Australian Government

ANSTO
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POSITION DESCRIPTION

Position Title:	Quality Systems & Compliance Manager
Cluster / Business Unit / Division	Nuclear Operations & Nuclear Medicine
Section or Unit:	Quality Assurance
Job Family:	Monitoring & Audit
Classification:	Band 7
Position Description Number:	PD-2186
Work Contract Type:	Professional
STEMM/NON-STEMM:	STEMM

POSITION PURPOSE

The primary objective of the Quality Systems & Compliance Manager is to manage the quality system functions of Nuclear Medicine to ensure compliance with the requirements of the TGA licence to manufacture therapeutic goods, Nuclear Medicine Product Quality System (PQS) and other regulatory requirements. This includes:

- Developing and maintaining the licensed state to manufacture both finished goods and APIs through oversight of the Pharmaceutical Quality System (PQS) with established standards and agency guidelines to ensure compliance.
- Ensuring a constant state of compliance and audit readiness is maintained in line with current regulations, Quality Standards, and business needs.
- Manage quality systems inclusive of management of change (MOC), corrective actions and preventative actions (CAPA), audits, document management, deviations, supplier management, out of specification-tolerance(OOS-OOT), Product Quality Review (PQR), customer complaints, and sterility assurance.
- Management of validation schedule ensuring compliance for process, equipment, and computer systems

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.

Nuclear Medicine 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 its 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

- As a manager and sterility assurance quality expert, lead and develop staff to ensure a depth of technical knowledge within Nuclear Medicine.
- Ensuring a constant state of compliance and audit readiness is maintained in line with current regulations, quality standards and business needs with the management of quality systems function and their associated records consistent with divisional/Corporate Regulatory Policy and Procedures.
- Conduct regular evaluation of quality compliance systems including analysis of changes in legislation, nuclear medicine policies, procedures, training, and communication.
- Manage quality systems inclusive of management of change (MOC), corrective actions and preventative actions (CAPA), audits, document management, deviations, supplier management, out of specification-tolerance (OOS-OOT), Product Quality Review (PQR), customer complaints, and sterility assurance.
- Quality system management of validation to ensure compliance with TGA requirements including computer systems, analytical methods, facility, utilities, cleaning, equipment, and process validations. Inclusive of maintenance of the overall validation portfolio and schedules.
- 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.
- Communicate across ANSTO key learnings at any of our sites through a regulatory audit or emerging regulations.
- Manage the quality systems budget and capital plan expenditure.
- Provide input to nuclear medicine quality operating plans, budgets, and capital expenditure proposals. Recommend work schedules to meet operational requirements.
- Conducting regular performance evaluations of individual employees or groups of employees to measure their progress toward meeting goals and achieving objectives.
- 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).
- 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 and allocation of resources as well as providing expert knowledge to the organisation to best support how to meet such objectives.
- This position will play a key role in leading, identifying and facilitating continuous improvement projects within the QMS process and providing expert input into them, as well as quantifying resulting improvements.
- The position is fully accountable for the accuracy, integrity, and quality of the content of advice provided and is required to ensure that decisions are based on sound evidence, but at times may be required to make effective judgements under pressure or in the absence of complete information or expert advice.

Key Challenges

The major challenges for this position include:

- Consistent compliance to TGA, GMP and ARPANSA regulations with compliance and validation activities.

- Ensuring the successful implementation of the strategic objectives and project completion whilst managing conflicting priorities and deadlines.
- Lead change management initiatives to achieve a performance-based culture.
- Manage effective balance between quality and safety compliance requirement.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Head of Quality/Senior Leadership	• Provide regular updates on key KPI's, challenges and critical issues that may impact customers, ANSTO's reputation. • Provides advice and direction to ensure products and systems related to quality follow TGA, FDA and other regulatory requirements relevant to the business. • Receive guidance and direction. • Provide expert, authoritative and evidence-based advice on operational quality of GMP, risk management and all matters related to product quality. • Provide accurate and timely reporting on key metrics and deliverables on a regular basis and/or as requested. • Negotiate and report on budgets and resources consistent with strategic plans and goals.
Work area team members	• Provide expert, authoritative and evidence-based advice on operational quality assurance elements of GMP, risk management and all matters related to product quality. • Contribute to group decision making processes, planning and goal setting. • Collaborate and share accountability. • Negotiate and resolve conflicts. • Work closely with and provide support to Business Improvement Projects.
Direct reports	• Supervise and provide leadership, guidance, and support. • Set performance requirements and manage performance and development. • Engage to monitor trends, performance and progress against the strategic plan and evaluate further support which may be required to ensure delivery against the plan.
External	
Who	**Purpose**
Key Stakeholders	• Engage in, consult, and negotiate the development, delivery, and evaluation of projects
Regulators, licencing authorities, and customers	• Provide evidence of compliance to regulatory agencies such as during audits / inspections. • Participate in regulatory audits as a Subject Matter Expert. • Liaise with regulators on matters of operational quality.
Customers	• Support investigation of customer complaints • Liaison with customers to provide technical expertise
Supplier/Contactors	• Where required participate in qualification and auditing of suppliers and contractors.

POSITION DIMENSIONS

Staff Data	
Reporting Line	Reports to the Head of Quality
Direct Reports	~8x Employees

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. Required to participate on an on-call Sunday roster normally working remotely After-hours work may be required where necessary for certain periods. Which may include weekends or Public Holidays, normally via telephone only. 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 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 Science or related discipline is essential, supported by relevant experience.
2. Extensive experience in Quality Assurance. Experience in a pharmaceutical industry preferable.
3. Experience and knowledge in managing a validation portfolio within pharmaceutical industry.
4. Knowledge of and demonstrated ability to apply the various Codes of GMP for Medicinal Products, of PIC/s code of GMP parts 1 and 2 as well as associated annexes EU Guidelines, BP, EP, USP, FDA, ISO 9001, ISO 14644, ARPANSA and radiation safety regulations.
5. Commitment to continuous improvement and ability to coordinate, lead and implement change, identify, and manage risks, the ability to problem solves and think laterally, modify designs, and test new techniques.

6. Proven experience leading and managing teams in a manufacturing environment.
7. Demonstrated ability to effectively communicate to all levels of the organisation and manage effective relationships with internal and external stakeholders.
8. Demonstrated ability to promote a strong safety and quality culture.

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:	Ivan Siladji	Name:	Ian Martin
Title:	Head of Quality	Title:	GM Nuclear Medicine
Signature:		Signature:	
Date:		Date:	