Job Description

POSITION TITLE:	Radiopharmaceutical Scientist Registrar
LOCATION:	SAHMRI, North Terrace, Adelaide
REPORTS TO:	Quality Assurance Manager
DEPARTMENT:	Molecular Imaging and Therapy Research Unit (MITRU)

PURPOSE AND SCOPE OF THE POSITION

The Radiopharmaceutical Scientist Registrar (RPS Registrar) reports to the Director of SAHMRI Molecular Imaging & Therapy Research Unit (MITRU) but will be supervised daily by the MITRU Quality Assurance Manager to contribute to the overall objectives of the MITRU program. The successful individual will work with a multidisciplinary team of scientists to manufacture radiopharmaceuticals under current Good Manufacturing Practise (cGMP) for routine clinical use and in clinical trials. This role is designed to enable the individual to gain the practical skills and experience required to complete the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) Radiopharmaceutical Science Training, Education and Assessment Program (RPS TEAP) and gain certification as a Radiopharmaceutical Scientist Specialist.

The successful individual will be enrolled in the ACPSEM RPS TEAP as part of the three-year training position within MITRU. The RPS Registrar will need to adhere to the requirements of the ACPSEM RPS TEAP, manage self-directed learning and submit regular reports as defined by the ACPSEM TEAP for external assessment.

KEY RESPONSIBILITIES

The specific duties include:

- Ensure training milestones are met according to the MITRU training plan and the RPS TEAP Curriculum.
- Perform all assigned duties associated with radiopharmaceutical manufacture in accordance with MITRU documented procedures.
- Engage in translational research and development of novel radiopharmaceuticals.
- Develop a detailed understanding of cGMP, TGA guidance, any default standards that apply under the Therapeutic Goods Act, Radiation Protection and Control Act, the Radiation and Control (Ionising Radiation) Regulations as well as any specific requirements issued by the Environmental Protection Agency (EPA) relevant to the work activities that the individual participates in at MITRU.
- Perform the necessary directed study and report writing in a timely manner to ensure TEAP requirements are met.
- Provide progress reports in timely manner for internal review and guidance before submission externally.
- Comply with 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.
- 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.**

Training Program Activities:

To gain the practical skills and experience necessary to complete the TEAP, the RPS Registrar will be trained and assessed for competency and compliance in the following:

- Gain experience in cyclotron operation and associated systems.
- Production of radionuclides using gas, liquid or solid targetry.
- Materials management involving the receipt, quarantine, and release of starting materials and intermediate materials as well as inventory management and ordering.
- Preparation and quality control of intermediate materials.
- Aseptic preparation of diagnostic and therapeutic radiopharmaceuticals using manual and automatic systems of production in cleanrooms and hot cells.
- Quality control testing of diagnostic and therapeutic radiopharmaceuticals.
- Qualification, use and maintenance of essential equipment for production and quality control of radiopharmaceuticals (e.g., hot cells, synthesisers, dispensers, HPLCs, GC, dose calibrators, dose monitors etc).
- Labelling and packaging of all material (e.g., starting, intermediate and final product).
- Environmental monitoring of cleanrooms for critical parameters including viable and non-viable particulate sampling.
- Completion of all records according to ALCOA+ data integrity principles.
- Contribute to the maintenance and improvement of MITRU's Pharmaceutical Quality System (PQS).
- Preparation of standard operating procedures, work instructions, test methods, validation protocols and reports.
- Analysis of data generated using complex and simple analytical QC systems.
- Conduct investigations into process deviations and out-of-specification results.
- Identify and perform corrective and preventive actions.
- Identification and assessment of suitable suppliers for MITRU.
- Participate in stability and validation studies, evaluate data produced and generate reports.
- Participate in an internal audit(s).
- Engage in translational research and development of novel radiopharmaceuticals.
- Communicate scientific data, analysis and conclusions through written reports and oral presentations.

SPECIAL REQUIREMENTS

- Some out of hours' work may be required. Significant portions of the training program will involve early morning starts to meet manufacturing timelines and customer delivery requirements.
- Successful individual will be expected to attain an SA Government EPA license for handling radioactivity in a timely manner. MITRU will provide learning support to achieve this goal.
- DCSI Employment Screening may be required.
- This position requires a pre-employment medical examination to determine suitability for the physical requirements of the role.

Person Specification

QUALIFICATIONS

It is essential that the RPS Registrar has a relevant postgraduate qualification (Masters or PhD) in an approved chemistry, pharmacy or pharmaceutical science discipline in order to complete the ACPSEM RPS TEAP. Applicants who have already obtained these qualifications will be considered favourably.

EXPERIENCE, KNOWLEDGE AND SKILLS

- Advanced-level knowledge of chemistry or pharmaceutical science and experience in research
- Practical synthetic chemistry skills and techniques
- Experience and knowledge in the use of standard analytical laboratory equipment including liquid, gas and thin-layer chromatography systems
- Knowledge of chemical waste management measures including risk assessments
- Experience in technical evaluations and process improvements
- Experience evaluating complex systems
- Well-developed analytical, troubleshooting and problem solving skills
- Highly committed to quality and safety
- Excellent oral and written communication skills
- Sound computer literacy with experience in Microsoft Office programs
- High attention to detail
- Knowledge of GMP and experience working in a TGA regulated environment is desirable
- Experience in pharmaceutical aseptic processing in a clean room environment is desirable
- Current or previous holder of a licence to use or handle radioactive material is 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 (2000) is desirable
- 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