



Title: QA Manager

Job Description

The Quality Assurance Manager is responsible for overseeing and managing quality assurance activities for RadioMedix's Contract Manufacturing Facility for both manufacturing sites, SPICA Center located 19705 Aldine Westfield Rd Humble, Texas 77338 and Richmond manufacturing facility at 9701 Richmond Avenue, Houston, TX 77042. This includes establishment of Quality processes for our manufacturing operations.

Duties and responsibilities

- Supports and/or lead onsite FDA Inspections and client audits
- Identifies and works with functional areas as appropriate to facilitate operational improvements.
- Reviews and approves product complaints and Annual Product Quality Reviews; tracks and trends product and line performance to drive quality improvements.
- Interacts and communicates with clients to assure expectations are established, agreed to, and achieved.
- Works to establish Quality Assurance processes/documents/systems for manufacturing operations.
- Builds impactful relationships and collaborations across the organization to achieve corporate goals.
- Performs Quality Assurance activities including, but are not necessarily limited to, review/approval of:
 - Critical compliance documents in support of GMP
 - Executed batch records for compliance
 - Certificate of Analyses against raw data and/or specifications for compliance
 - Stability report against protocol and raw data
 - Release of RadioMedix owned raw materials, packaging components and products as needed
 - Review of project specific procedures, protocols and reports as needed
 - Support Quality Assurance Audits
 - Support and/or lead RadioMedix Inspection Readiness Program including mitigation plans
- Coaches and develops direct reports
- Works on continuous improvement projects, knowledge management, and strive for operational excellence
- Promotes and integrates quality into every aspect of our business
- Establishes quality on-the-floor to assist and support the manufacturing team in detecting and solving compliance errors in real time
- Quality review of regulatory filings in support of projects
- Other duties as assigned.

Qualifications

- Bachelor's degree in a science discipline or related field is preferred
- Minimum of 6-10 years' experience in a quality assurance role of increasing responsibility, CQA a plus
- Higher level understanding of industry regulation 21CFR 211
- Experience in Radioligand therapy preferred

RadioMedix, Inc.
The Spica Center
19705 Aldine Westfield Rd
Humble, TX 77338

- Experience in supporting Quality Control partnerships
- Advanced knowledge of manufacturing and analytical services in the pharma industry, radiotheranostic therapeutic knowledge preferred
- Working knowledge of GMP international regulations and ICH guidelines
- Strong problem-solving skills
- Ability to work independently and effectively as a team member with multidisciplinary project
- Attention to detail with the ability to perform critical review of various types of documents
- Strong organizational and time management skills

Working Conditions

This job operates in an office setting between SPICA and Richmond manufacturing facilities.