Australian Government

ANSTO
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POSITION DESCRIPTION

Position Title:	QC / QA Analyst
Cluster / Business Unit / Division	ANSTO Nuclear Medicine (ANM)
Section or Unit:	Quality Control
Classification:	Band 4
Position Description Number:	PD-A0023
Work Contract Type:	Technical
STEMM/NON-STEMM:	STEMM Technical

POSITION PURPOSE

The purpose of the QA-QC Analyst is to provide technical support for the Quality Section in a commercial production environment by:

- Undertaking analyses of raw materials, intermediate reagents and finished goods.
- Undertaking Quality Assurance activities, particularly release of finished goods.

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 Pty Ltd (ANM) is a majority owned subsidiary of ANSTO and has been established to own and operate facilities which are being constructed under the ANSTO ANM program. These facilities will consist of a new Molybdenum-99 (Mo-99) production facility capable of producing up to 3,500 6 day Ci's of Mo-99 per week and an associated waste treatment facility which will utilise ANSTO's proprietary Synroc technology to treat the intermediate level liquid waste which will be generated during the Mo-99 production process.

The completion of the Mo-99 facility will enable ANM to play a significant role in the manufacturing of Mo-99 globally with the capability to produce approximately 25 -30% of the global demand for this isotope.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

The key accountabilities for this position include:

- Ensuring that all quality control activities are carried out in a manner that complies with the TGA licensing requirements, Quality Management System and appropriate safety regulations. Ensure all testing is carried out using adequately validated analytical methods approved to be in compliance with the requirements of GMP and pharmacopoeia.
- Ensure that all necessary testing is carried out using analytical methods that are adequately validated; and are approved to be in compliance with the requirements of GMP and pharmacopoeia.
- Assist with maintenance of the Quality Assurance system to ensure compliance with TGA requirements.
- Ensure all calibration, method development, and validation and maintenance activities in the QC laboratories are undertaken in the correct manner.
- Perform stability testing and compile stability protocol and reports
- Contribute to continuous improvement to bring about systematic improvement in Mo-99 production by ensuring:

- review processes, develop new or modified procedures and update relevant documentation;
- review laboratory records, and identify adverse trends as part of preventive actions;
- undertake statistical analysis;
- assist with validation requirements for the equipment improvement program and management
- Record all QC test results in accordance with regulatory requirements and ensure all documentation meets TGA, GMP and quality system requirements
- Comply with safety and regulatory work practices
- Prepare and maintain documentation such as procedures, work instructions, specifications, quality plans, and other quality and technical documents.
- Undertake additional duties as required and during period of leave of other staff.

Decision Making

In collaboration with the QC/QA shift supervisor the QC/QA Analysts;

- Provide practical support of QC calibration, validation and QC equipment maintenance activities within ANM
- Use theoretical knowledge and practical experience to develop responses to unforeseen problems
- Authorise the release of raw materials, intermediates, components and packaging materials for use in the manufacture of API in accordance with the release procedure.
- Authorise the release of API in accordance with the release procedure.
- Provide technical information, specifications, and validation information for submissions to regulating authorities and customers
- Assist with investigations into product and service quality issues, and to recommend solutions within the quality function.
- 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 QC/QA Analyst may deputise for the QC/QA Shift Supervisor during the Supervisor's absence.

Key Challenges

The major challenges for this position include:

- Carry out work in a heavily regulated environment and ensure the code of GMP and TGA guidelines and requirements are met.
- Prioritising workload where there are multiple regulatory and customer requirements and unplanned activities requiring to be completed within tight timeframes.
- Ensure vigorous testing occurs given delivery expectations of various significant stakeholders
- QC/QA Analysts operate on a 24/7 shift roster and report to the QC/QA Shift Supervisor. They are trained to undertake both QC and QA duties and undertake such duties as rostered.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Quality Control Manager	• Receive guidance and direction • Recommend and gain endorsement for plans and goals and other initiatives • Escalate issues and propose solutions • Provide expert, authoritative and evidence based advice • Staff engagement and quality recruitment
QC/QA Shift Supervisors	• Receive guidance and direction • Provide expert advice and analysis on Quality Control/ Quality Assurance matters

	• Contribute to group decision making processes, planning and goals • Collaborate and share accountability • Negotiate and resolve conflicts
QC/QA Analysts	• Provide expert advice and analysis on a full range of matters • Contribute to group decision making processes, planning and goals • Collaborate and share accountability • Negotiate and resolve conflicts • Support team members and work collaboratively to contribute to meet ANM objectives
ANM Operations Team	• Ensuring by a process of consultation and communication of Quality Requirements, and associated QC testing. • To coordinate with operations team when issues occur so that alternate plans are formulated as required
ANM Supply Chain Team	• Ensuring by a process of consultation and communication of Quality Requirements, and associated QC testing. • To coordinate with supply chain when issues occur so that alternate plans are formulated as required
External	
External Contract Laboratories	• Organising and follow up of external QC testing to ensure timely release of starting materials.

POSITION DIMENSIONS

Position reports to QC/QA Shift Supervisor

Staff Data	
Reporting Line	Reports to the QC/QA Shift Supervisor
Direct Reports	Nil
Indirect Reports	Nil

Financial Data (2015/2016)
Revenue / Grants
Operating Budget
Staffing Budget
Capital Budget
Assets

Special / Physical Requirements	
Location:	Lucas Heights Working in different areas of designated site/campus as needed
Travel:	N/A
Physical:	Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer) Labour intensive physical requirements (sitting, standing, manual handling) 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 Shift work After hours work may be required for short and infrequent periods
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 AP-2362 of the ANSTO WHS Management System	All Workers Other specialised roles identified within the guideline a position holder may be allocated to in the course of their duties

ORGANISATIONAL CHART

Refer SAP Organisational Chart

KNOWLEDGE, SKILLS AND EXPERIENCE

1. Minimum certificate qualification in chemistry or similar relevant science.
2. Experience in chemical analysis.
3. Experience in TGA, FDA, ISO and NATA audits and regulations desirable
4. Experience using statistical techniques.
5. Experience in validation of analytical method and instrumentation desirable
6. Experience using analytical instrumentation and analytical techniques
7. Experience with Good Manufacturing Practices (GMP) and knowledge of relevant nuclear and pharmaceutical production regulations and legislation.
8. Demonstrated ability to effectively communicate to a wide audience including tradespeople, professionals and management.
9. Pro-active, deadline driven, and reliable in following through with actions.
10. Strong time management, planning and organisational skills.
11. Strong customer service focus.
12. Demonstrated ability to work within and promote a strong safety 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:	Matthew Kwok	Name:	Micheal Gobrial
Title:	QC/QA Shift Supervisor	Title:	Quality Control Leader
Signature:		Signature:	
Date:		Date:	