Australian Government

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POSITION DESCRIPTION

Position Title:	Manufacturing Support Associate/Lead
Cluster / Business Unit / Division	Nuclear Operations and Nuclear Medicine
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

POSITION PURPOSE

The primary objective of the Manufacturing Support Associate(s) is to facilitate and improve manufacturing operations within Nuclear Medicine. The Manufacturing Support Associate(s) are responsible for supporting the safety, quality, risk and compliance of manufacturing processes, in line with the overall manufacturing strategy to support the safe, secure, sustainable supply of Nuclear Medicine.

At the higher level, the Manufacturing Support Lead(s) are specialised experts who own and manage the safety, quality, risk and regulatory compliance activities that underpin and optimise for manufacturing operations within Nuclear Medicine.

The position focusses on supporting the direct value streams within Nuclear Medicine Manufacturing, ensuring appropriate risk, issue and change management underpins processes and associated business 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

- Drive manufacturing robustness, capability and continuous improvement by developing, implementing and maintaining manufacturing support documentation, such as process flow

diagrams, manufacturing instructions and risk assessments 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 and standard operating procedures.

- Provide technical support to operational manufacturing 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 and Risk Register.
- Lead root cause investigations into safety, quality and operational incidents and execute corrective and preventative action plans in response.
- Monitoring, trending and reporting of the manufacturing compliance metrics, providing assurance that all change controls, corrective and preventative actions, deviations and controlled documents are completed in a timely manner and in line with regulatory requirements.
- Participate in manufacturing aspects of both internal audits and external regulatory inspections, taking a lifecycle approach to inspection readiness, providing manufacturing expertise and responding to any regulatory findings.
- Champion 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.
- 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 independently performing all Band 5 key accountabilities independently, the key accountabilities for a Band 6 position include:

- Design and manage the frameworks by which manufacturing compliance metrics are monitored, trended and reported, providing assurance that all quality and safety items are completed in a timely manner and in line with regulatory requirements.
- Mentor and develop other members of the operational manufacturing teams, providing technical mastery and decision making for process changes, investigations and continuous improvements.
- Initiate and manage manufacturing support projects and lead small teams, ensuring timelines are met, budget is controlled and risks are managed.
- Lead complex root cause investigations into safety, quality and operational incidents and drive corrective and preventative action plans in response.
- Lead manufacturing aspects of both internal audits and regulatory inspections, taking a lifecycle approach to inspection readiness, providing manufacturing expertise and responding to any regulatory findings.
- Ensuring end-to-end manufacturing operations are performing in line with safety, quality, risk and compliance requirements.

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.
- 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 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, ANSO, 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 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.
Process Performance Manager	• Closely collaborate to ensure business objectives are achieved
Quality Systems and Compliance Manager	• Closely collaborate to ensure business objectives are achieved. • Co-ordinate to ensure successful on time completion of quality compliance items.
Quality Assurance Manager – Operations Quality Control Manager	• Closely collaborate to ensure business objectives are achieved. • Provide resources to assist with quality investigations and audits.
Regulatory and Medical Affairs Manager	• Closely collaborate to ensure business objectives are achieved • Provide resources to assist with safety investigations and regulatory audits.
Engineering and Maintenance	• Closely collaborate to ensure business objectives are achieved • 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 Manager, Business Operations and Support
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 AP-2362 of the ANSTO WHS Management System	All Workers 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, risk analysis and problem-solving skills.
5. Excellent interpersonal skills and ability to work independently as well as part of cross-functional teams.
6. High level technical writing skills and highly competent in the use of MS Office Suite.
7. 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 effectively manage, motivate, delegate and stimulate achievement in a team within a matrix environment.
2. 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.
3. 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:	Joseph Bailey	Name:	Justine Murison
Title:	Manufacturing Manager, Business Operations & Support	Title:	Head of Manufacturing
Signature:		Signature:	
Date:		Date:	

Manufacturing Support Associate Linked Role (PD-2453)
Band 5 to Band 6 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 and requires unanimous agreement. Transition will only be authorised by the General Manager.

Requirements for Transition	Met Criteria
Performing Band 5 accountabilities, as described in this PD (or equivalent experience in a similar highly regulated manufacturing environment) and completion of the Band 5 to Band 6 transition criteria curriculum with 100% metric are completed.	Yes No
Demonstrated ability to independently plan, coordinate and drive continuous improvements in manufacturing operations effectively over a sustained period of time.	Yes No
Sustained application of technical mastery in Safety, Quality, Risk and Compliance, as demonstrated by:	
Participation in regulatory inspections and leading responses and remediations based on outcomes	Yes No
Champion continuous improvement activities and lead team members in the implementation of solutions to improve safety, quality, productivity, efficiency and capability within the team.	Yes No
Oversee manufacturing programs such as change management, risk register, internal audits, incident/event management.	
Train and mentor new team members and uplift the capability of direct value stream team members within Safety, Quality, Risk and Compliance	Yes No
Lead complex investigations of safety/quality events and implement appropriate corrective/preventatives actions in a timely manner.	Yes No
Demonstrated independent decision-making ability to ensure Manufacturing processes and programs are within appetite for safety, quality, risk and compliance.	Yes No
Demonstrated ability to engage and influence a wide range of internal and external stakeholders across a variety of different scenarios.	Yes No

Manufacturing 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:	