Quality Control Assistant

Location: Sydney
Work Type: full-time in a 12-months in Fixed Term Contract

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:

- **12-month fixed term** contract as a Quality Control Assistant.
- Entry level opportunity with research on technologies to develop upcoming IVD products.
- Working in an ISO 13485 accredited manufacturing environment.
- Successful candidate can expect to have lots of hands-on-time in the lab, working with state-of-the-art diagnostic equipment.
- 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.
- Monday-Friday office hours.

Your primary responsibilities will include:

- Assist in manufacturing IVD products compliant with ISO13485 and CFR 21 Part 820.
- Perform quality checks during the manufacturing process.
- Perform quality control testing and other laboratory activities.
- Format and record test result data into Quality Control reports.
- Perform real time stability studies testing.
- Participate in the design transfer process.

- Maintain activity records and file all paperwork.
- File discrepancy reports to the lab for corrective action.
- Prepare technical reports.
- Prepare reagents and reference materials for lab testing.
- Organize reference materials as to be readily available to lab staff. Notify management when inventories are low or insufficient.
- Clean lab benches, shelves, hoods, floors, and walls as needed to maintain a clean environment.
- Operate standard molecular laboratory equipment.
- Work according to the organization's laboratory safety, health and environment standards.
- Communicate adjustments to managers and other staffs when necessary.
- Perform general housekeeping duties.

Qualifications/ Technical & Specialist Skills/ Experiences:

- A tertiary degree in science, qualifications BSc or equivalent.
- Previous experience in Medical Device manufacturing is highly desirable.
- Previous experience with qPCR is highly desirable.
- Working knowledge of laboratory and QMS environment.

Personal attributes/ Interpersonal skills:

- Solid time-management skills and ability to work under pressure.
- Excellent communication skills in both written and verbal.
- Great interpersonal skills and team player attitude
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Please clearly state in your application if you have previous experience with qPCR and indicate 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: **Quality Control Assistant** to: **hr@speedx.com.au**