



Production Technician (Formulation) – Medical Devices

Location: Sydney

Work Type: Perm Full Time

About us:

SpeedX Pty Ltd is dynamic, rapidly growing company with a strong portfolio of technology at the cutting edge of molecular diagnostics. With our headquarters in Sydney, we are launching our technology into the market and have a pipeline of research and *in vitro* diagnostic assays. Our well-equipped offices and laboratories are centrally located at the Australian Technology Park in Eveleigh (Sydney) and are easily accessible by rail.

At SpeedX we believe 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. 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:

We have an exciting opportunity for a production technician to join our production team in a full-time, permanent capacity to support manufacturing activities and conduct reagent formulation within a strictly regulated environment.

Key responsibilities include but not limited to:

- Manufacturing SpeedX products compliant with ISO13485, CFR 21 Part 820 & cGMP;
- Formulate raw materials and components for IVD medical device;
- Manufacture components according to approved protocols and standard operating procedures;
- Perform in-process and final quality checks for in-house materials, bulk products for inventory and finished inventory products;
- Inspect raw materials and production consumables;
- Working efficiently to production schedules and meet manufacturing targets;
- Maintain accurate and detailed production records;
- Prepare documentation including but not limited to manufacturing procedures, labels, component specifications, work instructions and batch records that has been approved;
- Prepare new formulations procedures, work closely with validation scientists to determine specifications for new formulations, and write protocols as required;
- Participate in new product development/technical project teams as required;
- Perform general production duties as required;
- Maintain a clean work environment and assist in maintaining the level of cleanliness;
- Work according to the organization's laboratory safety, health and environment standards.

In order to be successful in this role you will possess the following key skills:

- Proven experience in a similar role, working in manufacturing environment and GMP experience preferred
- Previous laboratory experience preferred
- Have a positive outlook and open communication style combined with excellent written and verbal communication skills
- Be highly organized, able to multitask and possess excellent time management skills

- Have the ability to adapt to changing circumstances at short notice
- Great interpersonal skills and team player attitude

and minimum qualification

- A tertiary degree in Science
- Previous experience in Medical Device manufacturing is highly desirable
- Previous experience with qPCR is highly desirable
- 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
- Have keen and diligent work ethic with good people skills to work within this enthusiastic team

To be considered for this role, please address your suitability by indicating if you have previous experience with IVD medical devices and 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: Production Technician to: hr@speedx.com.au

Applications must be received by Friday, 11 June 2021.