familial status, genetic information, or any other consideration made unlawful by applicable federal, state or local law.

Nephron Pharmaceuticals is a drug free workplace.

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Print Name

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Signature Date