Position Description

POSITION TITLE:	Graduate Radiochemist
LOCATION:	SAHMRI, North Terrace
REPORTS TO:	Operations Manager, MITRU
DEPARTMENT:	Molecular Imaging and Therapy Research Unit (MITRU)

PURPOSE AND SCOPE OF THE POSITION

The Graduate Radiochemist role includes manufacture, testing and assisting development and validation of existing and novel diagnostic and therapeutic radioactive tracers. The role includes tasks in Production, QC and other pharmaceutical activities within MITRU. Training will be provided in the various tasks to build upon operators' education and previous experience. The rostering through production and QC will depend on the individual and training program. Due to the highly regulated manufacturing as a Therapeutic Goods Administration (TGA) licensed facility, Good Manufacturing Practices (GMP) are expected to be followed at all times. Due to the nature of the MITRU products, the Graduate Radiochemist will be required to reliably, efficiently and safely perform rostered duties in strict accordance to established procedures.

KEY RESPONSIBILITIES

The specific duties include:

- Completion of documentation related to all tasks including batch records, quality records and logbooks whilst adhering to GMP
- Acceptance and control of materials, including sampling, testing and dispensing materials for Production and QC
- Maintenance of adequate stock consumables and raw materials to allow critical work to continue uninterrupted
- Testing and packaging of radioactive shipments for customers
- Calibration and standardisation of equipment including assistance of service staff whilst on site
- Use of computerised Production systems and QC equipment
- Ensuring good working order of equipment and following maintenance schedules set out
- Monitoring of trends in various areas for alerting and continuous improvement of the processes
- Perform stability and validation studies as requested
- Participation in training programmes when requested
- Ensure Data Management and Data Integrity (DMDI) requirements are met
- Ensure Standard Operating Procedures (SOP's) are documented and review operational protocols and schedules
- Update documents for continual improvement and clarity of SOP's and associated documents
- Assist in drafting various documents and reports including training modules as required
- 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

- Ensure that duties are performed in keeping with the principles outline in SHAMRI's Vision, Mission and Values and the Code of Conduct
- Follow all health and safety regulations implemented at SAHMRI
- 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.

Production Responsibilities include the following:

- Manufacture all radiopharmaceutical products according to SOPs, aseptic methodology and principles of GMP
- Work within the clean room environment, including routine cleaning and monitoring functions
- Preparation of automated synthesis and dispensing modules
- Preparation of reagents and essential materials for radiopharmaceutical production
- Plan and carry out radiopharmaceutical production as required to meet clinical supply timeframes
- Verification that the premises and production equipment are correctly maintained

QC Responsibilities include the following:

- General laboratory tasks
- Daily maintenance and use of analytical equipment such as HPLC, GC-MS, analytical balances
- Preparation, use and storage of reagents and reference standards for use in analytical testing
- Receipt, sampling and storage of all Production samples received for analysis and retention
- Analysis of all radiopharmaceutical and pharmaceutical products according to SOPs, GLP methodology and principles of GMP

SPECIAL REQUIREMENTS

- Typical hours of operation will involve routine early morning starts to enable delivery of products to local hospitals by the commencement of their working day.
- Out of hours work will be required due to the nature of the work including weekends on occasion.
- This position requires a pre-employment medical examination to determine suitability for the physical requirements of the role.

Person Specification

QUALIFICATIONS

- Degree in a scientific discipline (Chemistry, Physics or Pharmaceutical Science or related science field). Individual's scientific experience and experience in pharmaceutical manufacturing and testing environment will be considered if discipline is in a related field.
- Formal training in laboratory operations and a working knowledge of radiation protection practices are highly desirable.
- The individual must hold or commit to acquiring relevant Environment Protection Authority (EPA) licence in a timely manner (less than six months).

EXPERIENCE, KNOWLEDGE AND SKILLS

- Knowledge, experience, or training in Good Laboratory Practices requirements would be advantageous
- Experience working in chemical laboratories working with analytical equipment is highly desirable
- Experience of pharmaceutical clean-room protocols and procedures would be advantageous
- Experience working with radiation and working knowledge of radiation protection practices is highly desirable
- Knowledge of the Work Health and Safety Act 2012 (SA), the Radiation Protection and Control Act (1982) and the Radiation and Control (Ionising Radiation) Regulations (2015), or the ability to quickly acquire this knowledge.
- General knowledge of chemical / radioactive waste management measures
- Can work under time-constraints and within a high pressure and fast-paced environment
- Highly developed attention to detail
- Well-developed analytical and problem-solving skills
- Ability to use their own initiative in tasks given to drive to completion
- High proficiency in oral written communication of English language with experience writing scientific reports
- Sound computer literacy with experience with Microsoft Office programs
- 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

LICENCES

- Current Driver's Licence