Position Description

POSITION TITLE:	Lead Radiochemist in Quality Control
LOCATION:	SAHMRI, North Terrace
REPORTS TO:	Operations Manager and Quality Assurance Manager
DEPARTMENT:	Molecular Imaging and Therapy Research Unit (MITRU)

PURPOSE AND SCOPE OF THE POSITION

The Lead Radiochemist in Quality Control (QC) is responsible for ensuring the routine QC staff are trained and equipped to analyse finished products as well as external samples following validated processes in compliance with Good Manufacturing Practice (GMP) guidelines and PIC/s regulations.

The Lead Radiochemist in QC role includes operational management of the daily functions in the QC department, including personnel, materials, routine tasks and equipment functionality.

The primary role is to reliably, efficiently and safely perform duties in strict accordance to established methods. The role requires experience and understanding of analytical equipment and associated systems.

KEY RESPONSIBILITIES

The specific duties include:

- Ensure adherence to the Radiation Protection and Control Act, the Radiation and Control (Ionising Radiation) Regulations, the Environmental Protection Agency (EPA), the Therapeutic Goods Administration (TGA) and other related legislation and guidelines.
- Take reasonable care to protect their own health, safety and welfare at work and avoid affecting the health and safety of any other person in MITRU.
- Qualify and validate all new and existing equipment to ensure GMP compliance.
- Confirm adherence to control of validated protocols and processes within QC.
- Performance of stability and validation studies.
- Maintain adequate stock levels of QC materials to allow continuity of critical work.
- Has limited financial responsibilities with the requirement to identify cost efficient resources for the MITRU QC areas.
- Coordinating regular QC materials inventory reviews.
- Ensuring QC Material Register and associated documentation are correct.
- Perform various analyses using specific equipment to assess the quality of finished products made in the GMP areas in MITRU.
- Maintain accurate records of tests/experiments performed and provide outcomes of the results to the APs and QA Manager.
- Ensuring regular maintenance and calibration of all QC equipment according to the established schedules.

- Responsible for developing a contingency plan for all QC related tests in the event of an equipment malfunction or downtime.
- Advanced use of computerised QC systems.
- Recommend disposition (approved or rejection) of product batches based upon test results to the AP.
- Monitoring trends in all QC areas for continuous improvement of the processes and alerting.
- Completing documentation related to all tasks including batch records, quality records and logbooks.
- Performing dispatch and returns of radioactive shipments when required.
- General laboratory housekeeping and maintaining a safe workplace within the QC laboratory and associated areas.
- Establish the QC procedures for raw materials testing as required.
- Confirm testing and qualify any raw materials or radiotracers stipulated in the relevant test methods.
- Confirm adherence to control of received samples/products, including storage, sampling and testing.
- Participate in training programmes as required.
- Prepare, update, maintain SOPs and pertinent GMP documents.
- Assist in drafting various documents and reports as and when required.
- Generate and maintain QC associated training modules and related documentation.
- Ensure QC related OOS, OOT, Deviations, CAPAs and Change Controls are investigated and addressed in a timely manner.
- Train other QC Radiochemists in all processes, test methods and QC functions.
- Manage QC radioactive waste and storage of long-lived radioisotopes.
- Transfer of technology from development to routine operations, including documentation and validation of the QC processes.
- Ensure timely QC data trending.
- Contribute to Product Quality Reviews by summarising QC trends and additional data and providing summaries for review by QA when requested.
- Manage test method validations and Performance Qualification (PQ) of equipment when required.
- Lead the QC Team.
- Understand and promote compliance with GMP.
- Communicating all QC related issues to the MITRU Management.
- Continue to expand knowledge in areas of research examined in MITRU and provide insights into future opportunities for expansion.
- Management of the QC operator roster as requested by Operations Manager.
- Work closely with the QA and AP to keep the Quality and systems suitable in all areas related to the release, manufacture and supply of goods accredited
- Participate in special projects to continuously improve processes, tools, systems and organisation.
- Take reasonable care to protect own health, safety and welfare at work and avoid affecting the health and safety of any other person at work.
- Participate in the implementation of the Institute's Work, Health and Safety Management System and related laws, regulations and guidelines.
- Ensure that duties are performed in keeping with the principles outlined in SAHMRI's Vision, Mission and Values and the **Code of Conduct Policy.**

SPECIAL REQUIREMENTS

- Some out of business hours work is required to ensure impact on commercial work is minimised.
- Irregular travel interstate.
- Must be available on an on-call basis for troubleshooting if there is unexpected equipment failure.
- Must participate in annual radiation safety assessments.
- This position requires a pre-employment medical examination to determine suitability for the physical requirements of the role.

Person Specification

QUALIFICATIONS

- Post-graduate qualification in chemistry, pharmacy, biological sciences or related field with experience in analytical methodology (chemical and microbiological), GMP, and an understanding of F-18 based synthesis.
- Studies in laboratory Management or previous relevant work experience (highly regarded)

EXPERIENCE, KNOWLEDGE AND SKILLS

- Prior Radiochemist experience (essential)
- Strong understanding of pharmacopeia monographs
- Strong knowledge of testing and manufacturing procedures is required.
- Demonstrated knowledge of analytical testing and the ability to identify and address potential issues associated with each test.
- General understanding of QC equipment and associated systems is required.
- Possess a strong working knowledge of radiation protection practices
- Previous leadership experience (preferred/desirable)
- Ability to train team members in test methods and GMP/GLP compliance
- Sound judgement and a strong commitment to quality
- Demonstrated ability to contribute to continuous improvement through innovation and efficiencies
- Strong attention to detail
- Well-developed analytical and problem-solving skills
- Commercial acumen
- Innovative, resourceful and creative
- Results driven with demonstrated ability to work in a dynamic environment and to set and meet deadlines to realise organisational objectives
- Possess good interpersonal skills and have a demonstrated capacity to work cooperatively in a team environment
- Commitment to providing internal and external client service of a high standard.
- Support SAHMRI's commitment to reconciliation and acknowledge the importance of working in partnership with Aboriginal and Torres Strait Islander People
- Able to demonstrate the following SAHMRI Values and Culture:
  - **Excellence** – Bold, Driven, Dynamic
  - **Innovation** – Persistent and Focused
  - **Courage** – Collaborative and Enabling
  - **Integrity** – Embrace Diversity, Demand Equity
  - **Teamwork** – Friendly, Fast, Flexible, Fun