Diagnostics Development Manager

Location: Singapore

Employment type: Full time

Contract type: Permanent

Company description: MiRXES Pte Ltd is a Singapore headquartered biotechnology company with sales globally. MiRXES develops cutting-edge assay technologies and products for the detection of miRNA for research and clinical diagnostic use. MiRXES partners multinational pharmaceutical companies and world-renown clinical institutions to develop next-generation blood based cancer diagnostic and prognostic tests. MiRXES is looking for passionate individuals to translate research ideas to clinical tests.

Description

The Diagnostic Development Manager is primarily responsible for the development, validation and tech transfer of qPCR based diagnostic tests.

Key Responsibilities:

- Work closely with the CTO and CSO in meeting customer requirements, product design and risk management process of qPCR based diagnostic test development
- Set up Bill of Material and product specifications
- Design analytical and clinical validation studies
- Lead research officers to execute the validation studies
- Work with the manufacturing group to set up manufacturing process based on part specification.
- Work with the R&D and QC departments to set up QC methods / processes and validate QC criteria
- Support and trouble-shoot issues in manufacturing and QC process
- Design and execute experiments for Guard-bands data to support robustness of the parts performance in manufacturing
- Bridge different groups for quality, regulatory and customer facing documentations

Requirements:

- Ph.D in Biochemistry / Molecular Biology / Chemistry or relevant majors. Post-doc experience is a plus.
- Minimal 3-5 years of relevant work experience in a related (pharmaceutical / biomedical / medical device industry.
- In-depth experience in qPCR technique is desired.
- Experience with ISO13485, CE-IVD and cFDA is desired.

- Experience in obtaining diagnostic kits approved for CE mark, cFDA and manufacturing facilities ISO 13485 approved is a plus
- Training and experience in statistical analysis and design of experiment methodology is required.
- Good documentation, organizational and resource planning skills.
- Must be prepared to work in a startup environment. Have high level of integrity and dependability with a strong sense of urgency and results oriented.
- Be prepared to occasionally work after office hour and during weekends.
- Good verbal communication, interpersonal and team skills.

What we offer:

- Work within a highly motivated team and innovative working environment
- Start-up experience
- Excellent development opportunities in a globally oriented company
- A competitive salary and bonus package with ESOP.

Quality Assurance Manager

Location: Singapore

Employment type: Full time

Contract type: Permanent

Company description: MiRXES Pte Ltd is a Singapore headquartered biotechnology company with sales globally. MiRXES develops cutting-edge assay technologies and products for the detection of miRNA for research and clinical diagnostic use. MiRXES partners multinational pharmaceutical companies and world-renown clinical institutions to develop next-generation blood based cancer diagnostic and prognostic tests. MiRXES is looking for passionate individuals to translate research ideas to clinical tests.

Description

The Quality Assurance Manager is primarily responsible to ensure all aspects of the operational business comply with ISO13485 quality management system.

Key Responsibilities:

- Work with regulatory consultant to establish company's ISO13485 structure and draft QM, WI and SOPs.
- Work with regulatory consultant during the ISO13485 audit and certification
- Participate as a representative of the Operational Quality Assurance (QA) in project teams
- Ensure that during project phases, all activities related to the Design, Development, Validation of qPCR diagnostic products comply with ISO13485 regulations
- Ensure that all required Quality procedures are in place prior to start of manufacturing of qPCR diagnostic kits
- Participate in the general QA activities and assist in the different aspects of the QA function (Compliance/Release/Change Control)
- Review ISO13485 relevant documents for compliance
- Coordinate within site and with relevant MiRXES global operations to ensure consistency with quality standards
- Manage quality issues and investigations (e.g. deviations; trends, OOS) with the respective departments

Requirements:

- Degree or Masters in Natural Sciences and Engineering (Biotech preferred)
- Minimal 3-5 years of relevant work experience in a related (pharmaceutical / biomedical / medical device industry.
- Strong experience in ISO13485 and regulatory authority inspections.

- Must be prepared to work in a startup environment. Have high level of integrity and dependability with a strong sense of urgency and results oriented.
- Be prepared to occasionally work after office hour and during weekends.
- Good verbal communication, interpersonal and team skills.

What we offer:

- Work within a highly motivated team and innovative working environment
- Start-up experience
- Excellent development opportunities in a globally oriented company
- A competitive salary and bonus package with ESOP.