Australian Government

ANSTO
Science. Ingenuity. Sustainability.

POSITION DESCRIPTION

Position Title:	QC Microbiology Team Leader
Cluster / Business Unit / Division	Nuclear Medicine
Section or Unit:	Quality Control
Job Family:	Compliance & Regulation
Classification:	Band 6
Position Description Number:	PD-2438
STEMM/NON-STEMM:	NON-STEMM
Work Contract Type:	Professional

POSITION PURPOSE

The primary purpose of the Quality Control (QC) Microbiology Team Leader is to lead a team of Microbiology Officers to enable operational excellence as well as fostering staff development. In addition, the QC Microbiology Team Leader will have oversight of the day-to-day microbiology 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 microbiology team in setting team KPIs and goals via the APEA process.
- Oversight of QC microbiology 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.
- Manage the QC microbiology 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, and finished product testings.
- Prioritise workload where there are multiple regulatory and customer requirements and unplanned activities requiring to be completed within tight timeframes.

- Review QC microbiology test records on all finished products and report KPI data associated with QC microbiology results and product quality.
- Ensure testing is carried out using microbiology methods that have been adequately validated.
- Manage the recoding of QC microbiology 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 microbiology 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.
- 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 as required.
- 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 microbiology 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 Microbiology team in relation to CAPAs, MOCs and deviations.
- Provide key decision making and troubleshooting when abnormal QC microbiology testing conditions are identified or abnormal QC microbiology test results are obtained.
- Assessment and approval of QC microbiology 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 - Operations	• 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	Approx. 3x Microbiology Officers
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. Relevant degree qualification in Science or related field.
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. Knowledge of and experience establishing and using microbiology analytical instrumentation and microbiology techniques, including, but not limited to, endotoxin testing, and sterility testing.
6. Demonstrated knowledge of and experience using statistical techniques.
7. Proven problem solving and the ability to think laterally, modify designs, and test new techniques.
8. Extensive experience co-ordinating and performing training of new team members in microbiology test methods and processes.

9. Demonstrated ability to identify areas for continuous improvement and manage the project through to implementation e.g., new testing methods and/or equipment.
10. Demonstrated time management, planning, organisational and leadership skills, including providing direction and advice to other team members to ensure operational and quality requirements are met.
11. Demonstrated ability to effectively communicate to a wide audience, including tradespeople, professionals and management.
12. Demonstrated pro-activity, deadline-driven and reliable follow through with actions.
13. Strong time management, planning and organisational skills.
14. 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:	Ian Martin
Title:	Quality Control Manager	Title:	General Manager, Nuclear Medicine
Signature:		Signature:	
Date:		Date:	