Affinity Labs

Position description

Title of position: Internal Projects and Validation Lead

Reporting to: General Manager Commercial Operations

Overview:
The Internal Projects and Validation Lead is responsible for leading the delivery of critical internal operational projects across Affinity Labs, under the direction of the GM Commercial Operations and Affinity Labs Leadership. This is a hands-on role. The role leads the projects and also carries a share of the delivery work itself – drafting procedures and validation documents, preparing and executing test scripts, managing contractors and access during physical works, and assembling the evidence packs that support accreditation and regulatory review.

Qualifications:
A relevant degree in Science such as BSc, BSc (Hons), or relevant industry experience.

Experience:
A minimum of 5 years experience in a regulated laboratory environment, or equivalent.

Principal accountabilities:

The initial project portfolio covers five concurrent bodies of work: the upgrade, installation and validation of LC-MS instrumentation in the Trace laboratory; the installation and validation of ICP-MS instrumentation; transfer and validation of testing methods, a laboratory refit and reorganisation to optimise operations; and coordination of the Affinity Labs contribution to the AWRI-wide CRM implementation.

Project Coordination and delivery

- Lead the day-to-day delivery of a portfolio of projects, from initiation through to close-out.
- Prepare and maintain project plans, schedules, milestones, resource requirements and risk assessments for each project.
- Coordinate the supply, delivery, installation and commissioning of instrumentation, working with vendors, service providers and internal technical staff.
- Track progress against plan and report status, risks and issues to the project sponsor on a regular cycle.
- Identify and escalate risks promptly – particularly any risk to accreditation scope, service continuity, sample integrity or study timelines.
- Ensure all project records are complete, current, attributable and retained in accordance with the facility's record-keeping and data integrity requirements.

Project Work

- Draft, review and format project and validation documents – validation plans, user requirement specifications, risk assessments, installation and operational qualification protocols, rest protocols and summary reports – for review and approval.
- Write and prepare test scripts, then execute or witness testing and records results accurately and contemporaneously.
- Compile traceability matrices linking requirements to specifications and test evidence.
- Run the user acceptance testing cycle end to end.
- Assemble the validation and project evidence packages, ready for quality review, NATA assessment or audit.
- Carry out supporting work where a project needs it – data gathering, spreadsheet and register maintenance, procedure drafting, contractor scheduling and follow-up of outstanding actions.

- Take ownership of defined workstreams within larger projects, delivering the component work directly rather than only reporting on it.

Stakeholder engagement and communication

- Act as primary point of contact for each project, coordinating between laboratory managers, analytical and technical staff, quality assurance, AWRI IT and shared services, and equipment or service vendors.
- Schedule and chair project meetings; prepare agendas, record decision and circulate minutes and action items.
- Translate scientific and technical requirements into clear project scope, and communicate technical constraints back to non-technical and scientific stakeholders in plain language.
- Manage expectations around timelines, dependencies and competing priorities across the laboratory's operational and commercial demands.
- Prepare project communications and training material to support user adoption and go-live.

Quality Assurance and Compliance

- Coordinate the validation lifecycle for new and upgraded instrumentation — requirements definition, risk assessment, qualification planning, testing, and the documentation that evidences it.
- Ensure instrument validation documentation meets the requirements of both ISO/IEC 17025 and the OECD Principles of GLP, as applicable to each instrument and study context.
- Support method verification or revalidation where instrument changes affect existing accredited methods, and coordinate the records that confirm methods remain fit for purpose.
- Work within the facility's quality management system and apply applicable standard operating procedures throughout, supporting NATA assessment and audit activity as required.
- Uphold data integrity expectations for records and electronic data, giving appropriate attention to electronic records and electronic signatures requirements.
- Escalate any practice, record or system issue that could compromise the integrity of analytical data or the facility's accreditation.

General

- Identify and communicate opportunities for improvements in workflow, efficiency or resource use.
- Accepts that all intellectual property, patents and discovery arising during the course of employment at the AWRI remain the property of the AWRI.
- Undertakes other duties as directed by the Managing Director.
- Promotes the general well-being of the AWRI by ensuring that all contact with clients, staff or the public is performed in a professional and confidential manner.

Person specification:

1. Demonstrated experience leading or coordinating projects, ideally within a laboratory, scientific, quality-regulated or technical environment.
2. A proven willingness and ability to do the hands-on work — drafting documents, preparing and executing test scripts, and working through tasks personally rather than delegating them.
3. Strong technical writing skills, with the ability to produce clear, precise procedures, protocols and reports from source material.
4. Strong organisational skills and the proven ability to manage several competing priorities concurrently without losing track of detail.

5. Excellent written and verbal communication skills, including the ability to present status and issues clearly to senior scientific and management stakeholders.
6. Confident facilitation skills — running meetings, capturing decisions and driving actions to completion.
7. Demonstrated discipline in documentation — accurate, timely, complete records that would stand up to review.
8. An understanding of, or demonstrable ability to work within, a formal quality system and standard operating procedures.
9. Experience with validation in a regulated environment — qualification and validation planning, risk-based testing, and the documentation that evidences it.
10. Working knowledge of the OECD Principles of Good Laboratory Practice (GLP) and ISO/IEC 17025, and an understanding of how validation, method and documentation obligations arise under each.
11. Experience in an analytical testing laboratory, contract research organisation, or comparable regulated scientific setting.
12. A collaborative, proactive working style with the resilience to work through ambiguity and competing operational demands.

Workplace Health and Safety responsibilities:

Employees and students must take reasonable care to protect their own health and safety, and have responsibilities to:

1. Ensure that they do not increase the risk to the health, safety or welfare of others through any act or omission.
2. Obey reasonable instructions that are designed to protect their health, safety and welfare.
3. Use, in the appropriate manner, equipment that is provided to protect their health, safety or welfare.
4. Not wilfully interfere with, or misuse, items or facilities provided in the interest of health, safety or welfare of employees.
5. Ensure that they are not affected by alcohol or any other drug to such an extent that they endanger themselves or others.
6. Report promptly, any hazards, incidents or injuries to their Manager/Team Leader.