Clinical Project Manager

Location: Texas, USA
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:

- **Permanent, full-time** as a Clinical Project Manager
- Supporting the Clinical team to expand product pipeline comprising infectious disease and anti-microbial resistance
- Assisting the team in clinical studies with strong writing skills
- Extensive training program to ensure smooth transition to the role and the company

The successful candidate will:

- Coordinate clinical projects, such as clinical trials and product evaluations by ensuring all documents are drafted and in place, the site is suitable for clinical study/evaluation and the subsequent report. More specifically manage or assist in managing;
    - Clinical trials by site selection and suitability, resourcing clinical study plan, transfer of data, and clinical study report, both nationally and internationally.
    - Clinical evaluations by assessing suitability and equipment delivery of reagents, any other relevant documentation and IFU, any necessary agreements required for testing evaluation kit. Support testing by obtaining results and drafting final report, both nationally and internationally.
- Ensures that all studies are conducted in accordance with federal, state and protocol requirements, standard operating procedures, and Good Clinical Practice (GCP)
- Ensure all activities are performed under ISO13485 standards

- Support development of relevant documentation for registering products under standards for RUO, CE-IVD, TGA and FDA
- Manage any necessary staff involved in the above processes
- Performs all duties within HIPPA regulations
- Must be located in Australia
- Other duties as assigned

Skills and Experience

You must have the following skills and experience:

- Minimum 9-10 years industry/academic experience
- Good project management skills
- Ability to mentor and train staff
- Communication and facilitating skills
- Ability to document all processes under ISO13485 standard
- Understanding of ethics
- Clinical trial quality processes
- Proven record in clinical knowledge and requirements
- Previous experience working in an environment where IVD tests are performed
- Strong analytical and problem-solving skills
- The ability to work quickly and to deadlines
- Mandatory fluency in English

Desirable skills and experience:

- PhD (Molecular Biology, Biochemistry, Biomedical)
- Previous customer-facing experience
- Familiarity with IVD regulatory requirements
- Experience working within a regulated environment
- Maintaining relationships with collaborators, licensees, contractors, scientific peers
- IRB and regulatory experience
- Experience with data and statistical analysis
- Basic knowledge of computer programs (e.g. Microsoft Word, Excel)

Signature Behaviours:

All staff are accountable for demonstrating SpeeDx's signature behaviours of:

- Focus on solutions (Positive attitude, change ready, improvement and insight)
- Stand up and contribute (Participation, collaboration, courage and respect)
- Do what you say (Honesty, integrity, transparency and trust)
- Support and Encourage (Encouragement, communication, empathy and cooperation)
- Own the outcome (Ownership, accountability, results and accomplishment)

If you believe you fulfill the criteria have current rights to work full-time in USA, please email your CV and accompanying cover letter and include in the subject the job title: **Clinical Coordinator to: hr@speedx.com.au**