Australian Government

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POSITION DESCRIPTION

Position Title:	Sterility Assurance and Microbiology Specialist
Cluster / Business Unit / Division	Nuclear Operations & Nuclear Medicine / Nuclear Medicine
Section or Unit:	Quality
Classification:	Band 6
Position Description Number:	PD-2254
Job Family:	Monitoring & Audit
Work Contract Type:	NON-STEMM

POSITION PURPOSE

The primary objective of the Sterility Assurance and Microbiology Specialist is to coordinate the Sterility Assurance functions of Nuclear Medicine. Lead the Sterility Assurance and microbiology function from a technical perspective The role ensures compliance with the local and international regulations and maintain 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 its 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.

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

- Provide technical leadership to the Sterility Assurance and Microbiology function of Nuclear Medicine for all Health processes in relation to the development, design and integration of processes.
- Provide leadership and take responsibility for new products, processes and equipment implementations. Improve microbiology process efficiencies through the implementation of new technologies and equipment.
- Implement the sterility and microbial assurance aspects of the Quality System, maintaining the sterility assurance oversight plan as part of the site Quality plan. Ensure compliance with established internal specifications, standard operating procedures (SOP) and government regulations.
- Champion a continuous improvement culture, improving the knowledge and capability of Nuclear Medicine staff and to introduce new products to the business in a controlled and disciplined way.

- Lead the quality oversight program for aseptic operations, including developing training material for aseptic observation. Mentoring QA and operational staff in aseptic processing and compliance attributes.
- Develop, implement and coordinate effective training programs for aseptic gowning, aseptic qualification (media fill) practices and QA observations
- Lead complex investigations, deviations, CAPAs, change controls and customer complaints related to significant sterility assurance and microbiological matters for safety, quality and operational incidents in a timely manner.
- Lead risk reduction strategies and process improvement planning including remediation plans associated with regulatory inspection deficiencies.
- Principal liaison for sterility and microbiology assurance information with the TGA and other regulatory agencies that licence ANSTO Health and internal /external customers
- Assess facility and quality systems' state of compliance with internal requirements and appropriate regulations. Lead the development of action plans to correct deficiencies and improve quality processes with respect to sterility and microbiology assurance.
- Oversee the development and support for strategies regarding to contamination control, media fill, environmental monitoring, PQs, decontamination, sterilisation, depyrogenation, and management of sterility breaches.
- Proactively strengthen relationships and collaborate with internal and external stakeholders to ensure Nuclear Medicine objectives are met.
- Provide advice and recommendations to the head of Quality, departmental leaders and senior management on microbiological and Sterility Assurance related topics.
- Challenge and influence the technical and scientific aspects of the facilities design and aseptic principles with Production, QA, QC, Engineering and other key stakeholders.
- Provide oversight and sterility assurance expertise to Operations to assure aseptic processing and adherence to all relevant codes, standards and regulatory including PIC/s Annex 1," Manufacture of Sterile Medicinal Products" for key products.
- Lead validation programs associated with sterility assurance and microbiology including process, cleaning, facility, utility, equipment and method validation.
- Lead the performance monitoring of autoclaves, cleanrooms, operational environment, process, operators and other equipment as required.
- Develop appropriate KPIs for the Sterility Assurance and Microbiology areas and monitor progress. Prepare monthly trending reports for Senior Management.
- Undertake additional duties as required which includes acting as the Sterility & Microbiology Manager and supervising team members from time to time.

Decision Making

- The position is fully accountable for the accuracy, integrity and quality of the content of advice provided to stakeholders and is required to ensure that decisions are based on sound evidence, but at times may be required to make effective judgements under pressure.
- 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).
- Ensuring that GMP and safety requirements are respected in all activities undertaken by the sterility assurance and microbiology team.
- Designing and maintaining a sterility assurance and microbiology documentation system that is fit for purpose to ensure that appropriate process records are kept in compliance with GMP requirements

- Facility and equipment readiness to produce the intended outcome based on calibration and qualification
- Managing the status of all sterilising and depyrogenation equipment to assure that they can reproducibly operate according to the validated cycle requirements
- Technical input to the business to enable correct prioritisation of activities related to sterility and microbiology assurance.
- Technical input to training program requirements for relevant sterility and microbiology assurance. processes

Key Challenges

- Ensuring that Sterility Assurance foundation and culture is supported across the manufacturing organisation and Sterility Assurance initiatives are developed and communicated in conjunction with key stakeholders.
- Ensuring that all testing and sterility assurance service elements are performed to delivery requirements to key significant stakeholders.
- 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.
- Being a change leader to step change of performance in a highly regulated environment
- Working with other stakeholders including regulatory bodies to achieve outcomes. Requires excellent interpersonal skills to influence and negotiate to obtain appropriate resourcing, co-operation and regulatory outcomes.
- Maintaining appropriate levels of control in a highly dynamic environment.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Sterility Assurance and Microbiology Manager /Head of Quality	• 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.
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. NST, 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 Sterility Assurance and Microbiology Manager
Direct Reports	Nil
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 Supervisors 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 qualification in an appropriate microbiology, Pharmacy or Bio Engineering discipline or equivalent demonstrated experience.
2. Extensive demonstrated experience in the sterility assurance and microbiology of regulated products within the Pharmaceutical or Veterinary sterile manufacturing industries.
3. 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.
4. Demonstrated experience with Good Manufacturing Practices (GMP) and pharmaceutical production regulations and legislation
5. Demonstrated experience in the application of Quality Risk Management to pharmaceutical processes.
6. 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
7. Ability to apply safety principles in a highly controlled environment
8. Proven experience in leading and managing operational activities; projects, effective allocation of resources, short and long term planning and developing and mentoring staff to achieve operational requirements in a highly regulated, time critical environment.
9. Demonstrated ability to effectively communicate to all levels of the organisation and manage effective relationships with internal and external stakeholders.
10. Demonstrated interpersonal effectiveness to influence regulators, customers, suppliers and internal /external 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:	Bhawna Sharma	Ian Martin
Title:	Head of Quality	General Manager, Health Products
Signature:		Signature:
Date:		Date: