Australian Government

ANSTO
Science. Ingenuity. Sustainability.

POSITION DESCRIPTION

Position Title:	Sterility Assurance and Microbiology Manager
Cluster / Business Unit / Division	Nuclear Operations & Nuclear Medicine/Nuclear Medicine
Section or Unit:	Quality
Classification:	Band 7
Position Description Number:	PD-2253
Job Family:	Monitoring & Audit
STEMM/NON-STEMM:	NON-STEMM

POSITION PURPOSE

The primary objective of the Sterility Assurance and Microbiology Manager is to manage the Sterility Assurance functions of Nuclear Medicine and manage and oversee the Microbiology laboratory. The role ensures compliance with the local and international regulations and maintains the licensed state to manufacture both finished goods and APIs in accordance with the requirements of PIC/s PE009-15 and relevant annexes.

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.

Nuclear Medicine (comprising 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 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

- Lead the site Sterility Assurance functions and objectives, ensuring manufacturing is executed in accordance with current GMP guidelines, enabling reliable supply of radiopharmaceuticals and radiochemicals to the market.
- Develop, manage and execute the strategic direction and remediation activities for Sterility Assurance across the organisation
- Provide expert support and advice to other divisions within ANSTO relating to microbiology and sterility assurance within a GMP environment.
- Development of the Microbiology and Sterility Assurance business plan, resourcing, key performance indicator measures and elevation of events.
- Manage and lead the Microbiology Team to effectively and efficiently maintain the laboratory in a safe and operable condition to ensure the Code of GMP and other regulatory requirements are met. This includes objective setting, managing performance, task allocation, training and coaching.

- Oversee all aspects of microbiological testing for starting materials, intermediate materials and finished products. Make recommendations on the microbial quality of the finished products, intermediates and raw materials and risk to product quality.
- Maintain the Microbiology Laboratory and oversee Microbiological testing operations to meet external regulatory requirements (TGA, ISO 9001 and ARPANSA) with a commitment to continuous improvement.
- As the Subject Matter Expert on microbiology in conjunction with Sterility Assurance specialists and Microbiology Officers :
    - train, coach and develop staff to ensure technical knowledge is shared across the quality and wider ANSTO team. Provide advice and guidance on ways of developing the skills and experience of others.
    - provide information, advice and strategies for addressing microbiology and sterility assurance within a GMP environment
    - act as principal liaison for microbiology related information with the TGA and other regulatory agencies that licence ANSTO Health
- Ensure all microbiology work carried out is in accordance with ARPANSA regulations, TGA licensing requirements, ANSTO, Health products procedures, WHS procedures, standards and regulations and ensure quality assurance of all work undertaken
- Identify, manage and implement continuous improvement processes and programs which includes the development of work instructions, procedures and the modification of designs/testing techniques.
- Manage all aspects of the Microbiology quality systems to ensure strict regulatory compliance with the requirements of PIC/S Code of GMP for sterile and non-sterile medicinal products. This includes maintaining and revising microbiology documentation, scheduling and coordinating the execution of validation and the calibration of microbiology equipment and test methods
- Lead investigations and perform risk analyses into 'out of specification' microbiology testing and environmental monitoring results and deviations which often involves trouble shooting and resolving complex issues and implementing corrective actions/plans.
- Manage the recording of microbiology test results according to regulatory requirements and ensure all documentation meets TGA, GMP and other quality system requirements.
- Manage and co-ordinate the completion of all microbiology Change Control and CAPA actions.
- Proactively strengthen relationships through collaboration and influence with internal and external stakeholders to ensure Nuclear Medicine/Quality/Sterility objectives are met.
- Prepare and manage the microbiology budget and capital plan expenditure.
- Undertake additional duties as required.

Decision Making

- 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 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 and allocation of resources as well as providing expert knowledge to the organisation to best support how to meet such objectives.
- This position will play a key role in leading, identifying and facilitating continuous improvement projects within the QMS process and providing expert input into them, as well as quantifying resulting improvements.
- The position is fully accountable for the accuracy, integrity and quality of the content of advice provided and is required to ensure that decisions are based on sound evidence, but at times may be required to make effective judgements under pressure or in the absence of complete

information or expert advice.

Key Challenges

- Ensuring that Sterility Assurance foundation and culture is adopted across the manufacturing organisation and Sterility Assurance initiatives are developed and communicated in conjunction with key stakeholders.
- Ensuring that all testing occurs given the just-in-time delivery requirements to key significant stakeholders, ensuring that strict regulatory compliance requirements are clearly communicated to Senior Management prior to release for sale being authorised.
- Consistent compliance to TGA, GMP and ARPANSA regulations.
- Maintaining rigour in sterility assurance in a manufacturing environment of radiopharmaceuticals via aseptic and terminal sterilisation methods.
- Keeping abreast of recent regulatory and technology developments relating to the microbiology field, ensuring continual improvement and implementation of best practise.
- Ensuring the successful implementation of strategic objectives and project completion whilst managing conflicting priorities and deadlines.

KEY RELATIONSHIPS

Who	Purpose
Internal	
General Manager Nuclear Medicine, Group Executive, NONM	• Provides advice and direction to ensure products and systems related to quality are in compliance with TGA, FDA and other regulatory requirements relevant to the business. • Receive guidance and direction. • Provide expert, authoritative and evidence based advice on microbiology and sterility assurance elements of GMP, risk management and all matters related to product quality.
Head of Quality	• Provides advice and direction to ensure products and systems related to quality are in compliance with TGA, FDA and other regulatory requirements relevant to the business. • Receive guidance and direction. • Provide expert, authoritative and evidence based advice on microbiology and sterility assurance elements of GMP, risk management and all matters related to product quality. • Provide accurate and timely reporting on key metrics and deliverables on a regular basis and/or as requested. • Negotiate and report on budgets and resources consistent with strategic plans and goals.
Work area team members	• Provide expert, authoritative and evidence based advice on microbiology and sterility assurance elements of GMP, risk management and all matters related to product quality. • Contribute to group decision making processes, planning and goal setting. • Collaborate and share accountability. • Negotiate and resolve conflicts. • Work closely with and provide support to Business Improvement Projects.
Direct Reports	• Supervise and provide leadership, guidance and support. • Set performance requirements and manage performance and development.

	• Engage to monitor trends, performance and progress against the strategic plan and evaluate further support which may be required to ensure delivery against the plan.
CI and Validation Manager	• Provide expert, authoritative and evidence based advice. • Co-ordinate and provide resources to ensure successful on time completion of validation activities. • Provide input into the development of an effective validation plan for microbiology methods and equipment.
Operational Quality Manager	• Provide expert, authoritative and evidence based advice. • Provide advice on Change Control and CAPA matters relating to sterility assurance and product quality. • Provide resources to assist with investigations. • Provide technical input into the Quality Risk Management Process.
Production	• Provide expert, authoritative and evidence based advice. • Support proposed projects and production changes which impact sterility assurance and product quality. • Provide resources for completion of gowning and operator aseptic validations and media fills.
Engineering & Maintenance	• Provide expert, authoritative and evidence based advice and support for proposed projects, changes, maintenance and clean room qualifications which impact sterility assurance. • Provide resources for completion of gowning validations and clean room monitoring post maintenance and qualifications.
ANSTO e.g. NSTLI, Business Development	• Provide expert, authoritative and evidence based advice and support for inquiries relating to microbiology and sterility assurance within a GMP environment. • Provide support for microbiology testing of finished products.
External	
Regulators	• Provide evidence of compliance to regulatory agencies such as during audits / inspections. • Participate in regulatory audits as a Subject Matter Expert. • Liaise with regulators on matters of microbiological quality.
Customers	• Support investigation of customer complaints where required.
Suppliers / Contractors	• Where required participate in qualification and auditing of suppliers and contractors. • Liaise with providers of microbiology testing services as required.

POSITION DIMENSIONS

Staff Data	
Reporting Line	Reports to the Head of Quality
Direct Reports	6
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 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 Some industrial laboratory physical requirements; sitting, standing, routine manual handling, lifting, standing for long periods and operating equipment Wearing sterile clean room garments for working in cleanrooms Wearing personal protective equipment for the handling of hazardous and radioactive materials Ability to work with chemical and testing materials Applicants should be able to lift heavy objects up to 23kg Must test free of colour blindness and pass an annual eye test
Radiation areas:	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 After hours work may be required for short and infrequent periods Shift work
Clearance requirements:	Satisfy ANSTO Security and Medical clearance requirements

Workplace Health & Safety	
Specific role/s as specified in AG-2362 of the ANSTO WHS Management System	All Workers Area Supervisor 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 Microbiology or related field is mandatory, supported by relevant experience.
2. Extensive industry experience managing a Microbiology, Sterility Assurance or Quality unit.
3. Extensive management experience in the pharmaceuticals industry or microbiology analysis.
4. Knowledge of and demonstrated ability to apply the various Codes of GMP for Medicinal Products, EU Guidelines, BP, EP, USP, FDA, ISO 9001, ISO 14644, ARPANSA and radiation safety regulations.
5. Demonstrated experience with Good Manufacturing Practices (GMP) and pharmaceutical production regulations and legislation.
6. Extensive experience in TGA/FDA and ISO audits as a Subject Matter Expert.
7. Extensive demonstrated experience in a sterile manufacturing operation and sterility assurance.
8. Demonstrated experience in the application of Quality Risk Management to pharmaceutical processes.
9. Commitment to continuous improvement and ability to coordinate, lead and implement change, identify and manage risks, the ability to problem solve and think laterally, modify designs and test new techniques.
10. Proven experience, leading and managing operational activities; effective allocation of resources, short and long term planning skills and developing and mentoring staff to achieve operational requirements in a highly regulated, time critical environment.

11. Extensive experience in validation of analytical methods and instrumentation.
12. Demonstrated experience contributing to the maintenance of the Quality Management System.
13. Demonstrated ability to effectively communicate to all levels of the organisation and manage effective relationships with internal and external stakeholders.
14. Demonstrated ability to promote a strong safety and quality 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:	Bhawna Sharma	Name:	Ian Martin
Title:	Head of Quality	Title:	GM ANSTO Health
Signature:		Signature:	
Date:		Date:	