Australian Government

ANSTO
Science. Ingenuity. Sustainability.

POSITION DESCRIPTION

Position Title:	QC Senior Chemist
Cluster / Business Unit / Division	Nuclear Operations & Nuclear Medicine/Nuclear Medicine
Section or Unit:	Quality Control
Classification:	Band 5
Position Description Number:	PD-2264
Job Family:	Compliance & Regulation
STEMM/NON-STEMM:	STEMM
Work Contract Type:	Technical

POSITION PURPOSE

The primary purpose of the QC Senior Chemist is to perform and supervise the day-to-day quality control activities as well as providing technical expertise as a product specialist in accordance with ANSTO policies and procedures and regulatory requirements to support the safe, secure, sustainable supply of nuclear medicine.

ORGANISATIONAL ENVIRONMENT

ANSTO is the national organisation for nuclear science and technology. We focus on undertaking leading edge research, delivering innovative scientific services and providing specialised advice to government, industry, academia and other research organisations.

ANSTO 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.

ANSTO 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

- Plan, coordinate and supervise the daily QC activities and contribute to training and coaching the QC staff.
- Act as a product specialist, managing all the continues improvement projects related to the product(s) under their portfolio.
- Assist the QC Manager with strategy development, planning and implementation as a product specialist, and CI coordinator.
- Contribute to, manage, and lead complex continuous improvements projects that are not part of routine work.
- Ensure that all quality control activities performed are carried out in a manner that complies with the TGA licensing requirements, Quality Management System and appropriate safety regulations.
- Ensure that all necessary testing is carried out using analytical methods that are adequately validated; and are approved in accordance with the requirements of GMP and pharmacopoeia.

- Prioritise workload where there are multiple regulatory and customer requirements and unplanned activities requiring to be completed within tight timeframes.
- As a technical expert, train, coach and develop staff to ensure technical knowledge is shared across the wider Quality Team. Provide advice and guidance to staff.
- Perform analyses of raw materials, intermediate reagents and finished goods and perform Quality Assurance activities, particularly release of finished goods.
- Assist with maintenance of the Quality Assurance system to ensure compliance with TGA requirements.
- Assist in coordinating all calibration, method development, validation and maintenance activities in the QC laboratories are performed in accordance with the applicable procedures.
- Coordinate and perform stability testing and compile stability protocol and reports.
- Contribute to continuous improvement initiatives by:
  - reviewing processes, developing new or modified procedures and updating relevant documentation;
  - reviewing laboratory records, and identifying adverse trends as part of preventive actions;
  - performing statistical analysis;
  - assisting with validation requirements for the equipment improvement program and management;
  - leading staff in the implementation of solutions to improve productivity and efficiency within the team.
- Perform the release raw materials, intermediates, components and packaging materials for use in the manufacture of API in accordance with the release procedure.
- Perform the release of Mo-99 API when required and in accordance with the release procedure
- Coordinate QMS functions relevant to the Quality Section, such as CAPAs, MOCs, Deviations and OOS/OOT.
- Active engagement in safety initiatives, safety investigations and coordinate implementation of relevant safety-related actions.
- Ensure all staff on the shift comply with safety and regulatory work practices.
- Prepare and maintain documentation such as procedures, work instructions, specifications, quality plans, and other quality and technical documents.
- Provide technical information, specifications, and validation information for submissions to regulating authorities and customers.
- Assist with investigations into product and service quality issues, and to recommend solutions within the quality function.
- Perform technical troubleshooting as a product specialist for a range instrumentation and test methodology.
- Undertake additional duties as required and during periods of leave of other staff.
- Participate in regulatory audits as a technical SME eg. TGA, FDA and ARPANSA.

Decision Making

In the absence of the QC Team Leader

- Planning, consulting and adjusting team and workloads based on resource availability and daily targets.
- Provide key decision making and troubleshooting when abnormal QC testing conditions are identified or abnormal QC test results are obtained (OOS/OOT investigation).
- Determining the need for new training programs or equipment upgrades to address hazards or knowledge gaps and acting on the outcomes.

Key Challenges

- Consistent compliance to TGA, GMP and ARPANSA regulations.
- Working safely with chemicals in a radiation environment.
- Working in a fast-paced production environment.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Quality Control Leader	• Immediately notifying of any incidents. • Escalating any concerns regarding product. • Performing delegated/higher duties as the Quality Control Leader if required or in their absence.
Quality Control Manager	• Coordinating as a Quality Control Leader delegate
Production Team	• Communicating to insure operations are not interrupted
Development Chemist	• Communicating to ensure workflow is not interrupted
Systems Officer	• Coordinating to address quality related issues
External	
Industry Regulators - ARPANSA	• Ensure compliance with ARPANSA licences within areas of responsibility.
Licensing Authority - TGA	• Ensure compliance with TGA and GMP code within areas of responsibility.

POSITION DIMENSIONS

Staff Data	
Reporting Line	Reports to the Quality Control Team Leader
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
Physical:	High attention to detail Laboratory environment
Radiation areas:	Ability to work with chemicals and testing materials in a radiation Environment under tightly controlled safety conditions.
Hours:	Shift work may be required. Willingness to work extended and varied hours based on operational Requirements.
Clearance requirements:	Satisfy ANSTO Security and Medical clearance requirements

Workplace Health & Safety	
Specific role/s as specified in AG-2362 of the ANSTO WHS Management System	• Work safely to reduce risk to self and others; • Use appropriate controls always considering the hierarchy of controls; • Report unsafe work practices, incidents and near hits and follow procedures if incidents occur; • Participate in investigations, inspections and risk assessments; • Attend WHS training, refreshers and tool box talks specific to role, task and work area; • Apply a questioning attitude towards work activities;

- Apply conservative decision making;
- Adhere to ANSTO's WHS Management System;
- Advise their supervisor of WHS improvements for the area; and
- Stop unsafe work.

ORGANISATIONAL CHART

On file

KNOWLEDGE, SKILLS AND EXPERIENCE

1. Relevant degree qualifications or alternatively Advanced Diploma / Diploma in Chemistry supported by relevant experience.
2. Demonstrated extensive experience in chemical analysis.
3. Experience in TGA, FDA, ISO and NATA audits and regulations desirable
4. Knowledge of and experience using statistical techniques.
5. Experience in validation of analytical method and instrumentation desirable
6. Knowledge of analytical instrumentation and analytical techniques, including nuclear instrumental counting techniques.
7. Experience with Good Manufacturing Practices (GMP) and knowledge of relevant nuclear and pharmaceutical production regulations and legislation.
8. Demonstrated ability to effectively communicate to a wide audience including tradespeople, professionals and management.
9. Pro-active, deadline driven, and reliable in following through with actions.
10. Strong time management, planning and organisational skills.
11. Strong customer service focus.
12. Demonstrated ability to work within and promote a strong safety culture.
13. Strong team working spirit, and demonstrated respectful workplace behaviour.

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:	Micheal Gobrial	Name:	Bhawna Sharma
Title:	Quality Control Manager	Title:	Head of Quality
Signature:		Signature:	
Date:		Date:	