Nucleus
RadioPharma

Job Title: **QUALITY CONTROL (QC) CHEMIST**
Reports to: **Director, Quality**
Classification: **Full Time, Exempt**
Work Location: **Rochester, MN - onsite**

ABOUT NUCLEUS RADIOPHARMA:
Founded by Mayo Clinic and Eclipse Ventures, Nucleus RadioPharma is a Contract Manufacturing and Development Organization built to ensure patients can access potentially life-saving radiopharmaceuticals through technologies to modernize the clinical development, manufacturing, and supply chain of these promising new treatment tools.

POSITION SUMMARY:
The **Quality Control (QC) Chemist** will play a key role in the execution of QC analytical methods and assist in the supervision of a highly effective QC team to support radiopharmaceutical drug production.

PRINCIPAL RESPONSIBILITIES:
- Supports the development and leads the execution of QC methods for radioactive drug products in a GxP environment, including radio-HPLC, TLC, GC, gamma spectroscopy, endotoxins, pH, etc.
- Assists in supervision of the QC Chemistry team which includes training, coaching, and offering performance and development management.
- Provides support and assistance for laboratory personnel in daily activities to fulfill client and GMP requirements.
- Responsible for training QC Techs on cGMP guidelines 21 CFR 210, 211, 212 (as applicable).
- Responsible for training QC Techs in analytical and QC testing methods.
- Serves as Subject Matter Expert for Quality Control testing on site.
- Collaborate with other groups within the facility to understand goals and communicate changes throughout the organization.
- Provide input for strategic planning for new product lines.
- Work closely with scientific staff to evaluate technical feasibility of new products.
- Maintain QC budget and responsible for communicating QC laboratory staffing and budget needs .
- Writes, maintains and updates necessary Standard Operating Procedures (SOPs), Validation Protocols and Validation Report.
- Performs other duties as assigned.

MINIMUM QUALIFICATIONS:
- Bachelor's degree in chemistry or related area required; Master’s degree in chemistry or related area preferred.

- Minimum of 5 years of related experience required.
- Minimum of 3 years in a leadership position within cGMP Quality Control pharmaceutical space
- Preferred qualifications:
    - 3 years of experience in leadership position within quality control of cGMP Radiopharmaceuticals

KNOWLEDGE, SKILLS, ABILITIES:

- Knowledge of 21 CFR 212 and USP 823 regulatory requirements preferred.
- Analytical instrument operation and maintenance (HPLC, GC, TLC, etc.) experience required.
- Radioactive material handling of gamma, beta and/or alpha emitters in radiological facilities (shielded glove boxes, hot cells etc.) experience preferred.
- Chemical and radiological laboratory safety (regulatory and best practices) experience preferred.
- Experience working in facilities compliant with ICH Q7, GxPs, 21 CFR 211 and 21 CFR 212 preferred. Knowledge of regulations applicable to drugs and devices (21 CFR Parts 210/211, ICH and FDA guidances, etc.) and the ability to apply them based on the phase of the project (GLP, Phase I, PhaseII/III, etc.) required.
- Writing of technical documents (procedures, records, forms, experimental reports etc.) experience required.
- Supervisory experience for scientific team experience required.
- Advanced ability to effectively lead one or more projects with competing priorities to meet the demands of a fast-paced and dynamic work environment required.
- Adaptable to quickly changing priorities required.
- In-depth critical thinking skills to evaluate issues and identify a potential solution. Creatively addresses complex or new problems required.
- Advanced interpersonal skills, including but not limited to problem-solving, teamwork development, and leadership with other team members. Works well with others to achieve common goals required.
- Ability to foster an inclusive and cooperative work environment required.
- Ability to work sitting and standing for extended periods, grasping/gripping, fine motor control with hands required.
- Ability to lift / move, transport, position equipment and work items weighing up to 30 pounds across on a frequent basis.

This job description is a summary of the typical functions of the position, not necessarily an exhaustive or comprehensive list of all possible position responsibilities, tasks and duties. The company reserves the right to assign or reassign duties and responsibilities to this job at any time. This job does not constitute a written or implied contract of employment; employment remains "at-will".

Nucleus RadioPharma is an equal opportunity employer and believes everyone deserves respect, dignity and equality. All applicants will be considered for employment without attention to race, color, religion, sex, sexual orientation, gender identity, national origin, veteran or disability status.