Quality Assurance & Regulatory Affairs Specialist

Location: Austin, Texas, USA
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. We are launching our technology into the market and have a pipeline of research and *in vitro* diagnostic assays. With our headquarters in Sydney, Australia we are expanding both domestically and internationally.

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:

SpeeDx are looking for a talented individual, that can join our high achieving team. Under the direction of the Director of Regulatory Affairs & Quality Assurance you will be responsible for assisting in leading strategy, preparation, submission and tracking of projects. This role will see you engaging with a broad range of internal and external stakeholders.

Key responsibilities include but not limited to:

- Establishes and maintains a Quality Management System compliant with CLIA Waive & Certification, ISO 13485, 21 CFR 820 and other standards and laws as required.
- Ensures the company achieves and maintains ISO 13485 Design, Development accreditation and assist in extension of the scope as required.
- Ensures the US Laboratory achieves and maintains CLIA waive certification.
- Develops quality assurance plans by conducting risk analyses; identifying critical control points and preventive measures; establishing critical limits, monitoring procedures, corrective actions, and verification procedures.
- Validates quality processes by establishing product specifications and quality attributes; measuring production; documenting evidence; determining operational and performance qualification; writing and updating quality assurance procedures.
- Organizes and participates in external audits, liaises with regulatory and other notified bodies as required.
- Maintains and improves product quality by completing product, company, system, compliance, and surveillance audits; investigating customer complaints; collaborating with other members of management to develop new product designs. May be required to take on project management role with regards to product development.
- Prepares quality documentation and reports by collecting, analyzing and summarizing information and trends including failed processes, stability studies, recalls, corrective actions, and re-validations.

- Updates job knowledge by studying trends in and developments in quality management; participating in educational opportunities; reading professional publications; participating in professional organizations.
- Develops and tracks in-house training of staff
- Maintains control of all QMS documentation

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

- Specific experience in ISO 13485, EN ISO 13485, EU IVDD 98/79-EC, EU IVDR 2017/746, MDSAP (Focus: Canada MDR SOR-98-282, US FDA 21 CFR part 820, Brazil ANVISA, CLIA Waive Certification.
- Ability to work with all levels; able to communicate up and communicate down
- Ability to adapt and respond quickly and effectively to changing environments
- Strong Written and Verbal Communication
- Strong Organisation and Time Management
- Have keen and diligent work ethic with good people skills; able and willing to work within our enthusiastic team
- Flexible approach to work, and work hours.

and minimum qualification

- Bachelors or equivalent - BSc or BA qualified. Science qualification
- Minimum of 1-4 years' QA & RA experience. desirable.

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 North America.

If you believe you fulfill the criteria, please email your CV and accompanying cover letter and include in the subject the job title: Quality Assurance & Regulatory Affairs Specialist to: hr@speedx.com.au

Applications must be received by Friday, 29 January 2021.