Australian Government

ANSTO
Science. Ingenuity. Sustainability.

POSITION DESCRIPTION

Position Title:	Computer System Validation Specialist
Cluster / Business Unit / Division	Infrastructure and Engineering Services
Section or Unit:	Project Deliver – Nuclear Medicine
Classification:	Band 6
Job Family:	Engineering and Technical
Position Description Number:	PD-2505
Work Contract Type:	Technical
STEMM/NON-STEMM:	STEMM
STEMM CATEGORY:	Engineering

POSITION PURPOSE

The Computer System Validation Specialist is responsible for the upgrading of industrial computer systems used within a pharmaceutical manufacturing environment and the upgrades must comply with GAMP and PIC/s regulatory requirements.

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.

The Infrastructure and Engineering Services group is responsible for supporting customers realise their business outcomes in delivering engineering projects in accordance with engineering business management systems ensuring delivery to required scope, quality, regulatory compliance, time, and cost. It provides engineering design expertise and delivery of projects and programs with independent oversight from a centralised Engineering Delivery PMO division.

ACCOUNTABILITIES & RESPONSIBILITIES

Key Accountabilities

- Undertake Computer Systems Validation audits and upgrade work on various industrial computer or specialised systems such as SCADA, robotics, HMI/PLC based machines, or Data Acquisition Systems (DAS), for the organisation.
- Ensuring the design, installation and operation of computer or SCADA systems are performed in accordance with requirements within the current Australian code of GMP (or other regulatory requirements) for medicinal products and;
- Prepare Validation Plans (VP) as required for computer validation and associated work schedules and report on the progress of this plan ensuring compliance with TGA, and other regulatory requirements as required (e.g. FDA);
- Prepare and execute Good Engineering Practice (GEP) requirements such as design specifications, procurement specifications, Factory Acceptance Test (FAT) documents, Site Acceptance Test documents, Commissioning Report, Disaster Recovery Procedures, Operation and Maintenance manuals.

- Provide validation advice and input into new engineering projects for industrial computer, OT or other specialised system related projects at ANSTO and Good Manufacturing Practice (GMP) manufacturing areas such as ANSTO Health and ANSTO Nuclear Medicine (ANM). The extent of this advice and input may extend also to any proposed new manufacturing systems, equipment, computer systems, specialised system, new products and facilities against GMP practice;
- Liaise with validation and quality specialists within ANSTO Health and ANSTO Nuclear Medicine (ANM) for co-ordination of industrial computer or specialised system validation activities, project timelines, periodic reporting and regulatory inquiries and inspections;
- Prepare and execute Good Manufacturing Practice (GMP) requirements such as design qualification (DQ); DQ reports; Traceability Matrices, Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) protocols for various industrial computer or specialised systems related validation activities including execution and writing of the final Validation Reports;
- Perform or assist with gap analysis and data management and integrity assessment for existing industrial computer or specialised systems against current and emerging codes. Recommend and implement remediation activities to comply with regulatory requirements;
- Facilitate Computer Systems Validation training activities, where required for validation familiarisation and the risk-based approach concept to other project engineers within CAVC as required;
- 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 CAVC portfolio and the client's expectations, 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 advice provided to ANSTO and client's GMP manufacturing areas, and is required to ensure that decisions are based on sound evidence, but at times may be required to make effective judgements under pressure e.g. in a regulator's audit environment, 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

- Backlog of projects and legacy systems requiring computer system validation.
- Working within a nuclear GMP pharmaceutical envirnoment.
- Working with tight project timelines and small shutdown windows.
- Continuous development of working relationships.

KEY RELATIONSHIPS

Who	Purpose
Internal	
Manager/Executive	• Provide expert, authoritative and evidence based advice • Recommend and gain endorsement for plans and goals and other initiatives
Work area team members	• Contribute to group decision making processes, planning and goals • Collaborate and share accountability • Provide support across the implementation of systems and organisational strategy

ANSTO Infrastructure & Engineering; GMP Manufacturing areas; quality and validation personnel	• Provide advice and support • Develop and maintain networks to enable effective and efficient transactions between the groups • Communicate on reporting, procedures and audits across the organisation
External	
Regulatory Bodies	• Liaise with health authorities such as TGA/FDA on computer validation during regulatory inspections

POSITION DIMENSIONS

The position may work as part of a team on projects within divisions or organisation wide. There is no budget for this position.

Staff Data	
Reporting Line	Reports to the Senior Chemical Engineer
Direct Reports	Nil
Indirect Reports	Nil

Financial Data
Revenue / Grants
Operating Budget
Staffing Budget
Capital Budget
Assets

Special / Physical Requirements	
Location:	Lucas Heights. Working in different areas of designated site/campus as needed
Travel:	May be required travel to various other ANSTO sites (Camperdown NSW, Clayton Victoria) from time to time.
Physical:	Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer).
Radiation areas:	Willingness to work in prescribed radiation areas in order to undertake duties.
Hours:	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 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 in Electrical Engineering (software) or Computer Science and extensive experience in performing computer system including Supervisory Control & Data Acquisition (SCADA) compliance audits, upgrades, rebuilds, new builds, and application compliance tests and checks.
2. Experience with various computer operating systems e.g. MS Windows; industrial software applications as used in PLC and SCADA system platforms, Allen Bradley PLC systems and Citect platforms; industrial dataloggers.
3. A background in pharmaceutical manufacture will be highly desired
4. Experience and working knowledge with risk-based approach, GAMP 5 guide principles and framework, data integrity, testing of GxP systems, PIC/S: Annex 11 compliance and FDA 21 CFR part 11 compliance.
5. Computer Validation experience in the pharmaceutical / radio-pharmaceutical industry.
6. Proficient in Microsoft Office products- MS Word, MS Excel, etc. Knowledge of SAP would be advantageous.
7. Proven leadership, communication and influencing skills.
8. Ability to work effectively in cross functional and multi-disciplinary teams.
9. Proven project management and technical report writing skills.
10. Demonstrated ability to produce outcomes on a short timeline.
11. Understanding and experience of regulatory body requirements (eg TGA, FDA, ARPANSA, ASD). Experience in audits from regulatory bodies

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:	Hamish Livingstone	Name:	Kaitlyn Gunderson-Briggs
Title:	Senior Chemical Engineer	Title:	Portfolio Manager Nuclear Medicine
Signature:		Signature:	
Date:		Date:	