Australian Government

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POSITION DESCRIPTION

Position Title:	GMP Process / Project Engineer – ANSTO Health
Cluster / Business Unit / Division	Engineering & Capital Programs
Section or Unit:	Engineering Delivery Office/CA&VC Portfolio
Classification:	Band 5/6 *Linked Role*
Position Description Number:	PD-1943
Work Contract Type:	Professional/Technical

POSITION PURPOSE

The GMP Process / Project Engineer is responsible for delivering engineering solutions including design, implement and manage efficient, safe and compliant production processes and facilities to meet the business requirements of ANSTO Health. This position operates within a well-defined project discipline and involves a range of multidisciplinary stakeholders at various levels across ANSTO Health - Production, Supply Chain and Quality groups, the Engineering and Capital Programs group and the Asset Management and Services Group.

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.

Engineering & Capital Programs (E&CP) provides comprehensive project management, engineering, technical and safety and reliability services and support for the organisation. E&CP is comprised of the Engineering Delivery Office, Technical Services Group, Systems Safety & Reliability, Special and External Projects Group, and an Asset Management Services Group

The Customer Advocacy & Value Chain (CA&VC) cluster within ANSTO includes a number of commercial businesses including ANSTO Health, ANSTO Nuclear Medicine, ANSTO Minerals, ANSTO Silicon Irradiations and ANSTO Radiation Services. The focus of this division is on the management of ANSTO's established businesses. The division generates revenue for ANSTO from the sale of products and services and has a strong quality focus on meeting customer needs with timely and value added products and services. The CA&VC cluster identifies and implements continuous improvement activities with the objective of simplifying the end to end supply chain to deliver ongoing value to both internal and external customers.

This role will be fully deployed into the CA&VC ANSTO Health's embedded E&CP Engineering Unit, and the role is responsible for the reliability and availability of ANSTO Health's radio-isotope manufacturing processing plants and its associated systems and ensures ongoing compliance with regulatory and statutory requirements. The role requires the applicant to "own the process" and to advise engineering of issues in manufacture.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

As a linked role, it is the intention that this position will be initially recruited into the band 5 level of which the employee will develop and acquire the competence, skills, knowledge and experience, over a period of time, to competently operate at the Band 6 level.

Transition from Band 5 to Band 6 will occur following a recommendation from the relevant manager, assessment by the E&CP/CAVC Portfolio Leader and approval from the Group Executive E&CP. Transition is not automatic and compliance with each transition criteria will need to be demonstrated, documented, assessed and signed off.

The key accountabilities for the Band 5 position include:

- Develop and design process and mechanical improvements for radiopharmaceutical production compliant with the regulatory requirements.
- Ensure compliance to GMP is maintained, through an excellent understanding of clean room and equipment regulatory requirements.
- Ensure production efficiencies are maintained, through an excellent understanding of hot cell and nuclear equipment requirements.
- Lead the manufacturing, testing, commissioning and validation of equipment.
- Initiate and manage projects complying with ANSTO's project management structures and reporting requirements.
- Identify areas for safety and efficiency improvements.
- Conduct root cause analysis of non-conformances and production misses to enable systemic improvements to performance, efficiency and regulatory compliance.
- Perform validation activities for equipment and processes including plan and protocol preparation and testing.
- Modify and improve production equipment and production methods (where possible).
- Provide technical advice to management, production, quality assurance and regulatory groups.
- Ensure maintenance records (SAP database, work orders, records sheets, etc) are prepared and updated in a timely manner
- Undertake additional duties as required and during periods of leave of other staff.

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

- Lead project teams including frequent communication, conflict resolution and negotiation and manage multi-disciplinary projects from conception to finalisation, including scope management, supervision, cost control, time management, quality control, and contract management ensuring work is delivered on time and budget.
- Independently initiate projects including consulting with stakeholders and management to gain acceptance of technical specifications and business cases. This includes developing cost benefit analyses of proposed options, seeking new solutions, and developing new techniques and methods.
- Develop and train project staff including coaching and mentoring.
- Develop asset management maintenance strategies
- Develop radiochemical processes and the associated intellectual property.
- Provide complex technical advice to management and other stakeholders, including background knowledge and facts and present up-to-date technical information in order to persuade them to choose the optimal solutions in related work.
- Utilise judgement to independently assess priorities of project tasks and job flow to deliver complete project.

- Utilise judgement and technical experience to undertake complex development and design consistent with current standards and statutory requirements. Conceptualise and conceive design approaches to ensure solutions are fit for purpose, cost effective and practical.
- Independently develop, construct, install, commission and arrange for validation of equipment and processes.
- Develop deep process knowledge to enable continued reliable and safe supply of radioisotopes
- Collaborate with validation specialists to design validation programs.
- Participate in the process engineering process from concept development through to, commissioning validation and product manufacturing.
- Review Asset management plans as defined by CAVC Asset Manager
- Undertake additional duties as required and during period of leave of other staff.

Decision Making

- The position works within a framework of legislation, policies, professional standards and resource parameters. Within this framework the position has some independence in determining how to achieve objectives of the unit, including deciding on methods and approaches, operations, project planning and allocation of resources.
- The position is fully accountable for the accuracy, integrity and quality of the content of his/her work provided to the CAVC/E&CP team, and is required to ensure that decisions are based on sound evidence, but at times may be required to make effective judgements under pressure or in the absence of complete information or expert advice.
- 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:

- Involvement in any production processes
- Adherence to Safety and GMP regulatory requirements
- Developing and documenting nuclear chemistry and processing engineering knowledge and maintaining currency of professional knowledge.
- Ensuring nuclear design regulations and applicable codes and practices are adhered to, including those relating to safety, GMP and nuclear technology.
- Interact with ANSTO Health staff to ensure production occurs in a timely and efficient manner in line with production schedules. Ensure delays, issues, problems are communicated appropriately with relevant stakeholders in the supply chain and to E&CP staff.
- High level of responsibility and accountability producing medical radioisotopes for human consumption.
- Compliance of all processes to GMP, ARPANSA, ISO regulations and guidelines.
- Participation in training and sharing of knowledge and experiences with other staff in Production processes and equipment.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Manager/Executive	• Receive guidance and direction • Provide expert, authoritative and evidence based advice • Staff engagement and quality recruitment • Negotiate and report on budgets and resources consistent with strategic plans and goals

	• Recommend and gain endorsement for plans and goals and other initiatives
Work area team members	• Provide expert advice and analysis on a full range of matters • Contribute to group decision making processes, planning and goals • Collaborate and share accountability • Negotiate and resolve conflicts
Direct Reports	• N/A
ANSTO Health Production, Supply Chain and Quality groups, the Engineering and Capital Projects group and the Asset Management and Services Group	• Collaborate and share accountability • Negotiate and resolve conflicts • Facilitate engagement to provide positive outcomes for ANSTO Health • Share relevant process issues including quality notifications as required.
External	
Clinical agencies	• No interactions
Contractors	• Manage contractor work to ensure delivery as per requirement
Regulators	• Participate in audits • Facilitate compliance

POSITION DIMENSIONS

Staff Data	
Reporting Line	Reports to the CAVC / E&CP Engineering Unit's Team Leader embedded in ANSTO Health.
	Nil
Indirect Reports	3-4 for project based work

Special / Physical Requirements	
Location:	Lucas Heights Working in different areas of designated site/campus as needed
Travel:	May be required to travel to different ANSTO sites from time to time May be required to travel both internationally and nationally
Physical:	Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer)
Radiation areas:	May be required to work in radiation areas under tightly regulated conditions
Hours:	Willingness to work extended and varied hours based on operational and project requirements After hours work may be required for short and infrequent periods
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 Officer (definitions found in appendix 1 of AG-2362) Group Executive / General Manager 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

This role reports to the E&CP/Engineering Delivery Office's Customer Advocacy and Value Chain Portfolio Leader and will be fully deployed into the Customer Advocacy & Value Chain (CA&VC) divisions ANSTO Health's Engineering Unit

KNOWLEDGE, SKILLS AND EXPERIENCE

The knowledge, skills and experience requirements for the Band 5 position include:

1. Degree qualification in Chemical/Process, Industrial Chemistry, Mechanical, Mechanical Process or Pharmaceutical Engineering,
2. Understanding of Pharmaceutical quality systems, GMP and principles of validation,
3. Knowledge of chemical processing technologies related to nuclear, pharmaceutical, biotech and related industries,
4. Experience in process equipment development, design and maintenance, clean room design and testing,
5. Ability to develop detailed working designs from requirements & concepts.
6. Professional experience within a production environment,
7. Understanding of ISO 9001 quality standard and ARPANSA and TGA regulations. Experience in project planning and management,
8. Understanding of radiation and radiation protection measures,
9. Demonstrated knowledge, experience and ability to independently and competently undertake the following:
    - Change Control Process and Validation process
    - Investigate, update and closeout Quality Notifications
    - Delivery of CAPA and TGA items to negotiated deadlines.
10. Understanding of importance of Work Health and Safety, Environment, Quality and Regulatory requirements,
11. Strong analytical and problem solving skills,
12. Good communication skills,
13. Willingness to pro-actively share knowledge, information and insight with team members.

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

14. Experience leading a team and ability to work independently without supervision,
15. Experience training, coaching and mentoring other staff,
16. Strong verbal communication skills with emphasis on the ability to adapt communication styles to suit the audience,
17. Experience in safely managing complex maintenance activities within a high dose and regulatory environment,
18. Proven experience building and maintaining effective and strong relationships with all members of the supply chain, production and quality teams to ensure customer requirements are met,
19. Demonstrated competency in asset management and associated preventative maintenance principles,
20. Significant experience in clean room design, testing and scheduling cleanroom downgrades and maintenance activities with full consideration of staffing schedules, clean, certification, test, safety and approval processes,
21. Significant experience in the development of processes to manufacture radiopharmaceuticals and intermediates,
22. Significant experience in project planning and management, including a minimum of a Cert IV diploma in Project or Frontline Management,
23. Demonstrated knowledge of and application of the PICS code to GMP processes across the range of manufacturing, quality, product release and equipment disciplines,

24. Demonstrated experience in applying chemical processing technologies related to nuclear, pharmaceutical, biotech or related industries,
25. Demonstrated experience resolving complex production, process, plant and equipment issues,
26. Significant experience investigating quality notifications and driving the completion of actions to resolve root cause controls until close out,
27. Understanding of ARPANSA and ISO regulations.

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: Gerard Breen	Name: Con Lyras
Title:	Title: Group Executive, Engineering and Capital Programs and Chief Engineer
Signature:	Signature:
Date:	Date: