Australian Government

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POSITION DESCRIPTION

Position Title:	Continuous Improvement (CI) QA Systems Associate
Cluster / Business Unit / Division	Nuclear Operations & Nuclear Medicine
Section or Unit:	Quality Assurance
Classification:	Band 4/5 Linked Role
Job Family:	Compliance and regulation
Position Description Number:	PD-2239
Work Contract Type:	Professional
STEMM/NON-STEMM:	STEMM

POSITION PURPOSE

The primary objective of the Continuous Improvement (CI) QA Systems Associate is to co-ordinate and maintain the Continuous Improvement Systems 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:

- Co-ordinate and maintain the Nuclear Medicine continuous improvement program activities for:
  - Management of Change (MOC)
  - Corrective and Preventative Actions (CAPAs)
  - Internal Audits
- Develop measurable objectives for all CI systems and trend monthly data generating detailed reports for management.
- Drive continuous improvement initiatives across the CI processes and systems.

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.

ANSTO Nuclear Medicine (comprising ANSTO Health Products and ANM) 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 it's 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 in oversighted by the ANSTO Board. Over 500,000 Australian patients benefit from ANSTO's radiopharmaceuticals annually.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities Band 4

- Effectively and efficiently undertake Quality assurance CI activities to ensure the Code of GMP and other regulatory requirements are met.
- Maintain key continuous improvement programs such as Management of Change (MOC), Corrective Actions and Preventative Actions (CAPA) and Internal Audits.

- Support the implementation of the continuous improvement program of quality processes, work instructions and procedures. Prepare, maintain, and control QA CI procedures for work instructions, quality plans, and other quality and technical documents.
- Ensure all quality documentation is completed correctly and filed appropriately.
- Support BAU including the release of starting materials and intermediates if required.
- Ensure all Continuous improvement activities are carried out in a manner that complies with the TGA licensing requirements, Product Quality System (PQS) and other regulatory requirements.
- Provide quality support and input into CI activities undertaken in Nuclear Medicine
- Ensure all work carried out is in accordance with ARPANSA regulations, TGA licensing requirements, Nuclear Medicine procedures, WHS procedures, standards and regulations and ensure quality assurance of all work undertaken
- Participate in the implementation of the continuous improvement program of quality processes, work instructions and procedures
- Participate in the review and implementation of risk assessment activities and recommendations as part of CI processes.
- Maintain the nuclear medicine audit program
- Support the co-ordination of the TGA regulatory remediation plans
- Participate in on-going GMP training.
- Provide training in support of CI quality-related documentation
- Trend monthly continuous improvement data generated from the CI systems and support the preparation of monthly status update slides for reporting at monthly quality management meetings.
- Undertake additional duties as required and during periods of leave of other staff.

In addition to performing all the Band 4 accountabilities, the key accountabilities for a Band 5 position include:

- Co-ordinate and maintain key continuous improvement programs such as Management of Change (MOC), Corrective Actions and Preventative Actions (CAPA) and Audit program.
- Drive continuous improvement initiatives across eQMS modules associated with Management of Change (MOC), Corrective Actions and Preventative Actions (CAPA) and Audit program.
- As Continuous Improvement systems subject matter expert: train, coach and develop staff to ensure technical knowledge is shared across the Quality and wider Nuclear Medicine.
- Provide quality advice in relation to CI activities undertaken in Nuclear Medicine and for projects impacting Nuclear Medicine.
- Develop as a qualified Lead Auditor and identify and record product and service problems, and to initiate, recommend and /or provide solutions, and then to verify those solutions.
- Participate in regulatory audits as a technical SME in quality CI systems e.g. TGA, FDA and ARPANSA
- Prepare TGA responses post TGA Inspections.
- Co-ordinate and drive forward the TGA regulatory remediation plans.
- Co-ordinate and maintain the nuclear medicine audit program undertaking both internal and supplier audits.
- Identify and implement opportunities for improving the Continuous Improvement processes.
- Establish measurable standards for Continuous Improvement systems and trend monthly data generating detailed updated reports for management. Recommend changes and improvements in CI processes following review.
- Cross-train across all three Continuous improvement Quality systems (Management of Change, Corrective Actions and Preventative Actions, Internal Audits).
- Undertake additional duties as required and during period 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 methodologies and approaches, operations, resource allocation and project planning.
- The position is required at times to make effective judgements under pressure and time constraints.
- The position is required to independently develop objectives for Continuous Improvement processes.
- 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:

- Facilitating and fostering an environment of continuous improvement across nuclear medicine including driving change.
- Training Nuclear Medicine staff on Continuous Improvements processes and principles.
- Encouraging teamwork, cooperation, communication, and consultation.
- Encourage sharing of knowledge and experiences within the team and keep up-to-date with current technology whilst being aware of its potential to impact on the work of the group

KEY RELATIONSHIPS

Who	Purpose
Internal	
Manager/Executive:	• Receive guidance and direction • Promote staff engagement and quality recruitment • Provide regular updates on key continuous improvement tasks, challenges and critical issues that may impact operations, customers, ANSTO's reputation • Recommend and gain endorsement for plans and goals and other initiatives • Escalate issues and propose solutions
Work area team members:	• Drive quality culture across nuclear medicine • Provide expert advice and analysis on a full range of matters associated with CI processes • Contribute to group decision making processes, planning and goals • Support team members and work collaboratively to contribute and meet objectives • Cross Train across all CI systems • Negotiate and resolve conflicts

POSITION DIMENSIONS

Staff Data	
Reporting Line:	Reports to the CI and Validation Manager
Direct Reports:	Nil

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 Infrequent travel within NSW or interstate

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 After hours work may be required for short and infrequent periods
Clearance requirements:	Satisfy ANSTO Security and Medical clearance requirements
Linked Role:	The transition from Band 4 to Band 5 is not automatic and requires a full written submission, in addition to the attached checklist, to demonstrate how the employee meets the requirements. Transition will only occur following approvals from the CI & Validation Manager, Quality Manager and the General Manager Nuclear Medicine Products.

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 – BAND 4

1. Diploma qualification in Science or other relevant discipline or relevant industry experience
2. Experience in working in a sterile and non-sterile GMP pharmaceutical manufacturing environment
3. Demonstrated QA experience working within the pharmaceutical industry
4. Experience and knowledge in maintaining continuous improvement quality systems within the pharmaceutical manufacturing industry such as management of change, CAPAs and audit program.
5. Understanding of and adherence to TGA, FDA, EU and ARPANSA requirements
6. Sound knowledge and understanding of the GMP requirements, ISO 9001 standard and knowledge of the TGA requirements and International Pharmacopoeia(s)
7. Experience in participating in TGA, FDA and ISO audits.
8. Understanding and experience of master control and SAP electronic systems (preferable)
9. Ability to work effectively in cross functional and multi-disciplinary teams
10. Excellent organisational, interpersonal and communication skills.
11. Excellent problem-solving skills and flexibility in responding to changing demands.
12. Ability to meet critical deadlines and maintaining accuracy and attention to detail.

In addition to the requirements at Band 4 level the following will be also required at the Band 5 level:

KNOWLEDGE, SKILLS AND EXPERIENCE – BAND 5

1. Degree qualification in Science or other relevant discipline or relevant industry experience
2. Extensive QA experience within the pharmaceutical industry
3. Extensive knowledge and understanding of Continuous Improvement (CI) quality systems within the pharmaceutical manufacturing
4. The ability to effectively plan, coordinate, maintain and drive the CI quality systems forward such as management of change, CAPA and Audit program.

5. Experience in regulatory audit participation as a technical SME in quality systems e.g. TGA, FDA and ARPANSA
6. Demonstrated experience in auditing.
7. Extensive experience in working with quality electronic systems such as Mastercontrol.
8. Ability to mentor and coach staff on Continuous Improvement quality systems/processes.
9. Ability to co-ordinate and drive forward TGA regulatory remediation plans.
10. Demonstrated ability to engage and influence a wide range of stakeholders.

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:	Margaret Sequeira	Name:	Ian Martin
Title:	CI & Validation Manager	Title:	General Manager Nuclear Medicine Products
Signature:		Signature:	
Date:		Date:	

Continuous Improvement (CI) QA Systems Associate Linked Role (PD-2239)

Band 4 to Band 5 Transition Checklist

Name:	
Commencement Date:	
Assessment Date:	

Note: Full written submission demonstrating and justifying how the employee meets the requirements must also be attached.

Requirements for transition	Met Criteria
Performing Band 4 accountabilities, as described in this PD (or equivalent experience in a similar highly regulated manufacturing pharmaceutical environment) and completion of the Band 4 to Band 5 transition criteria curriculum with 100% metric are completed	☐Yes ☐No
Demonstrated ability to effectively plan, coordinate, maintain and drive CI quality systems across Nuclear Medicine such as management of change, CAPA or Audit program.	☐ Yes ☐ No
Demonstrated ability to drive continuous improvement initiatives across eQMS CI modules associated with Management of Change (MOC), Corrective Actions and Preventative Actions (CAPA) or Audit programme, to improve productivity and efficiency. Demonstrated ability in mentoring and coaching nuclear medicine staff in CI quality processes.	☐ Yes ☐ No ☐ Yes ☐ No
Participated as a CI system SME in regulatory audits e.g. TGA, FDA and ARPANSA	☐ Yes ☐ No
Demonstrated ability to co-ordinate and drive forward TGA regulatory remediation plans through stakeholder engagement .	☐ Yes ☐ No
Completed audit training to become a qualified auditor for the nuclear medicine audit programme.	☐ Yes ☐ No
All quality assurance activities are carried out in a manner that complies with the TGA licensing requirements, Quality Management System and appropriate safety regulations.	☐ Yes ☐ No
Demonstrated decision making ability within CI processes in the absence of the QA and validation manager to ensure operations are not impacted.	☐ Yes ☐ No
Sustained commitment to demonstrating a proactive attitude and practical application of ANSTO values, identifying and resolving issues as they arise within skills, knowledge and expertise and proactively assisting others to meet deadlines or finish tasks in times when there is capacity	☐ Yes ☐ No
Demonstrated ability to engage and influence a wide range of stakeholders.	☐ Yes ☐ No

CI & Validation Manager Recommendation:

I have reviewed the employee's competence in accordance with Linked Role PD-2239 and certify that the employee meets all requirements for transition and recommend transition from Band 4 to Band 5 be endorsed.

Manager Name:	
Signature:	
Date:	

Quality Manager Assessment
I have assessed the submission and confirm that the employee meets all requirements for transition from Band 4 to Band 5

Quality Manager Name:	
Signature:	
Date:	

General Manager Nuclear Medicine Products:
I have reviewed all information and approve transition from Band 4 to Band 5.

GM Nuclear Medicine Products Name:	
Signature:	
Date:	
Effective Date of transition:	