

POSITION DESCRIPTION

Position Title:	Manufacturing Excellence Associate/Lead
Cluster / Business Unit / Division	Nuclear Medicine & Commercial
Section or Unit:	Manufacturing
Classification:	Band 5/6 (Linked Role)
Job Family:	Manufacturing
Position Description Number:	PD-2453
Work Contract Type:	Professional
STEMM/NON-STEMM:	STEMM
STEMM CATEGORY	Manufacturing

POSITION PURPOSE

The primary objective of the Manufacturing Excellence Associate(s) is to enable and improve manufacturing operations within Nuclear Medicine. The Manufacturing Excellence Associate(s) are responsible for the effective implementation and maintenance of manufacturing systems, processes and capabilities, in line with the overall manufacturing strategy to support the safe, secure, sustainable supply of Nuclear Medicine.

At the higher level, the Manufacturing Excellence Lead(s) are specialised experts who provide technical leadership and senior-level influence in safety, quality and regulatory compliance activities that underpin, enable and optimise manufacturing operations within Nuclear Medicine.

The position focusses on enabling the direct value streams within Nuclear Medicine, ensuring appropriate issue and change management underpins processes and associated facility operations 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 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 also 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

Manufacturing Operating Systems

- Drive manufacturing robustness, capability and continuous improvement by developing, implementing and maintaining operational documentation, such as process flow diagrams, instructions and procedures in line with safety, quality and regulatory expectations.

Performance & Data Insights

- Maintain the accuracy, completeness and integrity of operational performance, risk, investigation and compliance data within assigned systems.
- Monitor performance indicators and trends across safety, quality, risk, delivery and cost, as relevant to the assigned area.
- Analyse operational data to identify emerging risks, recurring issues, control degradation and improvement opportunities.
- Provide accurate operational data, analysis and insights to support established dashboards, performance reviews, escalation pathways and improvement priorities.
- Support implementation and effective operation of established performance-management cadences and reporting requirements.

Continuous Improvement

- Identify and implement process-level improvements to enhance safety, quality and efficiency.
- Lead root cause investigations into safety, quality and operational incidents with cross-functional SMEs and identify effective corrective and preventative action plans in response. Ensure improvements are embedded into process documentation, procedures and standard work.
- Monitor and trend investigations, change controls, corrective and preventative actions and controlled documents to identify efficiency and effectiveness improvement opportunities.

Risk & Safety Case Lifecycle Management

- Participate in critical control verification activities and support maintenance of evidence demonstrating control effectiveness.
- Monitor and trend risk indicators, critical control performance and emerging operational risks and escalate concerns.
- Support assessment of operational changes to ensure hazards, risks and control requirements are identified, reviewed with relevant specialists and appropriately addressed.
- Assist with periodic review and assurance activities including workplace inspections, control verification reviews and effectiveness checks of implemented actions.

Audit, Compliance and Inspection Readiness

- Participate in internal audits and external regulatory inspections, taking a lifecycle approach to inspection readiness, providing manufacturing expertise and responding to any regulatory findings.
- Maintain compliance through effective use of quality management systems (change control, deviation management, corrective and preventative actions, validation and standard operating procedures).

Operational Support & Technical Enablement

- Provide technical support to operational teams for the efficient and effective use of cGMP practices, QMS systems and processes, investigation methodologies and other systems such as Governance Risk & Compliance (GRC) tool.
- Facilitate effective issue, risk and change management within operational areas.
- Support smooth manufacturing operations by resolving issues and removing blockers.
- Champion a supportive environment of communication, consultation and continuous improvement.
- Ensure all work carried out is in accordance with ARPANSA regulations, TGA licensing requirements, Nuclear Medicine procedures, WHS procedures, standards, and regulations.
- Be proactive in encouraging and sharing of knowledge and experience within Nuclear Medicine.
- Undertake additional duties as required and during periods of leave of other staff.

In addition to performing all Band 5 key accountabilities independently, the key accountabilities for a Band 6 position include:

- Lead the implementation, application and continuous improvement of operational assurance frameworks within assigned areas, providing evidence and technical insight to confirm that safety, quality, risk and performance controls remain compliant, effective and fit for purpose.
- Mentor and develop others, providing technical mastery and decision making for process changes, investigations and continuous improvements.
- Lead defined projects, investigations or multidisciplinary working groups, coordinating deliverables, timelines, resources and risks within agreed authority.
- Lead reviews (and updates) of existing risk assessments for operational changes and facility modifications, in collaboration with Safety, Quality and relevant technical specialists.
- Act as manufacturing subject matter expert during risk assessments and safety reviews.
- Lead complex root cause investigations into safety, quality and operational incidents and drive corrective and preventative action plans.
- Lead the Manufacturing inspection readiness lifecycle, preparing for and participating in relevant internal audits and regulatory inspections, providing manufacturing expertise and coordinating timely response to findings.

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 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.

In addition to the above, the Band 6 position will have the following decision making responsibilities:

- Apply independent sound judgement to information received across several different subject matter experts, ensuring that cGMP, safety and regulatory requirements are accurately embedded in manufacturing processes.
- Review operational changes, making recommendations that ensure hazards, risks, controls and compliance requirements are appropriately considered before changes are approved for implementation.
- Identify and provide independent challenge where risks are not appropriately managed or controls are ineffective, escalating decision-making to the Manufacturing Excellence Manager.
- The position at times may be required to make effective judgements under pressure or in the absence of complete information or expert advice.

Key Challenges

- Developing, maintaining and improving manufacturing processes, systems and capabilities to empower Manufacturing teams to focus on core tasks and direct value-add activities.
- Leading the development of workable solutions to complex problems within a highly regulated environment where there are multiple stakeholder requirements, conflicting priorities and unplanned activities that need to be completed within nominated deadlines.
- Identifying risks and addressing safety, quality and compliance issues proactively that mitigate impact in a “no inventory” short life supply chain.
- Communicating effectively and working with a diverse team of subject matter experts with varying levels of technical understanding within and outside of Nuclear Medicine.
- 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	Identify emerging safety, quality and compliance issues/risks and their implications and propose solutions.
Manufacturing Excellence Manager (and other Manufacturing Leadership Team members)	- 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. - Closely collaborate to ensure business objectives are achieved.
Quality Leadership Team members	- Closely collaborate to ensure business objectives are achieved. - Co-ordinate to ensure successful on time completion of quality compliance items. - Lead and facilitate investigations and support regulatory audits. - Apply Quality requirements within Manufacturing systems and processes, and provide operational evidence, insights and feedback on their effectiveness.
Senior Safety Manager	- Closely collaborate to ensure business objectives are achieved - Lead and facilitate investigations and support regulatory audits. - Apply Safety requirements within Manufacturing systems and processes, and provide operational evidence, insights and feedback on their effectiveness.
Engineering and Maintenance	- Closely collaborate to ensure business objectives are achieved - Lead and facilitate investigations and provide technical input into projects and maintenance activities
Work area team members	- Provide expert advice and analysis on a full range of matters relevant to the production process including compliance with cGMP 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
Manufacturing Team	- Optimise engagement and influence constructively to achieve outcomes. - Support team by assisting in ancillary manufacturing tasks
Internal Stakeholders	- ANSTO Service Providers. - Monitor KPI's. - Work collaboratively on cross-functional investigations into safety, quality and compliance issues. - Build and engage positive working relationships that promote trust and credibility and enable effective collaboration
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	Manufacturing Excellence 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 <u>AP- All Workers</u> <u>2362</u> of the ANSTO WHS Management System	
Other specialised roles identified within the guideline a position holder may be allocated to in the course of their duties	

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. 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.
4. Proven root-cause investigation, hazard identification, risk assessment and problem-solving skills.
5. Understanding of risk management principles, including interpretation of operational data to determine control effectiveness and identify emerging risks and trends.
6. Excellent interpersonal skills and ability to work independently as well as part of cross-functional teams.
7. High level technical writing skills and highly competent in the use of MS Office Suite.
8. Strong time-management, planning and organisational skills.

In addition to demonstrating strong knowledge, skills and experience at a Band 5 level, the Band 6 position also requires:

1. Strong leadership skills including the ability to coordinate multi-disciplinary work, mentor colleagues, influence without formal authority , provide clear technical direction and support achievement within a matrix environment.
2. Demonstrated ability to influence process owners to address systemic risk and compliance gaps.
3. Proven ability to independently identify and deliver opportunities for process improvement within a manufacturing environment and lead positive change to enhance operational efficiency, quality and safety.
4. Demonstrated capability in maintaining risk assessments, applying critical control management, verification and assurance principles.
5. Demonstrated expertise in stakeholder engagement and autonomous decision-making, with the ability to integrate insights from multiple subject matter experts to make sound judgements.

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:		Name:	Justine Murison
Title:	Manufacturing Excellence Manager	Title:	Head of Manufacturing
Signature:		Signature:	
Date:		Date:	

**Manufacturing Excellence Associate Linked Role (PD-2453)
Band 5 (Associate) to Band 6 (Lead) Transition Checklist**

Name:	
Commencement Date:	
Assessment Date:	

Note: Full written submission demonstrating and justifying how the employee meets the requirements must be attached to support the transition. Review, assessment and endorsement of the transition will be achieved via employees presentation of the submission to the senior manufacturing leadership team (panel) and requires unanimous agreement. Transition will only be authorised by the General Manager.

Requirements for Transition	Met Criteria
Full performance of Band 5 accountabilities (level 5). Inclusive of knowledge, skills and experience described in this PD and the skills defined in the current Capability Matrix for this PD.	☐ Yes ☐ No
Proven proficiency in all Nuclear Medicine Capabilities defined in the current Capability Matrix for this PD. Including evidence of cross-functional influence, independent decision-making and leading complex ambiguity.	☐ Yes ☐ No
Demonstration of pursuing and building Band 6 accountabilities. Inclusive of knowledge, skills and experience described in this PD and the Manufacturing Excellence Skills defined in the current Capability Matrix for this PD.	☐ Yes ☐ No
Working towards mastery in Nuclear Medicine Capabilities defined in the current Capability Matrix for this PD.	☐ Yes ☐ No

Manufacturing Excellence Manager Assessment

I have assessed the submission and confirm that the employee meets all requirements for transition from Band 5 to Band 6.

Name:	
Signature:	
Date:	

Head of Manufacturing Endorsement

I have assessed the submission and confirm that the employee meets all requirements for transition from Band 5 to Band 6.

Name:	
Signature:	
Date:	

General Manager Nuclear Medicine Authorisation

I have reviewed all information and approve transition from Band 5 to Band 6.

Name:	
Signature:	
Date:	
Effective Date of transition:	