Nucleus RadioPharma

Job Title: **MICROBIOLOGIST**
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 **Microbiologist** will play a key role in the execution of microbiological QC methods and assist in the supervision of a highly effective microbiology QC team to support radiopharmaceutical drug production.

PRINCIPAL RESPONSIBILITIES:
- Leads the execution of microbiological methods for radioactive drug products in a GxP environment, including Sterility and Bioburden testing of radioactive drug products, intermediates, and raw materials per USP and Standard Operating Procedures (SOP).
- Review and interpret FDA, EU and other international regulations, standards and guidelines covering sterilization and microbial contamination control in the manufacture of aseptic radiopharmaceutical products.
- Perform Growth Promotion testing per USP Methods for various microbiological media.
- Prepare and analyze Biological Indicators in support of Validation and Qualification activities.
- Perform environmental monitoring (EM) activities.
- Analyze microbial samples to quantify growth and subculture pure isolates as required. Provide support and assistance with environmental monitoring activities.
- Assists in supervision of the Microbiology team which includes training, coaching, and relaying performance and development management to supervisor.
- Provides support and assistance for laboratory personnel in daily activities to fulfill client and GMP requirements.
- Responsible for training Microbiology Techs on cGMP guidelines 21 CFR 210, 211, 212 (as applicable) and Microbiological test methods.
- Responsible for training QC Techs in microbiological testing methods.
- Serves as Subject Matter Expert for Microbiological testing on site.
- Collaborate with other groups within the facility to understand goals and communicate changes throughout the organization.
- Writes necessary SOPs, Validation Protocols and Validation Report.

- General laboratory housekeeping duties and maintenance of the department, premises, and equipment.
- Manage inventory of laboratory supplies.
- Collaborate with other team members to ensure the consistent and timely completion of all testing and other tasks in support of business needs.
- Ensure a safe and quality-minded working environment through conformance with training, general awareness, compliance to safety/Quality guidelines and SOPs, and radiation protection guidelines.
- Attend mandatory trainings as required by site regulatory requirements and management.
- Perform other general duties associated with the position as required by supervision.
- Communicate laboratory budget and laboratory staffing needs to supervisor.
- Performs other duties as assigned.

MINIMUM QUALIFICATIONS:

- Bachelor's degree in biology or related area required; Master's degree in microbiology or related area preferred.
- Minimum of 3 years of related experience required within cGMP Microbiology laboratory.
- Working knowledge of 21 CFR 210, 211, 212 and USP 823 regulatory requirements preferred.
- 5 years of related experience with 3 years of experience in leadership position within micro lab of cGMP Radiopharmaceuticals

KNOWLEDGE, SKILLS, ABILITIES:

- Writing of Microbiological QC SOPs, test methods, protocols and reports, required.
- Experience with aseptic techniques while performing Sterility, Endotoxin, Particulate Matter and Bioburden testing of drug products, intermediates, and raw materials per USP and Standard Operating Procedures required. Testing of radioactive drug products, preferred.
- Radioactive material handling of gamma, beta and/or alpha emitters in radiological facilities (shielded glove boxes, hot cells etc.) preferred.
- Work in facilities compliant with ICH Q7, GxPs, 21 CFR 211 and/or 21 CFR 212 required. 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.
- Supervisory experience for scientific staff preferred.
- Advanced ability to effectively lead one or more projects with competing priorities to meet the demands of a fast-paced and dynamic work environment. Adaptable to quickly changing priorities.
- In-depth critical thinking skills to evaluate issues and identify a potential solution. Creatively addresses complex or new problems.
- 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.
- Ability to foster an inclusive and cooperative work environment.
- Ability to work sitting and standing for extended periods, grasping/gripping, fine motor control with hands.
- Communicate Microbiology QC laboratory budget and hiring needs to management.

- 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.