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QC Chemistry Operations Supervisor

Corporate Statement

Nephron Pharmaceuticals Corporation is a privately owned global leader in the manufacturing of generic respiratory medications. We are headquartered in Orlando, FL and have recently opened our newest facility in West Columbia, SC. All Nephron's products are proudly made in the USA! Our new SC 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 will utilize completely automated manufacturing, packaging, and distribution systems, in addition to, high volume and redundant utility systems that will ensure production system availability. Nephron specializes in blow-fill-seal (BFS) manufacturing, a technology that allows a vial of medication to be formed, filled and sealed in a continuous process without human intervention, and in a sterile, enclosed area.

As an industry leader in product safety and quality, Nephron continuously pursues product enhancements, such as easy to identify vial shapes, embossed lettering and color-coded packaging. In 2001, prior to FDA's 2004 mandate, Nephron led the market in the development and release of individually wrapped and bar-coded medication. Individually wrapped and bar-coded vials are a major patient safety feature and are now standard treatments in the bedside safety practices of US hospitals.

Nephron has longstanding relationships with major drug wholesalers to distribute its products among retail pharmacies, mail order pharmacies, hospitals, home care companies, and long term care facilities. Nephron has a dedicated sales force that covers all fifty states and Puerto Rico, and has additional sales channels throughout South America, the Middle East, and Europe.

Position Summary:

- Assist in overseeing the day-to-day operations of the QC Chemistry Laboratory in a high-growth, fast-paced, dynamic work environment while ensuring compliance with FDA and DEA regulations.
- Assist in the implement practical process improvements to reduce lead times and improve turn-around times for lab testing.
- Help maintain a flexible organization to allow fast changing manufacturing priorities to occur with minimum disruption and avoid back logs.
- Ensure the Quality Control group is fully compliant with all cGMP requirements including adequate maintenance and cleanliness of equipment and laboratories.
- Performs other duties as assigned or apparent.

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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.

- Plans, organizes, and manages resources on projects to assure technical and regulatory quality, budget and schedule adherence.
- Calibrate, maintain and troubleshoot analytical equipment, identify and purchase of new equipment as needed.
- Assist in overseeing the QC Chemistry lab operations and assure operations are conducted in accordance with regulatory requirements and expectations.
- Responsible for drafting SOPs related to Analytical Services functions, equipment, documentation, and/or processes.
- Develop and approve methods and results including: product specifications; protocols, SOPs, and reports for analytical method validation and stability studies; IQ/OQ/PQ protocols and reports for equipment; master production records.
- Direct, perform and resolve out-of-specification investigations and implement corrective and preventative actions

Knowledge, Skills & Abilities:

- Minimum Bachelor's degree and/or 5 years of experience working in Quality Control Chemistry and/or Research & Development.
- Experience with cGMP documentation systems and with implementation of quality control systems.
- Knowledge of FDA manufacturing/regulatory quality systems regulations, qualification, facilities and investigation requirements.
- Preferred experience in analytical method development, transfer and validation.
- Must possess a strong experience base in product QC testing and release procedures and documentation.
- Must be detailed 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.
- Must have skills in HPLC, GC, and mass spectroscopy detection technologies.
- Must have excellent communication and technical writing skills.

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- Expected to be a leader in the technology area and to train others for more routine and specific project-oriented applications.
- The ability and willingness to change direction and focus to meet shifting organizational and business demands.
- The ability to create and contribute environment that values people, encourages trust, teamwork, and open communication, and provides participation, learning, feedback and recognition.
- The ability to effectively manage one self, demonstrates integrity, be productive under pressure, and achieve development goals.
- The ability to manage a multitude of resources and to be accurate and current with data and information.
- Position requires bending, typing, climbing, lifting, reaching, vision, standing, sitting (10%), walking, and hearing.
- 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

_____ _____

Signature Date