Australian Government

ANSTO
Science. Ingenuity. Sustainability.

POSITION DESCRIPTION

Position Title:	Quality Control Team Leader
Cluster / Business Unit / Division	Nuclear Medicine
Section or Unit:	Quality Control
Job Family:	Compliance & Regulation
Classification:	Band 6
Position Description Number:	PD-2236
STEMM/NON-STEMM:	NON-STEMM
Work Contract Type:	Professional

POSITION PURPOSE

The primary purpose of the Quality Control (QC) Team Leader is to lead a team of QC Analytical Chemists to enable operational excellence as well as fostering staff development. In addition, the QC Team Leader will have oversight of the day-to-day quality control activities performed in accordance with ANSTO policies and procedures and regulatory requirements to support the safe, secure, sustainable supply of nuclear medicine.

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.

ANSTO Nuclear Medicine is a business unit within ANSTO engaged in the manufacture and sales of radiopharmaceutical and radiochemical products. Manufacturing is based upon the GMP Code of Manufacturing, where processes must meet high-level regulatory standards. The Quality Control department plays an integral role in ensuring this standard is met on just-in-time principles, where all processes are extremely time-critical.

ANSTO Nuclear Medicine has a dominant market share position in Australia and is expanding into the global market. ANSTO Health operates under external regulatory requirements such as ISO 9001, ARPANSA and TGA, within ANSTO's procedural framework and in oversighted by the ANSTO Board. Over 500,000 Australian patients benefit from ANSTO Nuclear Medicine radiopharmaceuticals annually.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

- Lead the QC team in setting team KPIs and goals via the APEA process.
- Oversight of QC projects to ensure department objectives are met as per the defined plan-on-page.
- Assisting the QC Manager with strategy development, planning and implementation to enable operational excellence as well as fostering staff development.
- Coordinate the Quality Management Review process for Mo-99 API.
- Manage the QC roster and appropriately allocate work tasks and resources to effectively meet the daily targets in a safe manner.
- Plan, coordinate and perform analytical testing of starting materials, intermediates, and API product testings.
- Prioritise workload where there are multiple regulatory and customer requirements and unplanned activities requiring to be completed within tight timeframes.

- Review QC test records on all finished products and report KPI data associated with QC results and product quality.
- Ensure testing is carried out using analytical methods that have been adequately validated.
- Manage the recoding of QC test results according to regulatory requirements and ensure all documentation meets TGA, GMP and other quality system requirements.
- Active involvement in regulatory audits and formulating QC responses to audit findings, such as TGA, FDA and ARPANSA
- Review lab records and identify adverse trends as part of preventative action.
- Record all non-conformances, follow up on issues raised during audits and ensure corrective actions are implemented.
- Authorise the release of Mo-99 API when required and in accordance with the release procedure.
- Act in the Quality Control Manager duties during weekends, public holidays, and non normal working hours, by taking quality related decisions to ensure operations are not impacted.
- Authorise the release of raw materials, intermediates, components and packaging materials for use in the manufacture of API.
- Prepare, maintain and control procedures for work instructions, quality plans, and other quality and technical documents.
- Lead continuous improvement programs and implement the outcomes related to quality processes, work instructions and procedures.
- As a technical expert, train, coach and develop staff to ensure technical knowledge is shared across Nuclear Medicine.
- Raise GRCs and conduct investigations of accidents or incidents to determine cause and contributing factors.
- Monitor employee performance, provide feedback, and address any performance issues or problems.
- Demonstrate strong team working spirit, and respectful workplace behaviour.
- Undertake additional duties as required and during periods of leave of other staff.

Decision Making

- Planning, consulting and adjusting team and workload based on resource availability and daily targets.
- Make decisions and provide direction to QC team in relation to CAPAs, MOCs and deviations.
- Provide key decision making and troubleshooting when abnormal QC testing conditions are identified or abnormal QC test results are obtained.
- Determination of product quality impacts associated with the manufacture and testing of Mo-99 to allow for product disposition and concessional product release when required.
- Assessment and approval of QC deviations in the absence of QC Manager.
- Determining the need for new training programs or equipment upgrades to address hazards or knowledge gaps and acting on the outcomes.

Key Challenges

- Consistent compliance to TGA, GMP and ARPANSA regulations.
- Working safely with chemicals in a radiation environment.
- Working in a fast-paced production environment.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Quality Control Manager	• Providing daily reports on team/product status. • Consulting on team KPI's and planned activities. • Immediately notifying of any incidents. • Escalating any concerns regarding people/product.

	• Performing delegated/higher duties as the Quality Control Manager if required or in their absence.
Head of Quality	• Coordinating as a Quality Control Manager delegate
Quality Assurance Manager	• Coordinating to address quality related issues
External	
Industry Regulators - ARPANSA	• Ensure compliance with ARPANSA licences within areas of responsibility
Licensing Authority - TGA	• Ensure compliance with TGA and GMP code within areas of responsibility

POSITION DIMENSIONS

Staff Data	
Reporting Line	Reports to the Quality Control Manager
Direct Reports	4 x Quality Control Analytical Chemists
Indirect 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
Physical:	High attention to detail Laboratory environment
Radiation areas:	Ability to work with chemicals and testing materials in a radiation Environment under tightly controlled safety conditions.
Hours:	Shift work may be required. Willingness to work extended and varied hours based on operational Requirements.
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. Degree qualifications in Chemistry or another relevant science or demonstrated extensive relevant experience.
2. Experience leading, managing, developing and mentoring staff.
3. Knowledge of and the ability to apply the GMP Code, EU Guidelines, BP, EP, USP, FDA, and ISO 9001.
4. Experience in TGA, FDA, ISO, and NATA audits.
5. Completed Competency-based training in TGA, ARPANSA, radiation safety, and quality systems.

6. Knowledge of and experience using analytical instrumentation and analytical techniques, including Gamma Spectrometry, HPLC, Radio-TLC, UV-VIS, FT-IR, ICPAES, Polarography, and other nuclear instrumental counting techniques.
7. Demonstrated knowledge of and experience using statistical techniques.
8. Proven problem solving and the ability to think laterally, modify designs, and test new techniques.
9. Demonstrated ability to effectively communicate to a wide audience, including tradespeople, professionals and management.
10. Demonstrated pro-activity, deadline-driven and reliable follow through with actions.
11. Strong time management, planning and organisational skills.
12. Demonstrated commitment to continuous 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:	Micheal Gobrial	Name:	Bhawna Sharma
Title:	Quality Control Manager	Title:	Head of Quality
Signature:		Signature:	
Date:		Date:	