Job Title: QUALITY MANAGEMENT SYSTEM (QMS) MANAGER
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 Management System (QMS) Manager** will play a key role in the oversight of the Quality Assurance (QA) program and the QMS at the site level to support radiopharmaceutical drug production.

PRINCIPAL RESPONSIBILITIES:
- Develop, manage, and maintain continual improvement of QA programs, policies and procedures for pre-clinical, clinical, and commercial radiopharmaceutical drug production.
- Maintain oversight of the QA program and QMS at a single manufacturing facility producing products under 21 CFR Part 210, 211, and 212 regulations.
- Apply quality assurance processes and procedures at the site level to ensure product quality and regulatory compliance.
- Strong collaboration, including problem solving and continuous improvement efforts, and communication with the Engineering and Operations team.
- Write, review, approve, and/or implement quality procedures, specifications, processes, and methods as required.
- Oversee the examination and evaluation of each lot of incoming material before use to ensure that the material meets its established specifications.
- Prepare and present periodic review of the quality system for regular 'Management Review'
- Final review and approval of batches for release and/or recall
- Ensure that components, containers, closures, in-process materials, packaging materials, labeling, and finished dosage forms are examined and approved or rejected to ensure that all these meet their current specifications.
- Development, review, and approval of facility, process, and equipment validations
- Ensure that team members are properly trained and qualified and that training tracking and documentation is accurate and maintained in a timely manner.
- Conduct periodic audits of the site to monitor compliance with established procedures and practices. May infrequently audit another site.

- Liaise with internal and external inspectors and representatives, particularly on QA-related topics.
- Oversee the metrology program at the site (i.e., equipment, personnel qualifications, validations, etc.).
- Ensure manufacturing and analytical equipment is appropriately maintained and calibrated. Ensure applicable facility certifications are maintained. Identify management problems in personnel, equipment, and the facility that require correction.
- Review documents associated with the site's QA program for completeness, errors, and omissions. Review executed CGMP records and product batch records to ensure compliance and product quality.
- Review trends (e.g., environmental monitoring, deviations, facility issues, etc.) to initiate corrective and preventive actions and/or for continuous process improvement.
- Conduct continuous review of aseptic operations to ensure compliance to internal procedures (e.g., gowning, cleaning, sanitation, sterility, environmental monitoring, etc.) and USP/FDA regulations.
- Ensure any deviations from normal procedures are documented and justified.
- Ensure an investigation is performed and documented when required, and corrective and preventative actions are taken (i.e., follow and maintain CAPA, deviation, and OOS protocols).
- Ensure compliance with all applicable standard operating procedures and regulations, including 21 CFR Part 210, 211, and 212 requirements.
- Ensure product complaints are managed in a manner consistent with SOPs and FDA regulations.
- Attend quality and operational meetings. Interface with QA and Operations on quality-related issues. Provide status updates as required management.
- Other responsibilities as required.

QUALIFICATIONS:

- Bachelor's Degree (B.S.) in an appropriate scientific or engineering field of study required, preferred fields of study include Microbiology, Biology, Medical Technology, Pharmacy, Biochemistry, or Engineering.
- 5 + years experience with cGMP required.
- 3 + years experience with managing a team required.
- Experience and/or full knowledge of manufacturing operations, preparation of sterile injectables, aseptic processing, and distribution of aseptic products preferred.
- Quality, Pharmacy, or CGMP manufacturing experience preferred.

KNOWLEDGE, SKILLS, ABILITIES:

- Knowledge of USP, FDA, and cGMP regulations required.
- Knowledge of how and ability to write, review, and revise Standard Operating Procedure (SOPs) required.
- Ability to read, analyze, and interpret governmental regulations, general business periodicals, professional journals, or technical procedures required.
- Ability to read and interpret documents such as safety rules, operating and maintenance instructions, and procedure manuals required.
- Ability to write reports, business correspondence, and procedure manuals required.

- Ability to effectively present information, deliver training, and respond to questions from groups of managers, clients, customers, and inspectors required.
- Ability to define problems, collect data, establish facts, and draw valid conclusions required.
- Ability to solve problems and handle issues required.
- Proficient in MS Office applications required.
- Strong interpersonal communication skills for interacting with site personnel, inspectors, and internal and external vendors required.
- Work in facilities compliant with ICH Q7, GxPs, 21 CFR 211 and/or 21 CFR 212. Knowledge of regulations applicable to drugs and devices (21 CFR Parts 210/211, Medical Device Regulations, ICH and FDA guidances, etc.) and the ability to apply them based on the phase of the project (GLP, Phase I, PhaseII/III, etc.)
- 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.
- Ability to foster an inclusive and cooperative work environment.
- 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.