Australian Government

ANSTO
Science. Ingenuity. Sustainability.

POSITION DESCRIPTION

Position Title:	Process Performance Lead
Cluster / Business Unit / Division	Nuclear Operations and Nuclear Medicine/Nuclear Medicine
Section or Unit:	Manufacturing
Classification:	Band 6
Job Family:	Manufacturing
Position Description Number:	PD-2012
Work Contract Type:	Professional
STEMM/NON-STEMM:	STEMM

POSITION PURPOSE

The primary objective of the Process Performance Lead is to lead and manage the manufacturing process performance tasks for manufacturing operations within Nuclear Medicine. The Process Performance Lead is responsible for performance robustness and continuous improvement of manufacturing processes, in line with the overall manufacturing strategy to support the safe, secure, and sustainable supply of Nuclear Medicine.

The position focusses on ensuring that Nuclear Medicine manufacturing processes are robust, validated, optimised and under effective control, and in accordance with compliance obligations and the expectations of our business, teams and customers.

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 Nuclear Medicine, 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.

Nuclear Medicine is engaged in the manufacture and sales of radiopharmaceuticals and radiochemical products. Manufacturing is based upon the GMP Code of Manufacturing, where processes must meet certain standards and Quality Control (QC) is essential, and on just-in-time principles, where all processes are extremely time critical.

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

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

- Drive process robustness and continuous improvement by developing, implementing and maintaining process performance framework deliverables across the product lifecycle, such as risk assessments, control strategies and performance monitoring in line with safety, quality and regulatory expectations.

  This includes the utilisation of QMS processes such as change control, deviation management, corrective and preventative actions, validation, master batch records, standard operating procedures and product quality review.
- Lead complex investigations into safety, quality, and operational incidents and provide root cause analysis in technical reports.

- Provide technical mastery and decision making for process changes, investigations and continuous improvements.
- Coordinate the monitoring, trending and reporting of manufacturing process performance metrics.
- Facilitating and contributing to a supportive environment of communication, consultation and continuous improvement across the Manufacturing team.
- Ensure all work carried out is in accordance with ARPANSA regulations, TGA licensing requirements, Nuclear Medicine procedures, WHS procedures, standards, and regulations.
- Undertake additional duties as required and during periods of leave of other staff.

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).
- Ensuring that GMP and safety requirements are embedded within manufacturing processes.
- Designing and maintaining process performance documentation system that is fit for purpose to ensure that appropriate process records are kept in compliance with GMP requirements and regulatory approvals.
- Technical input to the business to enable correct prioritisation of activities.
- Technical input to training program requirements for relevant processes.

Key Challenges

- Maintaining and improving process performance to empower Manufacturing teams to focus on core tasks and direct value-add activities.
- Leading efficient delivery of step-changes in process performance within a highly regulated environment.
- Identifying risks and addressing process performance issues proactively that mitigate impact in a "no inventory" short life supply chain.
- Ensuring compliance obligations across TGA, FDA, ARPANSA, ASNO, ANSTO and other agencies are delivered in full every day.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Head of Manufacturing	• Provide expert advice on Technical matters and contribute to decision making • Identify emerging process and equipment issues/risks and their implications and propose solutions
Process Performance Manager	• Receive broad guidance and direction. • Provide regular updates on key KPIs, challenges and critical priorities. • Escalate issues and propose solutions. • Recommend and gain approvals for operational enhancements, improvements, and process/procedure changes or improvements.
Manufacturing Manager	• Closely collaborate to ensure business objectives are achieved • Provide resources to actively manage and resolve process issues • Provide suitable batch documentation to support the production plan

Validation Manager	• Closely collaborate to ensure business objectives are achieved • Provide input into the development of an effective validation plan • Provide resources to advise on validation requirements for production processes and equipment • Co-ordinate to ensure successful on time completion of validation activities
Quality Assurance Manager - Operations	• Closely collaborate to ensure business objectives are achieved • Provide resources to assist with investigations relating to process issues (inclusive of impact assessment) • Provide feedback on process performance monitoring via product quality review and management review processes
Engineering (e.g. System Engineer or Project Engineer)	• Closely collaborate to ensure business objectives are achieved • Provide technical input into projects undertaken by the engineering team
Maintenance	• Closely collaborate to ensure business objectives are achieved • Provide technical input into preventative and breakdown maintenance activities • Assist in the development of appropriate schedules for preventative maintenance
Work area team members	• Provide expert advice and analysis on a full range of matters relevant to the production process including compliance with GMP and Safety requirements • 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
Internal Stakeholders	• ANSTO Service Providers • Monitor KPIs
External	
Key Stakeholders	• Optimise engagement and influence constructively to achieve outcomes
Regulators, licensing authorities and customers	• Ensure compliance within areas of responsibility • Build and engage positive working relationships that promote trust and credibility and enable effective collaboration (e.g. during inspections).

POSITION DIMENSIONS

Staff Data	
Reporting Line	Process Performance 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 May be required to travel interstate or internationally from time to time
Physical:	Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer) Public speaking Industrial facility physical requirements (lifting, standing for long periods, operating machinery, equipment and manipulators) Wearing personal protective equipment for the handling of hazardous and/or radioactive materials
Radiation areas:	May be 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 will be required on a regular basis
Clearance requirements:	Satisfy ANSTO Security and Medical clearance requirements Obtain and maintain appropriate federal government clearance

Workplace Health & Safety	
Specific role/s as specified in AG-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 or equivalent experience/qualifications within an engineering, science or supply chain discipline.
2. Significant experience in GMP manufacturing environment, experience in sterile or pharmaceutical manufacturing environment highly regarded.
3. Strong leadership skills including the ability to effectively manage, motivate, influence, delegate and stimulate achievement within a team and a matrix environment.
4. Demonstrated understanding of relevant regulatory standards and guidelines in the pharmaceutical or manufacturing industry, such as TGA, FDA, PIC/S, ICH or other applicable regulators such as ARPANSA.
5. Proven ability to identify opportunities for process improvement within a manufacturing environment and lead positive change to enhance operational efficiency, quality and safety.
6. Proven root-cause investigation, risk analysis and problem-solving skills.
7. Excellent interpersonal skills and ability to work both independently as well as part of cross-functional teams.
8. High level technical writing skills and highly competent in the use of MS Office Suite.
9. Strong time-management, planning and organisational skills.

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:	Robert Raposio	Justine Murison
Title:	Process Performance Manager	Head of Manufacturing
Signature:		Signature:
Date:		Date: