**Quality Assurance Inspector**

**Location:** Sydney

**Work Type:** Permanent Full-time

**About us:**

SpeeDx is a dynamic, and rapidly growing company with a strong portfolio of technology at the cutting edge of molecular diagnostics. Our growing team in offices and laboratories in Sydney, London, and Austin, work together in an innovative, challenging, and collaborative environment, towards our critical mission of developing clinically relevant tools to positively impact healthcare networks around the world.

At SpeeDx, we are passionate about improving patient outcomes; specializing in molecular diagnostic solutions that go beyond simple detection to offer comprehensive information for improved patient management. 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.

SpeeDx believes our employees are pivotal to our success and reputation, therefore we strive to offer true work/life balance with opportunity structured career development. We are committed to recruiting, developing, and retaining the best and diverse talent.

If you would like to work for a growing company that was awarded 2021 Australian Company of the Year at the AusBiotech and Johnson & Johnson Innovation Industry Excellence Awards, please apply now.

**About the Role:**

* Full-time permanent role
* Suitable for recent graduate
* Work closely with the Director of RA & QA and cross functional team from research team to the production team
* This role will be 70% product complaints management and 30% batch release
* 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.

**To apply for this opportunity,** please email your CV and accompanying cover letter and include in the subject the job title: **Quality Assurance Inspector** to: hr@speedx.com.au

In order to be eligible to work for SpeeDx, you must hold current working rights with no restrictions. Job offers will be subject to a National Criminal History Check.

Please note, only shortlisted candidates will be contacted.