Position description

Senior Quality Associate

About SVI
For more than 60 years, scientists at SVI have been inspired by discovery and driven by purpose.

Our team of 250 staff and students work collaboratively to tackle some of the most critical health challenges facing society today, including cancer, diabetes, osteoporosis, cardiovascular disease, infectious disease testing and dementia.

We celebrate fundamental biological discovery and practical application alike because both are required to improve the treatment, diagnosis and prevention of disease. Our NRL division is a WHO Collaborating Centre and designated as a WHO IVD Pre-qualification Evaluation Laboratory which provides a range of premium solutions and services to improve the quality of testing for infectious diseases. It has a global reputation for technical scientific excellence and fosters public health partnerships whilst delivering science as a service.

SVI is located across four sites on the campus of St Vincent's Hospital Melbourne and has a laboratory at Notting Hill. It is affiliated with The University of Melbourne and operates proudly in one of the world's most dynamic biomedical hubs. NRL operates from the Fitzroy campus as well as operating a molecular donor screening laboratory at Notting Hill.

Mission & vision
Research at SVI is inspired by discovery and driven by purpose. Our mission is to produce world-class science. Our vision is to make medical discoveries that transform lives
As a division of SVI, NRL's mission is to improve the quality of infectious disease testing globally.

Position details

Title	Senior Quality Associate
Classification	MS3
Superannuation contribution	12%
Salary packaging	Up to $15,900 FBT exempt
Meals & Entertainment packaging	Up to $2,650 FBT exempt
Location	NRL
Reports to	Quality and Regulatory Affairs Manager
Hours	38 hrs week

Job purpose

The primary purpose of this position is to provide quality knowledge and deliver quality objectives and activities related to the infectious disease functions and activities undertaken within the NRL laboratories. The incumbent will assist in maintaining the NRL Quality Management System (QMS), execute QMS activities, provide quality support in the translation of assays and other new work into routine operations and maintain compliance with industry legislation, codes, standards and guidelines to ensure ongoing regulatory registration, accreditation and certification.

The scientist appointed at this level will be scientifically, technically and quality experienced and capable of critical data and information analysis to enable informed decisions related to the QMS and the quality aspects of NRL activities and technical projects. The role will also involve training NRL staff in QMS processes and requirements and providing expert advice to internal stakeholders on quality related matters.

Key responsibilities

1. **Specialist Scientific Responsibilities.**
    - Assist in the development, implementation and maintenance of the Quality Management System (QMS) in accordance with ISO 9001, ISO 15189, ISO 17043, ISO 20387, the Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products (cGMP), and other applicable standards, TGA orders and NATA requirements
    - Execute QMS activities including, but not limited to, non-conformance (NC) management, corrective and preventive actions (CAPAs), internal audits, document control, change management, supplier management, management review, risk management, reviewing and approving technical documents, and monitoring trends and conduct effectiveness reviews
    - Facilitate root-cause analysis and other problem-solving activities to identify effective corrective and preventive actions and processes
    - Assist in 3rd party audits including pre-audit preparations, hosting, preparing responses and managing associated actions
    - Support Clinical and Research Services, from a quality perspective, in the translation of assays and other new work into routine operations
    - Support Scientific and Business Services, from a quality perspective, to deliver their products and services
    - Maintain a positive and productive working relationship with internal and external stakeholders
    - Be the Quality representative on Testing, EQAS, Evaluations and special projects to ensure quality requirements are identified and met
    - Develop and deliver QMS training for NRL staff
    - Assist in the completion and maintenance of a risk register documenting risk identification, prevention / mitigation and management
    - Deputise for the Quality and Regulatory Affairs Manager as required

Measures of performance:

- *Ongoing ISO 15189, ISO 17043 and ISO 20387 accreditation, GMP licencing, ISO 9001 certification and other applicable standards as required*
- *NRL's performance within the QMS meets expectations*
- *QMS activities executed according to procedures*
- *Effective and timely completion of quality management system activities including internal audits, document control, NCs and CAPAs (CARs), supplier management, contracts and participation in 3rd party audits*
- *Quality and Regulatory Affairs Manager deputy activities effectively completed as required*
- *Quality services delivered for Clinical and Research Services, and Scientific and Business Services in a timely manner to support new work projects*
- *QMS projects satisfactorily completed to schedule including effective and timely implementation*

2. Stakeholder Engagement

- The ability to effectively engage, influence, and manage relationships with stakeholders to ensure alignment, trust, and successful delivery of outcomes.

Measures of Performance:

- *Building strong, credible relationships with internal and external stakeholders*
- *Understanding stakeholder needs and translating them into actionable solutions*
- *Managing expectations, risks, and competing priorities*
- *Providing clear, timely, and professional communication*

3. Operational Efficiency & Quality

- Delivers high-quality outputs efficiently, optimising time, resources, and tools while maintaining accuracy and compliance.

Measures of Performance:

- *Delivering work within agreed timelines and budgets*
- *Prioritising tasks effectively across multiple engagements*
- *Minimising rework through quality planning and execution*
- *Using systems, data, and methodologies effectively*
- *Comply with internal and external QMS requirements*

4. Process Improvement

- The capability to identify, analyse, and implement continuous improvement to processes or ways of working that enhance efficiency and quality.
- Assist in the ongoing development, review and publication of QMS policies, procedures and associated documentation that reflect current relevant legislation, regulations, codes, standards and guidelines

Measures of Performance:

- Analysing existing processes to identify inefficiencies or gaps
- Designing and recommending practical improvement solutions
- Supporting implementation and change adoption
- Measuring, coaching and demonstrating the impact of continuous improvement

5. Team Work

- Contributing to effective collaboration, knowledge sharing, and collective performance within project teams and across the organisation.
- Provide training to NRL staff in QMS processes and requirements

Measure of Performance:

- *Collaborating constructively with diverse teams and disciplines*
- *Supporting colleagues and contributing to shared objectives*
- *Sharing expertise, insights, and best practices*
- *Demonstrating professionalism, respect, and accountability*
- *Effective and timely preparation and provision of QMS training*

6. Professional Development

- The commitment to continuously improving skills, knowledge, and professional capabilities relevant to role

Measure of Performance:

- *Participation in training, learning, or development activities*
- *Applying new skills or knowledge to improve work outcomes*
- *Keeping up to date with systems, policies, and best practices*
- *Seeking feedback and acting on development opportunities*

7. Project Management

- The ability to plan, execute, and monitor project activities to ensure delivery of agreed outcomes within scope, time, and budget constraints.

Measures of Performance:

- *Defining project plans, milestones, and deliverables*
- *Managing risks, issues, and dependencies*
- *Coordinating resources and tracking progress*
- *Reporting status and escalating issues appropriately*

8. Workplace Health and Safety

- SVI/NRL has a duty of care to all employees to provide a safe work environment.
- All employees must also take responsibility for their own safety, and that of fellow workmates, and should apply a commonsense approach to work methods to minimize risk to themselves and others.
- Work performed in accordance with NRL's specific workplace safety regulations and procedures

Measure of Performance:

- Adherence to SVI Occupational Health & Safety guidelines, including the wearing of personal protective equipment as provided;
- Use equipment in compliance with manufacturers' or relevant guidelines.
- Report any shortcomings to senior management
- Report any team concerns to senior management as per SVI policies

9. Other duties

- Duties may vary depending on immediate operational needs, but will not vary outside reasonable expectations

Experience, knowledge and qualifications

Essential

- Tertiary qualifications in medical or biological science
- Experience working in a scientific laboratory environment, ideally within infectious diseases and/or serology and understanding of quality control procedures and relevant standards
- Proven experience in a Quality or scientific role ideally in a scientific laboratory and/or manufacturing facility, responsible for maintaining ISO 15189, ISO 17043 accreditation, TGA cGMP registration and/or other accreditation or certification relevant to a laboratory environment
- Experience in the application of ISO 15189, ISO 17043, ISO 20387, ISO 13485 and/or cGMP
- Competency in software packages such as MS Outlook, MS Excel and Word

Highly Desirable

- Knowledge and experience in the operations, implementation and maintenance of electronic quality systems
- Expertise in Smartsheet project management software

Personal attributes

- Excellent interpersonal and communication skills, both written and verbal
- Ability to think independently and to provide proactive responses to unexpected results
- Strong attention to detail and accuracy
- Excellent organisational skills, able to multitask and prioritise work during busy periods
- Ability to follow documented procedures
- Able to troubleshoot unfamiliar scenarios and apply critical thinking and common sense

- Confidence in working autonomously and apply sound decision making, but able to exercise appropriate judgement and seek advice and support as appropriate

I understand and agree to undertake the requirements of the role, as described above:

Incumbent Name ……..……

Incumbent Signature……. Date……..