Australian Government

ANSTO
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POSITION DESCRIPTION

Position Title:	Operational Quality Assurance Manager
Cluster / Business Unit / Division	Nuclear Operations & Nuclear Medicine
Section or Unit:	Quality Assurance
Classification:	Band 7
Job Family:	Monitoring & Audit
Position Description Number:	PD-2187
Work Contract Type:	Professional
STEMM/NON-STEMM:	NON-STEMM

POSITION PURPOSE

The primary objective of the Operational Quality Assurance Manager is to manage the Operational Quality functions of ANSTO Nuclear Medicine, ensuring compliance with the local and international regulations and maintaining the licensed state to manufacture both finished goods and API's through oversight of the Pharmaceutical Quality System (PQS).

The Operational Quality Assurance Manager is responsible for ensuring compliance with the local and international regulations and maintaining the licensed state to manufacture both finished goods and API's through oversight of the Pharmaceutical Quality System (PQS) to ensure all operations are meeting cGMP's.

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.

Nuclear Operations & Nuclear Medicine bring together the key areas of Reactor Operations, Waste Management and the commercial businesses of Health and ANSTO Nuclear Medicine (ANM).

Reactor Operations provides nuclear services to ANSTO for the purpose of supporting the strategic objectives of the organisation. This includes the provision of neutron beams for research institutes and irradiation services to Health and ANM for the purpose of the manufacture and sales of radiopharmaceutical and radiochemical products.

Waste Management is responsible for the safe, compliant and effective management of legacy, current and future predicted radioactive waste arising in line with ANSTO's strategic objectives, regulatory requirements and public expectations.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

- Ensuring effective operation and continued development of nuclear medicine operational quality systems including the PQS
- Maintaining compliance with cGMP and licence conditions including TGA, FDA, ISO and ARPANSA while remaining compliant with safe working practices including radiation safety
- Managing critical operational compliance systems including Deviations, Customer Complaints, Risk Assessment and Supplier Qualification
- Manage document management systems within Nuclear Medicine including custodian responsibilities for the electronic quality management system

- Prepare, maintain, and approve documentation such as SOP's, work instructions, specifications, and other quality and technical documents.
- Manage overall release for supply and second stage release of finished goods and API in accordance with:
    - Market Authorisations
    - Specifications
    - Pic/s Part 1 and Part 2
    - PIC/s Associated Annexes, particularly annexes 1 and 3
    - Operational requirements
    - On-time needs considering the radioactive nature of the productManage the release of raw materials, intermediates, components and packaging materials for use in the manufacture of API and finished goods.
- Ensure compliance to sterility assurance is achieved operationally
- Oversee annual product quality reviews
- Manage supplier and contract manufacturer approvals
- Conduct regular evaluation of operational quality compliance systems including analysis of changes in legislation, nuclear medicine policies, procedures, training and communication.
- Monitor performance of operational compliance systems, report trends and implement corrective actions
- Lead regulatory and external audits for operational compliance and provide technical knowledge and documentation. Develop audit responses and lead implementation of operational quality corrective and preventative actions. Provide technical information and operational quality assurance information for customer enquiries and regulatory submissions
- End to end management of non-conformances, including oversight of identification and raising of issues, root cause analysis, identification and implementation of corrective and preventative actions
- Investigate and implement opportunities to improve efficiency through cost savings while maintaining safety and quality compliance, and customer satisfaction
- Pro-actively forecast and monitor operational quality costs
- Provide input into annual quality plans and budget and expenditure proposals
- Lead and manage the Operational QA Team. Plan and prioritise workload to meet deadlines. Set work objectives, manage and assess performance, complete team objectives, KPI's and appraisals.
- Recommend shift arrangements and work schedules to meet operational requirements
- Provide mentoring and guidance to further develop the Operational Quality Assurance team
- Undertake additional duties as required and during periods of leave of other staff.

Decision Making

- The position works within a framework of legislation, policies, professional standards and resource parameters. Within this framework the position has some independence in determining how to achieve objectives of the unit, including deciding on methods and approaches, operations, project planning.
- The position is required at times to make effective judgements under pressure and time constraints.
- 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:

- Improving understanding of cGMP's across all departments in Nuclear Medicine
- Ensuring all Quality activities comply to the code of GMP including sterility assurance

KEY RELATIONSHIPS

Who	Purpose
Internal	
Head of Quality/Senior Leadership	• Receive advice and report on compliance standard. • Provide regular updates on key KPI's, challenges and critical issues that may impact customers, ANSTO's reputation • Recommend and gain endorsement for plans and goals and other initiatives • Escalate issues and propose solutions • Develop and drive Continuous improvement
Management team peers	• Influence effectively to effect change and improvement • Earn trust and respect through knowledge and performance • Provide expertise, guidance and direction on quality assurance and validation matters.
Work area team members	• Provide expert advice and analysis on a full range of matters • Contribute to group decision making processes, planning and goals • Support team members and work collaboratively to contribute and meet objectives • Negotiate and resolve conflicts
Key Stakeholders	• Provide expert advice on Quality assurance continuous improvement systems and validation • Optimise engagement to achieve defined outcomes
External	
Key Stakeholders	• Engage in, consult, and negotiate the development, delivery and evaluation of projects
Regulators, licencing authorities, and customers	• Build and engage positive working relationships that promote trust and credibility and enable effective collaboration.

POSITION DIMENSIONS

Staff Data	
Reporting Line	Reports to the Head of Quality
Direct Reports	5x Senior QA Systems
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 May be required to attend annual Nuclear Medicine conference/s May be required to visit customers and stakeholders within hospitals / Private Practices within Australia
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.

	Must be willing to review, change and flexibly manage work hours, subject to the operational requirements of the business, which may include extended and/or varied hours.
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. Tertiary qualification in Pharmacy, Science or Chemistry is essential
2. Extensive experience in Quality Assurance in a pharmaceutical industry essential
3. Extensive experience in application of annex 1
4. Experience in manufacture of radiopharmaceuticals
5. Detailed understanding of PIC/s code of GMP parts 1 and 2 as well as associated annexes. Particular knowledge of annexes 1 and 3 is required
6. Experience in development and implementation of PQS
7. Experience in regulatory audits
8. Knowledge of BP, EP, USP, FDA, ISO 9001, ARPANSA and radiation safety regulations
9. Ability to make critical decisions in a high-pressure environment utilising just in time principles
10. Strong inter-personal skills
11. Excellent written and verbal skills with a strong attention to detail
12. Ability to work flexible working hours when required
13. Experience writing and reviewing product quality reviews
14. Excellent problem-solving skills and flexibility in responding to changing demands
15. Understanding of compliance and risk management frameworks
16. Ability to meet critical deadlines while maintaining accuracy and attention to detail

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:	Bhawna Sharma	Name:	Ian Martin
Title:	Head of Quality	Title:	GM Nuclear Medicine
Signature:		Signature:	
Date:		Date:	