Australian Government

ANSTO
Science. Ingenuity. Sustainability.

POSITION DESCRIPTION

Position Title:	Head of Quality
Cluster / Business Unit / Division	Nuclear Operations and Nuclear Medicine
Section or Unit:	Nuclear Medicine
Classification:	Band 9
Position Description Number:	PD-2513
Job Family:	Compliance & Regulation
STEMM/NON-STEMM:	STEMM/Medicine
Work Contract Type:	Professional

POSITION PURPOSE

The primary purpose of the Head of Quality is to deliver excellent outcomes for our Nuclear Medicine business and our customers. The role is part of the Nuclear Medicine senior leadership team, and significantly contributes to the objectives supporting safe, secure and sustainable supply of nuclear medicine.

The role is accountable to deliver the Nuclear Medicine Quality performance objectives in a 24x7 operating environment across three nuclear manufacturing facilities. As a role model of ANSTO's values, you lead a team of multi-disciplined quality specialist, ensuring our manufacturing facilities, processes and products operate within our compliance obligations and the expectations of our business, teams and customers.

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 Nuclear Medicine, 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 Medicine is engaged in the manufacture and sales of radiopharmaceutical and radiochemical products. Manufacturing is based upon the GMP Code of Manufacturing, where processes must meet certain standards and Quality Control (QC) is essential and also on just-in-time principles, where all processes are extremely time-critical.

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

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

Senior Leadership Team

- Provide input, advice and support to the General Manager, ANSTO and ANM Boards, and ANSTO on the strategic directions for the Nuclear Medicine Quality Management, to ensure the long-term strategic objectives of ANSTO and Nuclear Medicine are aligned and plans are in place to meet set objectives.
- Deliver excellence as assessed by the business balanced scorecard and key performance indicators.
- Provide strategic input, coaching and mentoring for internal functions of quality, manufacturing, supply chain, compliance and capability, and externally in finance, safety and risk.
- Assist with the development of plans and processes for the installation and operation of new nuclear medicine products and capabilities.

- Assist with coherent planning for securing funding and installing new capabilities for the facility to promote the facilities growth.
- Contribute to high-level strategic and operational decision making as a Senior Manager and member of the Executive Management Team.
- Management of the function's human resources through selection, training, development, performance management and review, recognition and coaching/mentoring of direct and indirect employees. Ensure the sustainability of the function through effective succession and workforce planning, talent management and employee development activities.

Head of Quality

- Development, maintenance, and delivery of the Pharmaceutical Quality System compliant with cGMP, FDA and ISO9001. Ensure the strategic goals of the facility are met and manufacturing services remain world-class.
- Quality operations include but not limited to supplier management, contract manufacturing, quality microbiological control, quality systems, operational quality and release.
- Lead the day-to-day quality operations of Nuclear Medicine consistent with its compliance obligations, workforce plan, operational objectives and financial budgets, thus ensuring that service obligations to customers are met.
- Provide specialist support to the development and execution of the capital works program to maintain facility performance levels and reliability at a world-class standard and ensure all KPI's are met.
- Contract the use of both internal and external quality resources to deliver against the Nuclear Medicine capital works program.
- Provide leadership and commitment to achieving excellence by encouraging continuous learning, knowledge sharing and fostering an environment for creativity and innovation, to ensure that the facilities remains at world-class or world-leading standard.
- Engage in complex cross functional problems through a systematic, risk based approach.
- Build and strengthen national and international networks to ensure the capabilities of ANSTO are widely recognised.
- Undertake additional duties as required and during period of leave of other staff.

Decision Making

- Nominated GMP License holder for Quality.
- Approval authority for the release of product, including the approval or rejection of starting materials, packaging materials and intermediate, bulk and finished products.
- Safe and compliant operations as required by regulators such as ARPANSA and TGA.
- Strategic and Operational KPI's for the Quality.
- Management of quality issues for direct and dotted line reports.
- Matters relating to execution of delegated integration activities.
- Operational matters relating to resources, proposals, new initiatives, projects, priorities, budgets, timelines etc. within the areas of responsibility that may be escalated to the role.
- Development opportunities and training for direct reports.
- Performance related matters.
- 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

- Leading a multi-disciplined, direct and indirect quality team supporting a 24x7 manufacturing operation of different needs, maturity and expectations.
- Sustained delivery of the quality performance and compliance in both ageing and new infrastructure.
- Initiate and manage change, allocate resources effectively, identify and manage risks.

- Maintaining the space for strategic thinking in an environment of complex operational execution
- Delivering very high customer service levels in a "no inventory" short life supply chain.
- Ensuring compliance obligations across TGA, ARPANSA, ASNO, ANSTO and other agencies are delivered in full everyday.
- Building the engagement and capability of the diverse team.

KEY RELATIONSHIPS

Who	Purpose
Internal	
General Executive/Board	• As required
General Manager	• Multiple times per week for discussions on operational and strategic matters affecting the business
Senior Leadership Team	• Multiple times per week to enable facility-wide decision making and direction.
Central functions and internal stakeholders incl. risk, compliance, legal, finance and procurement, major program office	• Weekly, collaborating on quality and compliance outcomes • Monitor KPIs • Monthly forecasting • Annual planning
ANSTO and Nuclear Medicine committees including safety environmental and emergency management	• As the management representative on these committees • Maintain oversight and execution
Work area team members	• Provide expert advice and analysis on a full range of matters, • Contribute to group decision making processes, planning and sales goals, • Collaborate and share accountability, • Negotiate and resolve conflicts, • Work closely with and provide specialist support.
External	
Quality Management Forums, external partners	• Seek out external best practices for adoption into ANSTO • Build partnerships with external industries
Suppliers	• Provide input to KPIS and Service Level Agreements (SLA)'s
Industry Regulators - ARPANSA	• Compliance with ARPANSA licences within areas of responsibility
Licensing Authorities - TGA	• Lead for quality regulators such as TGA, FDA etc

POSITION DIMENSIONS

Staff Data	
Reporting Line	General Manager, Nuclear Medicine
Direct Reports	Up to 4-8 Senior Leaders
Indirect Reports	Up to 50 employees

Financial Data (2022/2023)	
Revenue / Grants	$87M, significant contributor
Operating Budget	$5M (annual)
Staffing Budget	Included
Capital Budget	$90M (5 yrs)
Assets	$TBD M

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 • May be required to travel both internationally and nationally from time to time
Physical:	• Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer) • Public speaking • 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 • 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 • After hours work will be required on a regular basis
Clearance requirements:	• Satisfy ANSTO Security and Medical clearance requirements • Obtain and maintain appropriate federal government clearance

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

KNOWLEDGE, SKILLS AND EXPERIENCE

1. Degree or higher-level qualifications within an chemistry, engineering or other applicable science discipline.
2. Extensive experience delivering results within a FMCG/Pharmaceutical or similar manufacturing industry, leading and managing quality operations and diverse teams, including a position of significant leadership and decision-making authority within a quality function.
3. Extensive knowledge of eGMP, EU Guidelines, BP, EP, USP, FDA and ISO 9001; well versed in guidelines, compliance requirements, facility registration, validation, labelling, regulatory submissions, annual reviews, regulatory reporting requirements and recalls.
4. Experience in TGA, FDA, ISO and NATA audits; well-versed in devising and implementing regulatory compliance strategies and interacting with regulators.
5. Demonstrated ability to identify, manage and mitigate risks through risk contingency planning.
6. Demonstrated ability to initiate, lead and manage change initiatives.
7. Demonstrated personal commitment to safety and quality and the ability to initiate, manage and deliver significant change in safety and performance culture
8. Extensive working knowledge and experience in training others in quality systems requirements
9. Strong project management, organisational, financial acumen, planning and consulting skills.

10. Authentic leadership style with advanced strategic thinking, being able to effectively communicate with and influence key stakeholders, senior leaders and industry thought leaders.

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:	Ian Martin	Name:	Pamela Naidoo-Ameglio
Title:	General Manager, Nuclear Medicine	Title:	General Executive, NONM
Signature:		Signature:	
Date:	August 2024	Date:	