Australian Government

ANSTO
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POSITION DESCRIPTION

Position Title:	Validation Associate
Cluster / Business Unit / Division	Nuclear Operations & Nuclear Medicine
Section or Unit:	Quality Assurance
Classification:	Band 5
Job Family:	Compliance and Regulation
Position Description Number:	PD-1203
Work Contract Type:	Professional
STEMM/NON-STEMM:	STEMM

POSITION PURPOSE

The primary objectives of the Validation Associate are:

1. Assist in implementing activities from the Nuclear Medicine validation program, including programs for:
   - Facility & Utilities Qualification
   - Process and Laboratory Equipment Qualification
   - Method Validations
   - Process validation
   - Cleaning validation
   - Revalidation programs
   - Computerised Systems Validation

2. Responsible for the technical writing of validation and revalidation documentation and conducting and reporting on validation testing.

ORGANISATIONAL ENVIRONMENT

ANSTO leverages great science to deliver big outcomes. We partner with scientists and engineers and apply new technologies to provide real-world benefits. Our work improves human health, saves lives, builds our industries and protects the environment. ANSTO is the home of Australia's most significant landmark and national infrastructure for research. Thousands of scientists from industry and academia benefit from gaining access to state-of-the-art instruments every year.

ANSTO Nuclear Medicine (comprising ANSTO Health Products and ANM) is a business unit within ANSTO engaged in the manufacture and sales of finished goods radiopharmaceuticals (sterile and non-sterile), API and radiochemical products. Manufacturing is based upon the PIC/s Code for Good Manufacturing Practices and it's associated annexes, where processes must meet certain standards and quality assurance is essential with release of these materials undertaken according to just-in-time principles.

ANSTO Nuclear Medicine has a dominant market share position in Australia and is expanding into the global market. ANSTO Nuclear Medicine operates under strict external regulatory requirements including TGA, FDA, ISO 9001, ARPANSA and ASNO, within ANSTO's procedural framework and in oversighted by the ANSTO Board. Over 500,000 Australian patients benefit from ANSTO's radiopharmaceuticals annually

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

The key accountabilities for this position include:

- Ensure good manufacturing practices (GMP) are adhered to throughout Nuclear Medicine
- Contribute to the change of culture within Nuclear Medicine to ensure current industry thinking on validation principles is applied.
- Develop and maintain Product-focused validation schedules
- Performing Nuclear Medicine's Validation activities in accordance with cGMP requirements, for process, cleaning, facility, utilities, equipment and support computerised system validations. This may include protocols, plans and reports for, DQ's, IQ, OQ's and PQ using a risk-based approach
- Tracking the preparation and approval of qualification and validation documentation (e.g validation plans, DQ, IQ, OQ, PQ protocols and reports).
- Providing validation advice and input into new projects at Nuclear Medicine such as new manufacturing systems, computer systems, process/laboratory equipment, analytical methods, new products and utilities/facilities.
- Validation of SME impact assessments of proposed change controls.
- Validation of SME reviews of documents, as required.
- When required, act as the delegated Quality approver for validation activities which ensures that site validation activities are executed as per the site VMP and the Code of GMP
- Ensure timely completion of installation, operational and performance qualification (IQ/OQ/PQ) relating to validation or qualification activities.
- Ensure actions from validation activities are captured in the Nuclear Medicine Corrective and Preventative Action system
- Participate in regulatory audits as a technical SME in validation eg. TGA, FDA and ARPANSA
- Identify and implement opportunities and improvements for validation processes.
- Provide input to impact assessments relating to validation and qualification.
- Training nuclear medicine staff on validation principles as required.
- Identify and implement opportunities and improvements for validation processes
- Undertake additional duties as required and during periods of leave of other staff.

Decision Making

- The position is fully accountable for the accuracy, integrity and quality of the content of advice provided to relevant stakeholders and is required to ensure that decisions are based on sound evidence, but at times may be required to make effective judgements under pressure.
- The levels of authority delegated to this position are those approved and issued by the Chief Executive Officer. All delegations will be in line with the ANSTO Delegation Manual AS-1682 (as amended or replaced).

Key Challenges

The major challenges for this position include:

- Working with external contractors who are not accustomed to high standards of validation.
- Training Nuclear Medicine staff on validation principles.
- Facilitating and fostering an environment of continuous improvement.
- Encouraging teamwork, cooperation, communication, and consultation.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Manager/Executive	• Receive guidance and direction • Promote staff engagement and quality recruitment

	• Provide regular updates on key validation tasks, challenges and critical issues that may impact operations, customers, ANSTO's reputation • Recommend and gain endorsement for plans and goals and other initiatives • Escalate issues and propose solutions
Operational Quality Manager	• Provide expert, authoritative and evidence-based advice associated with validation. • Provide advice on Change Control and CAPA matters relating to Validation.
Departmental area team members	• Drive quality culture across nuclear medicine • Provide expert advice and analysis on a full range of matters associated with validation processes • Contribute to group decision making processes, planning and goals • Support team members and work collaboratively to contribute and meet objectives • Train across nuclear medicine on validation principles • Negotiate and resolve conflicts
External	
Regulators	• Provide evidence of compliance to regulatory agencies such as during audits / inspections. • Participate in regulatory audits as a Subject Matter Expert. • Liaise with regulators on matters of validation.

POSITION DIMENSIONS

Staff Data	
Reporting Line	Reports to the Validation leader
Direct Reports	No direct Reports

Special / Physical Requirements	
Location:	Lucas Heights Working in different areas of designated site/campus as needed
Travel:	May be required travel to ANSTO sites from time to time Infrequent travel within NSW or interstate.
Physical:	Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer)
Radiation areas:	May be required to work in radiation areas under tightly regulated conditions
Hours:	Willingness to work extended and varied hours based on operational requirements. After hours work may be required for short and infrequent periods
Clearance requirements:	Satisfy ANSTO Security and Medical clearance requirements

Workplace Health & Safety	
Specific role/s as specified in AP-2362 of the ANSTO WHS Management System	All Workers Officer (definitions found in appendix A of AP-2362) Managers / Leaders / Supervisors Other specialised roles identified within the guideline a position holder may be allocated to in the course of their duties

ORGANISATIONAL CHART

On file.

KNOWLEDGE, SKILLS AND EXPERIENCE

1. Relevant degree qualifications in science or engineering or relevant industry experience working in a sterile and non-sterile GMP pharmaceutical manufacturing environment.
2. Knowledge of pharmaceutical manufacturing and quality systems with extensive validation experience in the pharmaceutical / radio-pharmaceutical industry.
3. Demonstrated validation experience that includes New facility qualification, Process Validation, cleaning Validation, Computer System Validation, Facility/utility qualification and Process/laboratory Equipment qualification and Method validation.
4. Understanding of and adherence to TGA, FDA, EU and ARPANSA requirements.
5. Sound knowledge and understanding of the GMP requirements, ISO 9001 standard and knowledge of the TGA requirements and International Pharmacopoeia(s).
6. Experience participating in TGA, FDA and ISO audits.
7. Ability to work effectively in cross functional and multi-disciplinary teams.
8. Excellent organisational, interpersonal and communication skills.
9. Excellent problem-solving skills and flexibility in responding to changing demands.
10. Ability to meet critical deadlines and maintaining accuracy and attention to detail.
11. Highly developed technical report writing skills.

VERIFICATION

This section verifies that the line manager and appropriate senior manager/executive confirm that this is a true and accurate reflection of the position.

Line Manager		Delegated Authority	
Name:	Margaret Sequeira	Name:	Ian Martin
Title:	CI & Validation Manager	Title:	General Manager
Signature:		Signature:	
Date:		Date:	