



Position Description

POSITION TITLE:	Radiochemist
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 QC Radiochemist primary role is to test and qualify any radiotracer as described in the British Pharmacopeia (B.P.) in the facility and adhere to the principles of GMP (Good Manufacturing Practices). The Production Radiochemist primary role is to manufacture all radiotracers according to SOPs and principles of GMP. General understanding of production equipment and associated systems is required.

KEY RESPONSIBILITIES

Specific responsibilities for the QC Radiochemist include the following:

- Performing various analyses using specific equipment to assess the quality of finished products made in the GMP areas in the MITRU.
- Recommending disposition (approved or rejection) of product batches based upon test results to the QC Manager and AP.
- Understanding and promoting compliance with GMP.
- Testing and qualifying (verification) of raw materials and suppliers used in various steps of production.
- Tracking of materials used in QC and assist to maintain stock levels to allow work to be conducted (including long lead time materials).
- Performing calibration and standardisation of equipment.
- Verifying that the premises and QC equipment are correctly maintained.
- Ensuring the good working order of equipment and follow the maintenance schedules set out.
- Maintaining accurate records of tests/experiments performed in the MITRU and provide outcomes of the results to the AP, QC Manager and QA Manager.
- Monitoring of trends in all QC areas for continuous improvement of the processes and alerting.
- Performing investigations.
- Performing stability and validation studies.
- Preparing and updating of SOPs and GMP documents.
- Participation in training programmes.
- Expanding knowledge in areas of research examined in the MITRU and provide insights into future opportunities for expansion.



Specific responsibilities of the Production Radiochemist include the following:

- Manufacture all radiotracers according to SOPs, aseptic methodology and principles of GMP.
- Understanding and promoting compliance with GMP.
- Preparation of the synthesis and dispensing modules.
- Preparing reagents and loading modules in readiness for F-18-based synthesis.
- Carrying out routine synthesis of F-18 based synthesis for clinical supply timeframes.
- General understanding of production equipment and associated systems is required (including basic trouble shooting).
- Preparing sterile vials, stoppers and essential glassware.
- Packaging radioactive shipments for customers.
- When required, operating the cyclotron for isotope production and/or performing quality control on F-18 based tracers (if cross-trained).
- Logging in raw materials and supplies used in the manufacturing processes in the MITRU.
- Verification of raw materials and suppliers used in various steps of production.
- Tracking of materials used in production processes and assist to maintain stock levels to allow work to be conducted (including long lead time materials).
- Performing calibration and standardisation of equipment.
- Verifying that the premises and production equipment are correctly maintained.
- Ensuring the good working order of equipment and follow the maintenance schedules set out.
- Maintaining accurate records of tests/experiments performed in the MITRU and provide outcomes of the results to the AP, Production Manager and QA Manager.
- Monitoring of trends in all production areas for continuous improvement of the processes and alerting.
- Performing investigations.
- Performing stability and validation studies.
- Preparing, updating, maintaining and taking custody of SOPs and pertinent GMP documents.
- Participating in training programmes.
- Expanding knowledge in areas of research examined in the MITRU and provide insights into future opportunities for expansion.
- 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 hours work may be required.
- This position requires a pre-employment medical examination to determine suitability for the physical requirements of the role.



Person Specification

QUALIFICATIONS

- The radiochemist must have a degree in chemistry, pharmacy or biological sciences with experience in analytical methodology (chemical and microbiological), GMP, and an understanding of F-18 based synthesis

EXPERIENCE, KNOWLEDGE AND SKILLS

- A minimum of 1 year's relevant post-qualification experience is required.
- It is essential that the radiochemist possess an understanding of and familiarity with tests that need to be carried out, and with the associated potential problems accompanying each of the analytical tests.
- Good understanding of pharmacopeia monographs.
- Previous training/study in laboratory operations and a working knowledge of radiation protection practices are required.
- Be well versed with the preparation of production related documents.
- The Radiochemist may have to operate the cyclotron, necessitating cross-training in both areas of production and QC testing.
- Possess working knowledge and have regular training in radiation protection.
- 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