Australian Government

ANSTO
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POSITION DESCRIPTION

Position Title:	Computer System Validation and Data Integrity 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 Computer System Validation (CSV) and Data Integrity (DI) Manager are to:

1. Co-ordinate the computer system activities of the ANSTO Health (Building 23 and B54) validation program ensuring they are executed in accordance with requirements within the current Australian code of GMP for medicinal product for:
    a. New projects
    b. Retrospective Projects
2. Establish a frame work for computer Validation for ANSTO and ANSTO Health
3. Consult with ANSTO on computer validation and provide advice

The position is part of a Validation Team working together on completing a number of key validation tasks 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

- Co-ordinate computer validation program activities ensuring they are executed in accordance with requirements within the current Australian code of GMP for medicinal products.
- Develop, implement, and maintain Data integrity framework across Nuclear Medicine.
- Develop procedures and policies for Data Integrity

- Provide expert advice on all CSV and Daa Integrity related matters
- Coordinate integration of data integrity principles in the existing PQMS system, manufacturing, and engineering processes.
- Prepare the Validation Master Plan for computer validation and associated work schedules and report on the progress of this plan ensuring compliance with TGA and ARPANSA licences, and other regulatory requirements as required (eg FDA)
- Track the preparation and approval of qualification and validation protocols ensuring compliance with TGA and ARPANSA licences, and other regulatory requirements
- Provide validation advice and input into new projects at ANSTO Health or projects impacting ANSTO Health – such as new manufacturing systems, equipment, computer systems, new products and facilities benchmarking against best practice
- Delegated as the Quality approver for validation activities, ensure the site validation activities are executed as per the site VMP and code of GMP
- Write and review the protocols for various computer related validation activities including execution or writing of reports
- Recommend changes and improvements in the computer validation program including the development of templates and procedures for the execution of computer validation activities
- Perform gap analysis for existing computerised system.
- Ensure actions from validation activities are captured in the site Corrective and Preventative Action system
- Liaising with TGA or others during regulatory inspections regarding validation
- 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, 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 CSV and DI • 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	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 and experience in pharmaceutical/ radio-pharmaceutical industry
2. Demonstrated experience with GAMP 5 guide principles and framework, PE009-8: Annex 11 compliance and CFR part 11 compliance
3. Extensive Computer Validation experience in the pharmaceutical / radio-pharmaceutical industry
4. Excellent understanding of Data integrity
5. Proficient in Microsoft Office and knowledge of SAP
6. Proven leadership, communication and influencing skills
7. Ability to work effectively in cross functional and multi-disciplinary teams
8. Proven project management and technical report writing skills
9. Demonstrated ability to produce outcomes on a short timeline
10. Understanding and experience of regulatory body requirements (eg TGA, FDA, ARPANSA). Experience in audits from regulatory bodies
11. Ability to make recommendations and decisions on changes to practices 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:	