ROLE: Radiochemist

Company: SAHMRI Ltd- South Australia Health Medical and Research Institute Ltd

City/State, Country: Adelaide/South Australia, Australia

Department Name: MITRU - Molecular Imaging and Therapy Research Unit

Location: Level 0, SAHMRI Ltd, North Terrace, Adelaide SA 5000

Reports To: Operations Manager and Quality Assurance (QA) Manager.

Summary of 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 Accountabilities / 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 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 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 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 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.

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Key Behavioural Competencies Required:

Able to demonstrate the following SAHMRI values:

- Excellence – be the best you can be
- Imagination – challenge conventional thinking and pursue novel, ground-breaking ideas
- Integrity – act fairly, ethically and respectfully
- Courage – take initiative, be adventurous, creative and bold
- Teamwork – collaborate openly and inclusively

Experience / Knowledge / Technical Skills Required:

The radiochemist must have a diploma or 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 would be advantageous. 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. This especially includes the need for a good understanding of pharmacopeia monographs. Courses in laboratory operations and a working knowledge of radiation protection practices are required.

The radiochemist should be well versed with the preparation of production related documents. In a small facility, the radiochemist may have to operate the cyclotron and necessitating cross-training in both areas of production and QC testing.
The radiochemist should also possess working knowledge and have regular training in radiation protection.

Document Revision History

Revision	Effective date	Section(s) revised and brief description
01	01 Sep 2014	New issue
02	13 Oct 2017	Template change
03	12 Jun 2020	Minor formatting changes. Review period changed to 36 months.