Australian Government

ANSTO
Science. Ingenuity. Sustainability.

POSITION DESCRIPTION

Position Title:	Process Specialist
Cluster / Business Unit / Division	Nuclear Operations & Nuclear Medicine (NONM)
Section or Unit:	Nuclear Medicine
Classification:	Band 6
Position Description Number:	PD-A0028
Work Contract Type:	Technical

POSITION PURPOSE

Ensure the processes to supply our existing products are sustainable and efficient, meeting the safety and quality requirements of our facility. To champion a continuous improvement culture, improving the knowledge and capability of our team and to introduce new products to the business in a controlled and disciplined way.

This will be achieved by providing an effective interface between operations, quality, validation, engineering and maintenance to assure that production processes are under effective control.

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 a business unit within ANSTO engaged in the manufacture and sales of radiopharmaceutical and radiochemical products. Manufacturing is based upon the GMP Code of Manufacturing, where processes must meet high-level regulatory standards. The Quality Control department plays an integral role in ensuring this standard is met 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. ANSTO Health operates under external regulatory requirements such as ISO 9001, ARPANSA and TGA, within ANSTO's procedural framework and in oversighted by the ANSTO Board. Over 500,000 Australian patients benefit from ANSTO Nuclear Medicine radiopharmaceuticals annually.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

- Provide technical leadership for the ANM process in relation to the development, design and integration of processes
- Provide leadership and take responsibility for new products, processes and equipment implementations
- Develop and update Standard Operating Procedures, work instructions and one point lessons
- Identify, coach and lead sustainable continuous improvement initiatives
- Develop procedures and policies for operations and provide technical training to all employees
- Lead complex investigations for safety, quality and operational incidents in a timely manner

- Lead risk reduction strategies and process improvement planning
- Provide technical support to Manufacturing Leaders and Operations Manager
- Provide assurance that all processes are effective as per the API, PIC/S Guide to GMP)
- Develop appropriate KPIs for the area and monitor progress
- 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 respected in all activities undertaken by the Operations Team
- Designing and maintaining a batch documentation system that is fit for purpose to ensure that appropriate process records are kept in compliance with GMP requirements
- Equipment readiness to produce the intended outcome based on calibration and qualification
- Technical input to the business to enable correct prioritisation of activities
- Technical input to training program requirements for relevant processes

Key Challenges

- Being a change leader to step change of performance in a highly regulated environment
- Working with other stakeholders to achieve outcomes. Requires excellent interpersonal skills to influence and negotiate to obtain appropriate resourcing and co-operation
- Maintaining appropriate levels of control in a highly dynamic environment
- Identifying and addressing risks to delivery prior to it resulting in a process problem

KEY RELATIONSHIPS

Who	Purpose
Internal	
General Manager	• Provide expert advice on Technical matters and contribute to decision making • Identify emerging process and equipment issues/risks and their implications and propose solutions
Operations 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
Quality Assurance Manager includes Validation	• Closely collaborate to ensure business objectives are achieved • Provide resources to assist with investigations relating to process issues • Provide advice on Change Control matters relating to process and equipment • Provide technical input into the Quality Risk Management process • Closely collaborate to ensure business objectives are achieved • Provide input into the development on 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
Engineering (e.g. Program Manager)	• Closely collaborate to ensure business objectives are achieved • Provide technical input into projects undertaken by the engineering team • Provide feedback to assure satisfactory completion of Engineering projects
Technical Manager	• 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 PM • Provide feedback to assure satisfactory completion of 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 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
Direct Reports	• Provide leadership, guidance and support • Set performance requirements and manage performance and development
Internal Stakeholders	• ANSTO Service Providers • Monitor KPIs
External	
Customers	• Radiopharmaceutical domestic and International customers • Ensure DIFOT
Suppliers	• Radiopharmaceutical domestic and International Suppliers • Monitor KPIs and Service Level Agreements (SLA)

POSITION DIMENSIONS

Staff Data	
Reporting Line	Operations 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 qualification in an appropriate Life Science, Pharmacy or Engineering discipline or equivalent demonstrated experience.
2. Extensive demonstrated experience in the production of regulated products within the Pharmaceutical or Veterinary Industries.
3. A thorough understanding of Good Manufacturing.
4. Demonstrated experience in the application of Quality Risk Management to pharmaceutical processes.
5. Continuous Improvement leadership
6. Ability to apply safety principles in a highly controlled environment
7. Ability to communicate to all levels of the organisation
8. Ability to co-ordinate and lead change
9. Ability to manage effective relationships with key stakeholders
10. Understanding of maintenance practice and project management beneficial

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:	Justine Murison	Ian Martin
Title:	Head of Manufacturing	GM ANSTO Health/Head of Operations ANM
Signature:		Signature:
Date:		Date: