

## Position description

# Senior Scientist – Evaluations

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### 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

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Title	Senior Scientist, Evaluations
Classification	MS3 (\$108,360 - \$122,771)
Superannuation contribution	12%
Salary packaging	Up to \$15,900 FBT exempt
Meals & Entertainment packaging	Up to \$2,650 FBT exempt
Location	NRL (Fitzroy campus)
Direct Reports	2 - 6 FTE
Reports to	Executive Manager, Scientific and Business Relations
Hours	Full time

## **Job purpose**

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NRL is designated as a World Health Organisation (WHO) Prequalification Evaluation Laboratory. On behalf of WHO and the Australian Therapeutic Goods Administration (TGA), NRL Evaluations conducts assessments of IVDs that test for infectious disease ensuring the associated evidence is scientifically sound and key performance, quality and safety criteria are met. NRL Evaluations also works directly with commercial IVD manufacturers, NGOs and other stakeholders on ad-hoc, independent IVD evaluations and projects that support public health initiatives.

This position is responsible for the operations and management of NRL Evaluation services including managing relations with regulatory stakeholders such as the WHO and the TGA, non-government agencies and IVD manufacturers. The incumbent will apply specialist technical, regulatory and scientific knowledge and demonstrate competence in the development / review of evaluation protocols; acquisition, preparation and management of samples and stock materials; management of evaluation testing; analysis of results, as well as provision of final reports. This role involves robust project management of test kit evaluations/activities as well as oversight of Evaluations day-to-day operations.

The Senior Scientist will manage staff and the program of work to ensure that timelines of activities and budgets are met. The incumbent will serve as an expert to troubleshoot scientific and technical issues related to evaluations, provide advice to stakeholders and have overall responsibility for the outputs of the Evaluations team.

The Senior Scientist appointed at this level will be recognised as an expert in the field of test kit evaluation including validations and verification, and have a comprehensive understanding of IVD regulatory requirements, relevant standards and professional evaluation guidance documents (e.g CLSI, EU Common Technical Specifications, WHO TSS). The incumbent will be capable of critical evaluation of scientific data, have a high-level understanding of infectious diseases testing and excellent communication and writing skills. The role will also involve periodic, independent assessment of IVD technical dossiers as contracted by the TGA and WHO, and ad hoc provision of advice to key regulatory authorities and test kit manufacturers.

## **Key responsibilities**

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### **1. Operational Management of NRL Evaluations**

- Contribute to the strategic development of the NRL Evaluations service stream, in line with the NRL Strategy and Business plan
- Responsible for the budget, risk and quality of NRL Evaluations services including delivery of all associated projects
- Effective Stakeholder management, business development and review of business proposals via NRL's acceptance of new work framework including development of costings/quotes, risk assessments and finalisation of contracts in collaboration with the Executive Manager, Scientific and Business Relations.
- Manage Evaluation's projects/pipeline of work (including resource planning) ensuring high quality execution, timely delivery and accurate budget management and projections
- Undertake periodic, independent technical dossier assessments for TGA and WHO, as required
- Manage the day-to-day operation of the Evaluations division
- Supervision and training of Evaluations staff
- Active member of NRL's Leadership team

*Measures of performance:*

- Perform designated responsibilities with a high degree of autonomy
- Complete Evaluations projects on time, to high quality and within budget
- Sound management and appropriate resourcing for the pipeline of new Evaluation activities
- Align Evaluation financials with budget forecasts
- Demonstrated competency in the scientific requirements of the role
- Maintain and lead a team of competent staff
- Maintain the Evaluations repository of samples including WHO sample panels

**2. Leadership, Judgement and Analysis**

- Represent NRL in a professional manner, communicate effectively, establish trust and manage constructive relationships with colleagues, external clients, stakeholders and contractors
- Ensure alignment of work with NRL strategy and Annual Business Plan for the successful delivery of outcomes
- As part of the NRL Leadership team participate in relevant meetings proactively contributing to discussions as they impact the Evaluations team or the wider organisation in striving for service excellence
- Contribute to troubleshooting discussions regarding evaluation protocols, data analysis, panel design and other aspects related to the assessment of IVD performance
- Prepare and deliver internal and external written and oral presentation/publications of analysed data, trends and other scientific findings
- Participate in organisational activities and prepare reports, as directed by the NRL Executive

*Measures of Performance:*

- High level of stakeholder and IVD Manufacturer satisfaction
- Demonstrates strong leadership and sound judgement
- Manage expectations, risks, and competing priorities
- Provide clear, timely, and professional communication
- Analyse existing processes to identify inefficiencies or gaps
- Prepare and deliver professional reports and well-practiced oral presentations, as required

**3. Operational efficiency, Supervision and Training**

- Supervision / co-ordination of training of staff and students to ensure efficient operations and effective work outcomes, including facilitating cross-training to maintain business continuity and capacity during staff absences or surges in activities
- Supervise and manage staff (including mentorship); provide feedback and performance development to direct reports, and undertake annual reviews in accordance with guidelines
- Ensure effective delivery of high-quality outputs through optimisation of time, use of resources, and tools, whilst maintaining accuracy and compliance.
- Adherence to the NRL Quality Training Framework

*Measures of Performance:*

- Delivery of work within agreed timelines and budgets
- Appropriate prioritising of tasks effectively across multiple engagements

- Minimising risk and rework through quality planning, process improvement and effective execution
- Management, training and development of staff which includes adequate capacity for back up of critical tasks
- Up to date training and competency records maintained, as it relates to the Evaluation staff training

#### **4. Financial Management**

- Prepare and review cost centre budgets in conjunction with the Finance Business Partner (FBP) and Executive Manager, Scientific and Business Relations.
- Prepare appropriate quotations for each new Evaluation project, for approval by the NRL Director and FBP and oversee ongoing monitoring of financials and reporting against budgets/forecasts
- Review finance performance reports and provide justification for variances
- Manage expenditure in line within the delegation of authority
- Submit financial data in line with funding body reporting requirements as required
- Post project financial review performed

##### *Measures of performance*

- Individual projects accurately costed prior to implementation, budget is monitored and communicated throughout the process with final outcomes reported
- Budget for each project and Evaluations services overall are within expectations, or variances are explained and justified
- Adequate planning and monitoring of staffing levels per project requirements to ensure budget forecasts remain accurate and predictable

#### **5. Quality and Risk Management**

- Undertake all activities in accordance with NRL's quality management system (QMS) and compliance with relevant accreditation and regulatory standards
- Ensure all Evaluation team members adhere to NRL's QMS requirements including maintaining and undertaking periodic document reviews and ensuring the training/competency records are up to date as per the Training Framework
- Identify, analyse, and implement continuous improvement that enhance quality whilst remaining efficient
- Proactively identify, evaluate, mitigate and manage risks to the Evaluations program or operations and ensure effective documentation of risk identification, mitigation and management per projects/activities
- Lead and foster a team aligned with a quality and risk aware culture

##### *Measures of Performance:*

- NRL QMS documents are maintained appropriately and up to date
- Demonstrates leadership, compliance and commitment to NRL's QMS, quality and risk culture
- All outputs for Evaluations projects are conducted efficiently in a quality assured manner

#### **6. 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:*

- Ensure adherence to SVI Occupational Health & Safety guidelines, including the wearing of personal protective equipment as provided;
- Operating in alignment with NRL's safety policy and procedures
- Ensure the use of equipment/infrastructure complies with manufacturer or relevant guidelines.
- Report any shortcomings, areas for improvement or risks to senior management
- Report any team concerns/near misses/safety incidents or breaches to senior management as per SVI policies

**7. Other duties**

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

**Experience, knowledge and qualifications**

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- Tertiary qualification(s) in medical science (Bachelor, Honours, Masters or PhD)
- Expert understanding of the evaluation of infectious diseases test kits and IVD regulatory systems
- Evidence of strong project management skills including managing staff over multiple projects/activities
- Considerable experience (>10 years) in test kit evaluations including successfully managing a program of work that involved multiple projects concurrently
- High level of skill and expertise in the analysis and interpretation of scientific/technical data
- Broad understanding of infectious diseases NAT and serology testing
- Proven history of working highly autonomously in a dynamic environment
- Experience in representation at scientific fora
- Well-developed skills in Microsoft Outlook, Word and Excel and other IT literacy

**Personal attributes**

- Excellent interpersonal and communication skills, both written and verbal
- Advanced analytical and problem-solving skills
- Excellent organisational skills, able to multitask and prioritise work during busy periods
- Confident decision-maker with strong leadership skills
- Ability to think critically and independently to provide proactive responses to unexpected results/troubleshooting
- Strong attention to detail and accuracy, and adherence to documented procedures
- Confidence in working autonomously and applying sound decision making, but able to exercise appropriate judgement as to when to seek advice and support
- Self-motivated, strong work ethic and reliable

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

Incumbent Name .....

Incumbent Signature..... Date.....