



Title: Director of Quality Assurance and Regulatory Affairs

Job Description:

Mission: RadioMedix's mission is to improve patients' lives by providing innovative radiotheranostics and accelerating discoveries in nuclear medicine.

Key Responsibilities:

1. Quality Management Systems (QMS) Development:

- Establish and maintain a robust QMS to ensure all radiopharmaceutical products comply with regulatory standards (FDA, EMA, and ICH) including **21 CFR Parts 210, 211, and 212**.
- Implement and oversee risk management processes, change control, and document management systems.

2. Regulatory Compliance:

- Ensure strict adherence to 21 CFR Part 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs), 21 CFR Part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals), and 21 CFR Part 212 (Current Good Manufacturing Practice for Positron Emission Tomography Drugs).
- Prepare for and lead regulatory inspections and audits, including those from the FDA and other regulatory agencies.
- Stay updated on evolving regulations and update company practices to maintain compliance with all relevant CFR parts.
- Provide strategic oversight for all quality-related aspects of regulatory filings (e.g. IND).

3. Quality Control Oversight:

- Collaborate with QC teams to validate and verify product testing, stability studies, and control strategies for radiopharmaceutical products.
- Oversee the qualification and maintenance of laboratory equipment and facilities to ensure compliance with 21 CFR Parts 210, 211, and 212.

4. Product Release and Batch Review:

- Approve or reject batches of radiopharmaceuticals based on quality standards and batch documentation, ensuring compliance with regulatory requirements.
- Monitor batch records, deviation reports, and corrective actions, ensuring issues are resolved per 21 CFR guidelines.



5. Quality Events and Investigations:

- Lead and oversee the investigation of quality events, including deviations, out-of-specification (OOS) results, complaints, and other non-conformances.
- Conduct thorough root cause analyses for all quality events and ensure timely and effective corrective and preventive actions (CAPA).
- Implement tracking and trending systems to monitor and reduce quality events, promoting continuous improvement.
- Develop and maintain SOPs for the documentation, investigation, and resolution of quality events.

6. Training and Development:

- Develop and implement training programs on compliance, safety, and regulatory requirements under 21 CFR Parts 210, 211, and 212 for QA and other staff.
- Mentor and lead the QA team to build expertise in radiopharmaceutical quality assurance.

7. Continuous Improvement:

- Drive initiatives to improve processes and reduce deviations and product quality issues.
- Collaborate with cross-functional teams to enhance manufacturing efficiency and product quality while maintaining adherence to CFR regulations.

8. Cross-functional Collaboration:

- Collaborate with the R&D, Manufacturing, Regulatory, and Clinical teams to ensure seamless integration of quality processes across the organization.
- Serve as an advisor to the executive team, ensuring that quality is prioritized in decision-making and operational activities.

Requirements:

- **Educational Background:** Bachelor's or Master's degree in Biology, Chemistry, or a related field; advanced knowledge in radiopharmaceuticals is highly desirable.
- **Experience:** Minimum of 15 years in quality assurance within pharmaceuticals, with experience in radiopharmaceuticals preferred.
- **Certifications:** GMP, Six Sigma, or related quality management certifications preferred.
- **Skills:**



- Strong knowledge of 21 CFR Parts 210, 211, and 212 and their application to radiopharmaceutical production and handling.
- Demonstrated expertise in managing quality events and investigations, including root cause analysis and CAPA.
- Proficiency in tracking, trending, and addressing quality events within a GMP environment.
- Excellent leadership, communication, and problem-solving skills.