Australian Government

ANSTO
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# POSITION DESCRIPTION

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| **Position Title:** | Product Quality Associate |
| **Cluster / Business Unit / Division** | NONM/Nuclear Medicine |
| **Section or Unit:** | Quality |
| **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 Product Quality 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 with oversight from the ANSTO Board. Over 500,000 Australian patients benefit from ANSTO's radiopharmaceuticals annually

## ACCOUNTABILITIES & RESPONSIBILITIES

### Key Accountabilities

- Driving the transformational quality culture initiatives across the site by liaising with cross functional teams. Embed quality processes into all facets of manufacture through the quality on the floor program. Provide Quality leadership to cross-functional teams working on FMEA, root cause analysis, and other investigative tools to ensure a holistic and systemic quality approach is imbedded in everything we do.
- Provide specialist advice to staff and management. SME on issues related to ANSTO Nuclear Medicine Product quality.
- Key point of contact for product quality queries and investigations.
- Provide leadership and act as the key product quality SME during regulatory inspections.
- Through active engagement with the divisional Quality team and external stakeholder groups, define GxP practices and standards for the site and lead gap assessments and improvement projects as required for product(s).

- Responsible for end-to-end product quality.
- Oversee and coordinate a portfolio of Product Quality 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
    - Customer Complaints
    - Risk Assessments
    - Release for supply and release for further processing
    - 2nd stage release in accordance with PIC/s annex 3
- Authoring annual product quality reviews as assigned including
    - undertaking trending and analysis of quality systems and manufacturing data
    - providing recommendations as appropriate
- Escalate to the Head of Quality and SLT any trends and quality issues that are detected during batch review, systemic in nature or observed in facility.
- Lead investigations arising from process / product deviations and recommend preventative actions for the future.
- Perform the role of 'Authorised Person' - release for supply of licensed medicines inclusive of Finished products, API, intermediate and starting materials (per applicable regulations).
- Lead, identify and propose continuous improvement to the Quality system and operational processes
- ensuring regulatory compliance.
- Coordinate Customer complaint investigations and correspondence and evaluate trends arising from customer complaints and recommend corrective actions. Customer liaison point with respect to product quality complaints and product quality related enquiries.
- Maintain a working knowledge of any new regulatory requirements.
- Provide leadership and participate in internal and external audits. Support vendor quality management activities both at site and divisional level.
- Key quality contact for material or process introduction and evaluation for product(s).
- Assist in the review and implementation of product risk assessment activities and recommendations with the use of risk-based thinking and risk-based tools.
- Prepare and maintain relevant quality-system documentation to ensure compliance with regulations and QMS requirements.
- Delivery of GMP training for Nuclear Medicine in conjunction with the Operational QA Manager and the Learning & Development Advisor
- Review and approval of manufacturing standard operating procedures, testing procedures and validation related documents
- Compilation and submission of regulatory documentation for product(s). Work with Group Regulatory Affairs by providing expert GMP advice regarding new submissions and variations / supplements.
- 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).
- Critical decision-making responsibility is delegated to this role with respect to release for supply of products value ANM 15.1 million, Health 32.5 million annually.

**Key Challenges**

- Influencing staff in different sections within ANSTO Nuclear Medicine to provide input and advice on product quality
- Execution of end to end quality philosophy programme (quality on the floor)
- 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<br>• Receive guidance and direction<br>• Escalating any issues and proposing solutions where appropriate. |
| Product Quality Team<br><br>Quality Systems Team | • Communicate quality concerns and issues across the team to enable efficient release of product<br>• Support team by undertaking additional duties during team absences<br>• Liaise regarding quality system trends and improvements<br>• Support timely closure of investigations |
| **External** | |
| Regulators | • Provide evidence of compliance to regulatory agencies such as during audits / inspections<br>• Participate in regulatory audits |
| Customers | • Support investigation and closure of customer complaints.<br>• Key point of contact for quality queries |
| Suppliers/Contractors | • Where required undertake inspections of suppliers and contractors |

**POSITION DIMENSIONS**

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

| **Special / Physical Requirements** | |
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| Location: | Lucas Heights<br>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<br>Perform duties in an area where radioactive materials are handled under tightly controlled safety conditions<br>Perform duties with and in an area where hazardous chemicals or materials are handled under tightly controlled safety conditions |
| Hours: | Shift work is required.<br>Willingness to work extended and varied hours based on operational requirements |

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| Clearance requirements: | Satisfy ANSTO Security and Medical clearance requirements |

| **Workplace Health & Safety** | |
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| Specific role/s as specified in AP-2362 of the ANSTO WHS Management System | • All Workers<br>• Officer (definitions found in appendix A of AP-2362)<br>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. In depth 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 and conducting internal and external audits.
5. Ability to work effectively as an individual or as part of a team.
6. Proven problem solving and the ability to think laterally, modify designs, and test new techniques.
7. Excellent interpersonal and communication skills with the ability to communicate to a wide audience, including tradespeople, professionals, and management.
8. Highly competent in the use of MS Programs such as Word, Excel, PowerPoint, Project etc. Demonstrated experience managing multiple systems, experience with SAP and MasterControl highly regarded.
9. Ability to manage multiple priorities and re-prioritize tasks as required. Excellent problem-solving skills, Pro-active, deadline-driven, and reliable in following through with decisive actions.
10. Strong project management, time management, planning and organisational skills.
11. Familiarity with Root Cause Analysis tools and with risk-based thinking or risk-based tools.
12. Knowledge of equipment, facility, and utility IQ/OQ/PQ.
13. Familiarity with various analytical equipment, techniques, and methodology and microbiological test methods and environmental monitoring.

**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: | Michael Gobrial |
| Title: | Operational Quality Assurance Manager | Title: | Head of Quality |
| Signature: | | Signature: | |
| Date: | | Date: | |