Australian Government

ANSTO
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POSITION DESCRIPTION

Position Title:	Sterility Assurance Advisor
Cluster / Business Unit / Division	Nuclear Precinct/Health
Section or Unit:	Microbiology
Job Family:	Monitoring & Audit
Classification:	Band 5
Position Description Number:	PD-1204
Work Contract Type:	Professional
STEMM/NON-STEMM:	STEMM

POSITION PURPOSE

Review Health's existing sterile manufacturing operations and ensure it meets all the various GMP Regulatory requirements. The position will also be responsible for planning and implementing changes to the processes and practices in sterile operations.

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.

The Nuclear Precinct brings together the key areas of Reactor Operations, the commercial businesses of Health, ANSTO Nuclear Medicine (ANM) and Waste Management.

Reactor Operations provides nuclear services to ANSTO for the purpose of supporting the strategic objectives of the organisation. This includes the provision of neutron beams for research institutes and irradiation services to Health and ANM for the purpose of the manufacture and sales of radiopharmaceutical and radiochemical products.

Waste Management is responsible for the safe, compliant and effective management of legacy, current and future predicted radioactive waste arising in line with ANSTO's strategic objectives, regulatory requirements and public expectations.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

The key accountabilities for this position include:

- Provide oversight and sterility assurance expertise to Operations to assure aseptic processing with excellent knowledge and adherence to all relevant codes, standards and regulatory including PIC/s Annex 1," Manufacture of Sterile Medicinal Products",
- Assesses facility and quality systems' state of compliance with internal requirements and appropriate regulations, and participates in the development of action plans to correct deficiencies and improve quality processes
- Review microbiology operations within the microbiology team, including recommending and implementing changes. This may include:
    - Influencing and convincing others to adhere to regulations and standards
    - Updating and revising Microbiology documentation, procedures, work instructions and work sheets in line with regulatory changes.

    - Undertake trend analysis of all data from environmental, other monitoring and reporting sources.

- Develop document and maintain contamination control strategy for production processes from incoming raw materials through to final product release.
- Assures adequate treatment of EM deviations, adverse trends identified, CAPAs, Investigations and Complaints related to aseptic processing with Business partners e.g QA, QC and Production
- Supports regulatory and client audits as Aseptic sterility assurance subject matter expert
- Provide microbiological and sterility expertise for cGMP documents including, but not limited to, SOPs, batch records, media fill/APS protocols and reports, validations and specifications
- Provides expert coaching and mentoring support locally on sterility assurance knowledge, practices and sterility awareness as part of the developing culture for the site
- Challenges technical and scientific aspects of the facilities design and aseptic principals, with Production, QA, QC, and Engineering etc.
- Ensures the implementation of adequate training for aseptic gowning, aseptic qualification, practices and QA observations
- Responsible for the generation of key performance indicators, regulatory compliance and efficiency targets.
- Review sterile manufacturing operations and make recommendations for changes to processes. This may include process mapping and review of equipment and documentation.
- Participate in the validation and monitoring of the performance of autoclaves, cleanrooms and other equipment as required.
- Work with other parts of ANSTO regarding projects at ANSTO Health which may impact the sterile manufacturing operations.
- Participate in the continuous improvement of quality systems, as an ongoing function of ANSTO Health including Participation in internal and external audits as required.
- Participate in qualification and auditing of new suppliers and contract laboratories.
- Undertake additional duties as required and during periods of leave of other staff.
- Fulfil OHSE responsibilities as specified in AP-2362 of the ANSTO OHSE system.

Decision Making

- The position is fully accountable for providing oversight and sterility assurance expertise to Operations to assure aseptic processing with excellent knowledge and adherence to all relevant codes, standards and regulatory including PIC/s Annex 1," Manufacture of Sterile Medicinal Products".
- The position is fully accountable for developing and maintaining contamination control strategy for production processes from incoming raw materials through to final product release.
- This position is fully accountable for providing expert coaching and mentoring support locally on sterility assurance knowledge, practices and sterility awareness as part of the developing culture for the site.
- This position provides microbiological and sterility expertise for cGMP documents including, but not limited to, SOPs, batch records, media fill/APS protocols and reports, validations and specifications.
- This position is responsible for the generation of key performance indicators, regulatory compliance and efficiency targets.
- This position is accountable for working with other parts of ANSTO regarding projects at ANSTO Health which may impact the sterile manufacturing operations.

- 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).

Key Challenges

The major challenges for this position include:

- Consistent compliance to TGA, GMP and ARPANSA regulations
- Facilitating and fostering an environment of continuous improvement.
- Encouraging teamwork, cooperation, communication and consultation.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Manager/Executive	• Receive guidance and direction • Provide expert, authoritative and evidence based advice
Work area team members	• Provide expert advice and analysis on a full range of matters • Review microbiology operations within the microbiology team, including recommending and implementing changes. This may include: o Influencing and convincing others to adhere to regulations and standards o Updating and revising Microbiology documentation, procedures, work instructions and work sheets in line with regulatory changes. o Undertake trend analysis of all data from environmental, other monitoring and reporting sources.
Direct Reports	• Nil
Other departments: (Production operations, Engineering, Quality Assurance and Quality Control, Validation and other projects' teams)	• Ensures the implementation of adequate training for aseptic gowning, aseptic qualification, practices and QA observations. • Challenges technical and scientific aspects of the facilities design and aseptic principals, with Production, QA, QC, and Engineering etc. • Review sterile manufacturing operations and make recommendations for changes to processes. This may include process mapping and review of equipment and documentation. • Participate in the validation and monitoring of the performance of autoclaves, cleanrooms and other equipment as required. • Work with other parts of ANSTO regarding projects at ANSTO Health which may impact the sterile manufacturing operations.
External	
TGA, FDA, ISO, ARPANSA, Clients	• Supports regulatory and client audits as Aseptic sterility assurance subject matter expert

Suppliers	• Participate in qualification and auditing of new suppliers and contract laboratories.

POSITION DIMENSIONS

Staff Data	
Reporting Line	Reports to the Microbiology Quality 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 travel to ANSTO sites from time to time May be required travel to ANSTO sites within Australia
Physical:	Ability to work with chemical and testing materials Ability to stand for periods Must be fit & able to lift up to 23kg as the role includes some manual handling Must test free of colour blindness This position may be required to provide technical assistance outside of normal working hours. Willingness to work in an area where radioactive materials are handled under tightly controlled safety conditions Willingness to work extended and varied hours based on operational requirements in various locations Satisfy ANSTO Security and Medical clearance requirements.
Radiation areas:	May be required to work in radiation areas under tightly regulated conditions Willingness to work 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.
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: Individuals are responsible for undertaking their activities in a safe manner and cooperating with OHSE requirements of their division to improve OHS in their workplace by: o Reporting unsafe work practices, equipment, incidents and near misses; o Working safely to reduce risk to self and others; o Using appropriate controls; and o Taking a proactive approach to OHSE

ORGANISATIONAL CHART

On file.

KNOWLEDGE, SKILLS AND EXPERIENCE

1. Degree in Microbiology and/or Chemistry or related discipline, although others may be considered with relevant experience.
2. Minimum of three years of experience in sterile GMP
3. Practice experience and knowledge of Code GMP, EU Guidelines, BP, EP, USP, FDA and ISO 9001
4. Experience in TGA, FDA and Validation
5. Sound computer skills
6. Ability to work with others in a team environment, and influencing others
7. Ability to make recommendations and decisions on changes to practices
8. Experience in aseptic techniques
9. Excellent understanding of application of PQS principles within sterile manufacturing environment including change controls, CAPA and deviations.
10. Demonstrate critical thinking and decision making.
11. Experience in regulatory audit including close out of inspection findings.
12. Strong Scientific and technical writing skills.
13. Ability to work autonomously and in a team environment.

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:	Microbiology Quality Manager	Name:	Bhawna Sharma
Title:	Sam Qassis	Title:	Head of Quality
Signature:		Signature:	
Date:		Date:	