Quality Assurance Specialist – Genomics Laboratory

Location : Bengaluru, Employment : Full-time

Job Summary

We are seeking a meticulous and experienced **Quality Assurance Specialist** to support the quality assurance and compliance needs of our **US-based genomics laboratory** from India. The ideal candidate will have 3-4 years of relevant experience, showcasing expertise in quality systems, regulatory compliance, and continuous process improvement in a regulated **genomics or molecular diagnostics laboratory** environment.

Key Responsibilities

- Assist in implementation of laboratory policies and procedures aligning with applicable US regulatory standards and state-specific requirements.
- Support documentation efforts for internal audits, inspections, and proficiency programs, ensuring compliance with US regulatory and quality standards including **genomic workflows.**
- Collaborate with US-based teams and external stakeholders to address quality issues, performing investigations, root cause analysis, and implementing corrective and preventive actions (CAPA).
- Contribute to project management tasks, including gap analysis, risk management, document control, and process improvement, tailored to **genomics laboratory operations.**
- Maintain comprehensive and accurate records of QA activities, including SOPs, laboratory manuals, QMS documentation, and validation protocols, ensuring alignment with US standards.
- Assist the US lab in preparing for regulatory audits and inspections, ensuring full compliance with US research and quality standards.
- Communicate quality-related updates effectively to US teams, fostering a culture of innovation, accountability, and adherence to quality standards.
- Provide quality system support for processes end-to-end (involving next-generation sequencing (NGS), including sample chain of custody, sample preparation, library preparation, sequencing, data security policies, RFI, qPCR, and other genomic technologies, ensuring best practices and regulatory compliance). Additionally, ensure availability for weekly US time zone meetings and audits.
- Roles and responsibilities may change as per management / company needs.

Education

- Bachelor's or Master's degree in Biology, Molecular Biology, Genetics, Genomics, Chemistry, or a related field.

Experience

- 3-4 years of experience in a **genomics or molecular diagnostics clinical laboratory** or a quality assurance role in a regulated environment.
- Hands-on experience with regulatory audits or inspections NABL, ISO standards like ISO15189 or state agencies.
- Familiarity with quality management systems, process improvement, and US regulatory standards applicable to **genomic workflows.**

Please e-mail your CV to **careers-us@medgenome.com**

MedGenome Labs Ltd. (Corporate Office)
Sy. Nos. 94/1C and 94/2, Tower 1, 3rd Floor,
Veerasandra Village, Attibele Hobli, Electronic City Phase-1,
Bangalore , Karnataka - 560100

Skills

- Strong understanding of QA principles, including CAPA, root cause analysis, and proficiency testing for genomic assays.
- Exceptional written and verbal communication skills, with high attention to detail and organizational capability.
- Proficiency in project management, with demonstrated success in process creation and improvement for genomic workflows.
- Ability to collaborate effectively across departments and communicate technical ideas professionally with US-based teams.
- Proficient in utilizing Microsoft Word, Excel, and related software to efficiently document, analyze, and report laboratory quality assurance data, ensuring accuracy and compliance with QA standards.

Preferred Qualifications

- Direct experience in quality assurance for genomics laboratory processes or molecular diagnostics.
- Experience working in regulated environments with a strong focus on compliance and process improvement for genomic technologies.

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