Quality Assurance Supervisor

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 with opportunity for further training and structured career development.

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:

- **Permanent full-time** as a QA Supervisor
- Supervising QA & RA staff
- Maintaining the compliances of Quality Management System
- Developing quality and regulatory plans for new products
- Conducting surveillance audits internal and external as part of QMS maintenance
- Working in an ISO 13485 accredited manufacturing environment

Your primary responsibilities will involve but not limited to:

- Establish and maintain a QMS compliant with ISO 13485 and other standards and regulations as required
- Ensure the company achieves and maintain ISO 13485 design, development accreditation and assist in extension of the scope
- Prepare quality and regulatory documentation and reports
- Works with senior management to ensure the company develops, achieves, and maintains the company's quality objectives
- Organise and participate in external audits, liaise with regulatory and notified bodies as required
- Conducting risk analyses by identifying critical points and preventive measures

- Validates quality process by establishing product specification and quality attributes
- Maintain and improves product quality by conducting surveillance audit
- Prepare and compile technical files for the execution of TGA and CE Mark submissions
- Maintain standards and regulatory oversight for SpeeDx
- Collaborate with other team members of management to develop new product designs
- Develop quality in-house training for SpeeDx staff
- Up-to-date with new trends

Qualifications/ Technical & Specialist Skills/ Experiences:

- Minimum qualification of Bachelors in Science or Engineering
- Minimum 3 years' experience in quality or regulatory
- Experience in QMS ISO 13485, auditing, managing regulatory submission & liaising with regulatory body are essential
- Regulatory experience in TGA, Health Canada, UKCA, US QSR & EU IVDR regulations and additional relevant ISO standards are highly desirable

Personal attributes/ Interpersonal skills:

- Organised, detail oriented and self-motivated
- Strong analytical, writing and decision-making skills
- Excellent communication and management skills
- Ability to supervise and motivate team members
- Strong self-starter and self-motivated

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 Supervisor** to: **hr@speedx.com.au**.