



## Quality Assurance Inspector

**Location:** Sydney

**Work Type:** Permanent, Full-time

### About us:

At SpeedX, we are passionate about improving patient outcomes and specialize in molecular diagnostic solutions that go beyond simple detection to offer comprehensive information for improved patient management. With our headquarters in Sydney, our technology supports clinical diagnostic products for infectious diseases with a range of products in the market and a pipeline of research and In Vitro Diagnostic (IVD) assays since 2009.

Our well-equipped offices and laboratories are centrally located at the Australian Technology Park in Eveleigh (Sydney) and are easily accessible by rail. SpeedX believes our employees are pivotal to our success and reputation, therefore we strive to offer true work/life balance.

We like to recruit the best talent to join our growing company that was awarded 2021 Australian Company of the Year at the AusBiotech and Johnson & Johnson Innovation Industry Excellence Awards. Make no mistake, we expect a lot from our people as they do of us. So, if you can rise to the challenge, we will provide you with a dynamic and rewarding career.

### About the Role:

- Full-time permanent role
- Suitable for recent graduate
- Supporting our ISO 13485 and MDSAP compliant quality management system and activities to lead our company through the launch of our pipeline of products worldwide.
- Extensive training provided to ensure smooth transition to the role and the company
- Opportunity to grow your career in Molecular Diagnostic company for the right candidate

### Your primary responsibilities:

- Perform QA incoming inspections for incoming materials and components to ensure product quality requirements are met.
- Conduct batch release activities and release of finished products for sale in production and external warehouses.
- Ensure that any product or material non-conformances are investigated and resolved in accordance with the control of non-conformance SOP.
- Provide staff QMS training, track in-house staff training, and ensuring the effectiveness of the staff training program.
- Manage and maintain document control system such as manufacturing documents (manufacturing specs, material specs, manufacturing WI etc) and records (CoA, batch records, manufacturing process control records etc) through eQMS, in compliance with ISO13485, EN ISO 13485 and MDSAP document control and records requirements.
- Maintain and improve our QMS, SOPs and Work Instructions
- File documentation, conducting internal audits, as well as external audits of suppliers
- Deal with CAPAs and support for approval and release of products and control of non-conforming product and materials



**Qualifications & Experiences:**

- A tertiary degree in science, engineering, or a related field
- Previous experience and knowledge of Quality Assurance processes and procedures in a regulated and related industry (e.g., IVD, Medical Devices or pharmaceuticals) is highly desirable

**The Successful Applicant will:**

- Have a high intellect, enthusiasm, strong analytical skills, and a genuine desire to make a difference
- Have a positive outlook and open communication style combined with excellent written and verbal communication skills
- Have the ability to adapt to changing circumstances at short notice
- Be highly organized, able to multi-task and possess excellent time management skills

Recent Graduates with a genuine interest in pursuing a future career in quality assurance are welcome to apply.

**Please clearly state in your application if you have full rights to work in Australia**

If you believe you fulfill the criteria, please email your CV and accompanying cover letter and include in the subject the job title **QA Inspector** to: [hr@speedx.com.au](mailto:hr@speedx.com.au).