Australian Government

ANSTO
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POSITION DESCRIPTION

Position Title:	Senior Operational Quality Assurance Associate
Cluster / Business Unit / Division	NONM/Nuclear Medicine
Section or Unit:	Operational Quality Assurance
Classification:	Band 5
Position Description Number:	PD-2249
Job Family:	Monitoring & Audit
STEMM/Non-STEMM:	STEMM/Medicine
Work Contract Type:	Professional

POSITION PURPOSE

The primary objective of the Senior Operational Quality Assurance (OQA) Associate is to maintain the operational elements of the Quality Management System (QMS) in accordance with the TGA licenses to manufacture therapeutic goods, the PIC/s Code of GMP for Medicinal Products parts 1 and 2 and the associated annexes, ISO 9001, TGA, FDA, ARPANSA regulatory requirements.

ORGANISATIONAL ENVIRONMENT

ANSTO is the national organisation for nuclear science and technology. We focus on undertaking leading edge research, delivering innovative scientific services and providing specialised advice to government, industry, academia and other research organisations.

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

- Oversee and coordinate a portfolio of operational quality-system elements within the ANSTO Nuclear Medicine QMS which will assist in ensuring ANSTO Nuclear Medicine meets all of it's regulatory and customer obligations. This includes
    - Deviations
    - Product Quality Review
    - Customer Complaints
    - Risk Assessments
    - Suppliers and Materials
    - Documents
    - Release for supply and release for further processing
    - 2nd stage release in accordance with PIC/s annex 3

- Coordinate the monitoring, trending and reporting of the performance of the quality system you are responsible for.
- Authoring annual product quality reviews as assigned including
    - undertaking trending and analysis of quality systems and manufacturing data
    - providing recommendations as appropriate
- Provide advice to staff and management within ANSTO Nuclear Medicine on issues related to ANSTO Nuclear Medicine quality system. Assist Managers in promoting the quality system and an understanding of what is required in order to ensure compliance
- Facilitate investigations arising from process / product deviations and recommend preventative actions for the future.
- Perform the role of authorised position for Release for Supply - release of starting, intermediate and finished products.
- Continuously improve the quality system operational processes ensuring regulatory compliance. Lead, identify and propose improvements to the Quality system.
- Coordinate Customer complaint investigations and correspondence. Evaluate trends arising from customer complaints and recommend corrective actions
- Coordinate the Supplier and Material Approval process including evaluation for suitability and continued certification
- Maintain a working knowledge of any new regulatory requirements of the QMS
- Assist in the review and implementation of risk assessment activities and recommendations
- Participate in the internal and external audit program for Nuclear Medicine
- Facilitate Document Control activities and assist other business stakeholders with their documentation requirements as appropriate
- Prepare and maintain relevant quality-system documentation to ensure compliance with regulations and QMS requirements.
- Delivery of GMP training for ANSTO Health in conjunction with Operational QA Manager and Learning & Development Advisor
- Undertake additional duties as required and during periods of leave of other staff

Decision Making

- 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

- To ensure the nominated quality systems are maintained in accordance with cGMP and ISO requirements.
- Influencing staff in different sections within ANSTO Nuclear Medicine to provide input and advice on the QMS
- Execution of end to end quality philosophy programme (quality on the floor)
- Identifying and managing improvements in the nominated quality systems to enhance compliance and productivity.
- Facilitating and fostering an environment of continuous improvement, communication and consultation.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Operational QA Manager	• Provide reports on adverse trends in Operational Quality Assurance systems • Receive guidance and direction • Escalating any issues and proposing solutions where appropriate.
Operational Quality Assurance Team	• Communicate quality concerns and issues across the team to enable efficient release of product • Support team by undertaking additional duties during team absences
External	
Regulators	• Provide evidence of compliance to regulatory agencies such as during audits / inspections • Participate in regulatory audits
Customers	• Support investigation and closure of customer complaints.
Suppliers/Contractors	• Where required undertake inspections of suppliers and contractors

POSITION DIMENSIONS

Staff Data	
Reporting Line	Reports to the Operational QA Manager
Direct Reports	Nil
Indirect Reports	Nil

Special / Physical Requirements	
Location:	Lucas Heights Working in different areas of designated site/campus as needed
Travel:	May be required to travel to ANSTO sites from time to time
Physical:	High attention to detail
Radiation areas:	May be required to work in radiation areas under tightly regulated conditions Perform duties in an area where radioactive materials are handled under tightly controlled safety conditions Perform duties with and in an area where hazardous chemicals or materials are handled under tightly controlled safety conditions
Hours:	Shift work is required. Willingness to work extended and varied hours based on operational requirements
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) • 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 qualification (science or other related field) or significant relevant industry experience.
2. Experience in pharmaceutical manufacturing (GMP) environment (minimum 3 years preferred), experience in sterile or radiopharmaceutical manufacturing environment highly regarded
3. Knowledge of and ability to apply the Code GMP, EU Guidelines, BP, EP, USP, FDA, and ISO 9001.
4. Experience in TGA, FDA and ISO audits.
5. Experience conducting internal and external audits.
6. Ability to work effectively as an individual or as part of a team
7. Proven problem solving and the ability to think laterally, modify designs, and test new techniques.
8. Demonstrated ability to effectively communicate to a wide audience, including tradespeople, professionals and management.
9. Highly competent in the use of MS Word and demonstrated experience managing multiple systems, experience with MasterControl highly regarded
10. Pro-active, deadline-driven, and reliable in following through with actions.
11. Strong time management, planning and organisational 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:	Amanda Lawson	Name:	Bhawna Sharma
Title:	Operational Quality Assurance manager	Title:	Head of Quality
Signature:		Signature:	
Date:		Date:	