Australian Government

ANSTO
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POSITION DESCRIPTION

Position Title:	Quality Assurance Specialist
Cluster / Business Unit / Division	NONM/Nuclear Medicine
Section or Unit:	Operational Quality Assurance
Classification:	Band 6
Position Description Number:	PD-2250
Job Family:	Monitoring & Audit
STEMM/Non-STEMM:	STEMM/Medicine
Work Contract Type:	Professional

POSITION PURPOSE

The primary objective of the Quality Assurance Specialist is to support the maintenance and execution of the Operational Quality Assurance functions at ANSTO Nuclear Medicine. The Quality Assurance Specialist is a key point of contact for Operational QA advice across the Nuclear Medicine Business.

A key objective of the Quality Assurance Specialist is to develop and execute an effective Operational Quality Excellence programme which will embed an end to end quality philosophy in radiopharmaceutical manufacturing (quality on the floor strategy).

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 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

- Provide technical leadership to the Operational Quality function of Nuclear Medicine for all ANM and Health systems in relation to development, design and integration
- Lead the Quality on the Floor Program including development, implementation and maintenance to achieve cultural transformation
- Champion a continuous improvement culture, improving the knowledge and capability of Nuclear Medicine staff and to introduce new products to the business in a controlled and disciplined way
- Lead the annual product quality review system for Nuclear Medicine as per TGA and FDA guidelines
- Lead complex investigations, deviations, CAPAs, change controls and customer complaints related to operational quality in a timely manner.

- Lead risk reduction strategies and process improvement planning including remediation plans associated with systemic gaps and regulatory inspection deficiencies.
- Provide leadership and take responsibility for introduction of new suppliers, materials, contractors and service providers to ensure sustainable supply of Nuclear Medicine.
- Authorise release of materials and finished goods in accordance with applicable laws and guidelines including PIC/s part 1 and 2 and associated annexes (particularly annexes 1 and 3), FDA code of federal regulation and ANSTO's internal release procedures including assessment and authorisation of non-conformances as applicable.
- Co-ordinate the release programme for all finished goods and starting materials in a time critical environment to maintain a sustainable supply of nuclear medicine nationally and globally
- Approve to return to operation for facilities, equipment and utilities after shutdown, maintenance or unexpected events.
- Co-ordinate regulatory audits and respond to any operational quality assurance deficiencies. Principle liaison in regulatory audits for PQR and investigations.
- Provide specialist operational quality assurance advice to business stakeholders within ANSTO Nuclear Medicine (including operations, engineering and QC teams) as well as those outside of the core business unit as required.
- As a technical expert, train, coach and develop staff to ensure technical knowledge is shared across the Quality Assurance and wider Nuclear Medicine Team. Develop and deliver training program to upskill nuclear Medicine staff in Operation Quality Assurance principals.
- Development and implementation of GMP training for Nuclear Medicine in conjunction with the Learning & Development team
- Proactively strengthen relationships and collaborate with internal and external stakeholders to ensure Nuclear Medicine objectives are met.
- Fully accountable for maintaining Operational QA KPI's including deviations, OOS, complaints, documents, risk assessments and suppliers
- Co-ordinate quality management review process for finished goods and API. Prepare trend reports for quality management review
- Provide advice and recommendations to the head of Quality, departmental leaders and senior management on quality assurance related topics.
- Oversight of Operational QA projects to ensure department objectives are met as defined in the business plan on page
- Authorise closure of quality investigations including deviations, out of specification and customer complaints
- Conduct Internal Audits as a lead auditor
- Maintain currency of approved suppliers, documents and GMP risk assessments within Nuclear Medicine.
- Delegated as quality approver for documents and investigations
- Act as Operational QA Manager during their absence

Decision Making

- The position is fully accountable for the accuracy, integrity and quality of the content of advice provided to stakeholders (including disposition decisions) and is required to ensure that decisions are based on sound evidence, but at times may be required to make effective judgements under pressure
- Provide key quality decisions and troubleshooting based on product quality impact, patient safety impact and applicable laws and guidelines using a risk based approach.
- 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).

- Ensuring that GMP and safety requirements are respected in all decisions undertaken within Nuclear Medicine
- Facility and equipment readiness to produce the intended outcome based on calibration and qualification
- Technical input to the business to enable correct prioritisation of activities related to sustainable supply of nuclear medicine
- Technical input to training program requirements for relevant groups

Key Challenges

The major challenges for this position include:

- Maintaining safe, secure, sustainable supply of Nuclear Medicine in fast paced environment, utilising just in time release principles
- This is an independent role which is required to be influential across multiple functions to achieve cultural transformation
- Critical decision making in accordance with all applicable regulations, licences and market authorisations in a fast-paced environment
- Ability to transition between different tasks and priorities with fluidity to meet operational requirements

KEY RELATIONSHIPS

Who	Purpose
Internal	
Operational Quality Assurance Manager	• Provide reports on adverse trends in Operational Quality Assurance systems • Provide regular reports on effectiveness of Operational Quality Assurance systems • Escalate concerns regarding product quality and staff/stakeholder engagement • Receive guidance and direction • Provide accurate and timely reporting on key projects
Operational Quality Assurance Team	• Authorise closure of quality investigations • Provide mentoring and guidance • Provide disposition decisions in cases of concessional release, non-conformances or operational abnormalities
Work area team members[1]	• Provide expert, authoritative and evidence based advice and education on GMP compliance, risk management and key aspects of a GMP based Quality Management Systems
External	
Regulators	• Provide evidence of compliance to regulatory agencies such as during audits / inspections • Participate in regulatory audits
Customers	• Oversee investigation and closure of customer complaints. Review all customer complaint responses
Suppliers / Contractors	• Where required undertake inspections of suppliers and contractors

Note 1 : This includes staff from Quality Control Chemistry, Microbiology, Production, Operations, Engineering & Maintenance, Sales & Marketing, and Customer Service.

POSITION DIMENSIONS

Staff Data

Reporting Line	Reports to the Operational Quality Assurance 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 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) Wearing personal protective equipment for the handling of hazardous and/or radioactive materials
Radiation areas:	May be required to work in radiation areas under tightly regulated conditions Willingness to 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:	Willingness to work extended and varied hours based on operational requirements in various ANSTO Health Products locations
Clearance requirements:	Satisfy ANSTO Security and Medical clearance requirements

Workplace Health & Safety	
Specific role/s as specified in AG-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

Online.

KNOWLEDGE, SKILLS AND EXPERIENCE

1. Degree in Chemistry, Microbiology or other related science or extensive demonstrated experience.
2. Experience in pharmaceutical quality assurance, ideally within a highly regulated sterile manufacturing environment.
3. Strong understanding of legal implications of authorised person responsibilities
4. Proven experience in leading and managing operational activities; projects, effective allocation of resources, short and long term planning , and developing and mentoring staff to achieve operational requirements in a highly regulated, time critical environment.
5. Experience as a lead auditor in internal and external auditing.
6. Sound computer literacy skills and experience working with electronic document management systems (experience with MasterControl highly regarded)
7. Ability to make critical decisions in a fast-paced environment
8. Demonstrated experience in the application of Quality Risk Management principles to pharmaceutical processes.
9. Expert knowledge and understanding of the GMP requirements (FDA and PIC/s), ISO 9000 standards and knowledge of International Pharmacopoeia(s) with experience in regulatory audits
10. Proven problem solving and the ability to think laterally, modify designs and test new techniques

11. Strong interpersonal skills and keen focus on stakeholder engagement with demonstrated ability to effectively communicate and influence a wide stakeholder group including regulators, senior management and internal/external stakeholders.
12. Pro-active, deadline driven, and reliable in following through with actions.
13. Strong time & project 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:	