Australian Government

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POSITION DESCRIPTION

Position Title:	Data Integrity Assurance Manager
Cluster / Business Unit / Division	Nuclear Operations & Nuclear Medicine
Section or Unit:	Quality Assurance
Job Family:	Monitoring & Audit
Classification:	Band 6
Position Description Number:	PD-2189
Work Contract Type:	Professional
STEMM/NON-STEMM:	NON-STEMM

POSITION PURPOSE

The primary objectives of the Data Integrity (DI) Assurance Manager are to:

1. Establish a framework for GMP Data Integrity compliance across Nuclear Medicine.
2. Co-ordinate the activities of the Nuclear Medicine GMP Data Integrity programme ensuring they are executed in accordance with requirements within the current Australian Code of GMP for Medicinal Products:
    a. During introduction of new processes, systems, and equipment.
    b. Changes to existing processes, systems, and equipment.
3. Continuous review and monitoring of GMP Data Integrity controls within Nuclear Medicine.
4. Consult and provide advice to ANSTO on GMP Data Integrity.
5. Support the development of GMP Data Integrity-related requirements and specifications for processes, systems, and equipment, ensuring PIC/S GMP Annex 11 and PIC/S Data Integrity Guidelines (PI-041) requirements are met.

The position is part of the ANSTO Nuclear Medicine Quality Team working with other units within ANSTO to manage GMP Data Integrity compliance activities to a defined timetable. The position may also be included in project teams at ANSTO.

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

- Subject Matter Expertise (SME) for all GMP Data Integrity operational compliance matters impacting Nuclear Medicine.
- Provide updates to ANSTO Business Units on changes to Data Integrity regulatory requirements that impact paper-based processes, computerised and hybrid systems in Nuclear Medicine.
- Coordinate integration of GMP Data Integrity principles into the Pharmaceutical Quality Management System (PQMS) for all processes, systems and equipment supporting GMP processes across Nuclear Medicine.
- Develop, maintain, and enhance the GMP Data Integrity framework (procedures, work instructions, templates, and training material) that impact paper-based processes, computerised and hybrid systems in Nuclear Medicine.
- Ensure data integrity requirements are in place and in use for manufacturing and laboratory technology supporting GMP processes.
- Coordinate routine monitoring of GMP Data Integrity controls implemented in paper-based processes, computerised and hybrid systems; report and monitor risks and issues identified.
- Maintenance of the Nuclear Medicine Computerised System Validation Master Plan (CSVMP)
- Ensure qualification or validation of computerised/hybrid systems and equipment supporting GMP processes follows the requirements of the Nuclear Medicine GMP Data Integrity & CSV Policies and procedures.
- Quality Unit Delegate for review or approval roles required by PQMS processes impacted by GMP Data Integrity requirements.
- Represent GMP data integrity and related subject matter during regulatory inspections.
- 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:

- Backlog of projects
- Training staff on computer validation
- Facilitating and fostering an environment of continuous improvement
- Encouraging teamwork, cooperation, communication, and consultation
- Encourage sharing of knowledge and experiences within the team and keep up to date with current technology and be aware of its potential impact on the work of the group
- Continuous development of working relationships

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, or 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 an goals. • Support team members and work collaboratively to contribute and meet objectives. • Negotiate and resolve conflicts
Key Stakeholders	• Provide expert advice on CSV and DI • Optimise engagement to achieve defined outcome
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	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. 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:	Perform duties in an area where radioactive materials are handled under tightly controlled safety 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)
	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 qualifications or experience in pharmaceutical/radio-pharmaceutical industry.
2. Extensive GMP Data Integrity experience in the pharmaceutical / radio-pharmaceutical industry.
3. Excellent understanding of GMP Data Integrity requirements defined in the 'Good Practices For Data Management And Integrity In Regulated GMP/GDP Environments' (PI041).
4. Demonstrated understanding and experience implementing the requirements of 'PIC/S Guide to GMP for Medicinal Products' (PE009) impacted by GMP Data Integrity.
5. Demonstrated understanding and experience implementing the controls described in PIC/S Annex 11 (Computerised Systems), and associated validation lifecycle activities and deliverables defined in ISPE 'Risk based Approach to Compliant GxP Computerised Systems' (GAMP 5).
6. Proficient in Microsoft Office and knowledge of SAP.
7. Proven leadership, communication and influencing skills.
8. Ability to work effectively in cross functional and multi-disciplinary teams.
9. Proven project management and technical report writing skills.
10. Demonstrated ability to produce outcomes in a short timeline.

11. Understanding and experience of regulatory requirements (e.g., TGA, FDA, ARPANSA). Experience in audits by regulators.
12. Ability to make recommendations and decisions on changes to current work practices.
13. Demonstrated understanding of Operational Excellence principles and process improvement.

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:	