Position: Quality Manager
Reports To: Chief Scientific Officer (CSO)
Status: Exempt

POSITION OVERVIEW

We are seeking a highly motivated, independent contributor to join our Seattle-based team as a Quality Manager. The Quality Manager is a new professional role that will be responsible for setting up a QC/QA function at TwinStrand Biosciences. This role encompasses the start-up and leadership of both laboratory quality operations and documentation/QC systems, to ensure that TwinStrand Biosciences commercial products are tested and released in a rigorous manner. Laboratory operations will include release testing, stability testing, internal transfer of methods from an assay development group and oversight and auditing of suppliers. In addition, the Quality Manager will write key sections of regulatory submissions, will participate in meetings with regulatory agencies and will be responsible for preparing for and participating in audits by clients and partners. This role will report to the CSO and will interact with multiple departments at TwinStrand Biosciences including Research & Development, Program Management, Bioinformatics and Commercial. We are looking for a dynamic and collaborative person with multifaceted QC/QA experience to fill this important role.

RESPONSIBILITIES

- Key subject matter expert for procedure-based NGS assay qualification, validation, and technology transfer.
- Assess new materials to determine test methods, metrics, nucleic acid standards and validation/qualification requirements.
- Support development of novel Duplex Sequencing methods and products including NGS procedures. Work in conjunction with other departments to develop, qualify, and transfer QC analytical methods as applicable.
- Prepare and review documentation (change controls, specifications, protocols, reports, raw data packages, etc.) pertaining to release, stability, nonconformances, deviations, investigations, method transfers, method verification/validation and reference standard characterization, etc.
- Oversee QC related activities and provide regular stability updates to cross-functional teams and stability related investigations.
- Coordinate and/or perform testing, complete test records, document observations, and generate reports for raw material, in-process, and finished goods qualification testing.
- Establish stability monitoring program and retain policy in accordance with cGMP requirements and ensure activities are carried out in compliance with established policies and procedures

- Develop and implement statistical tools and implement software solutions for Quality Systems monitoring and review.
- Lead investigations for failures during Quality control testing; perform troubleshooting, process development or improvement activities including providing corrective action plan for out-of-specification and/or non-conforming test results.
- Serve as contact for other departments regarding QC related activities, quality issues, nonconformance investigations and root cause analysis.
- Ensure Quality Control systems are compliant with corporate and site procedures, regulatory requirements and industry standards.
- Ensure maintenance of QC equipment – qualification, calibration and maintenance.
- Identify and implement improvement opportunities for established Quality Systems, processes, procedures, and training to support CAPA, Change Control, Deviation, Risk Management, and Investigation processes.

EXPERIENCE

- Requires a Bachelor's Degree in Biochemistry, Molecular and Cellular Biology, or Biology
- At least 5 years of relevant experience with a minimum of 3 years in Quality Control Testing
- Extensive experience with molecular biology techniques
- Experience with FDA 21CFR820 QSR & ISO 13485
- Experience with risk assessment ISO 14971
- Strong data analysis and troubleshooting skills
- Familiarity with auditing practices
- Experience with Test Method Validations
- Strong organizational and communication skills, including technical writing

PREFERRED BACKGROUND AND SKILLS

- Self-starter with the ability to work independently and quickly learn new skills.
- Proficient in a variety of office software email tools, spreadsheets, databases.
- Familiarity with quality, process management/LIMS software solutions
- Outstanding track record of successful teamwork with excellent interpersonal and communication skills.
- Excellent written and verbal communication skills.
- Process-oriented thinker who is always looking to improve.
- Ability to multi-task while maintaining excellent attention to detail.
- Desire to work at a fast-paced startup company with ambitious goals and timelines.
- Bachelor's degree with an emphasis on quality and/or manufacturing
- Your friends would describe you as someone who "just gets it done".

ABOUT TWINSTRAND

We are a vibrant young company committed to applying a powerful new genomic technology across disciplines to improve human health and accelerate scientific discovery. Our mission is to develop and deliver the unprecedented accuracy of Duplex Sequencing™ for applications in medicine and life sciences where it can do the greatest good for the greatest number of people.

Our business is multifaceted and encompasses internal development projects, external collaborations and empowering of partner organizations. Our mission is strongly rooted in academic principles of responsible citizenship within the broader scientific community, yet executed with the nimbleness of a startup, such that research can be rapidly translated into products that benefit many. To the greatest extent possible, we strive for open sharing of knowledge and discovery through publication.

At TwinStrand we put a premium on creativity, dynamic thinking and a rigorous scientific approach. You will be challenged to push the boundaries of your knowledge, skills and comfort zone and to take ownership of your area of specialty. We expect all team members to take on some form of leadership role over time and mentor new team members as we continue to expand. We want every member of our community to come to work excited each day and able to take pride in the high-quality science to improve human health that they are contributing to.

Our new state-of-the-art NGS laboratory is ideally situated on the Downtown Seattle waterfront overlooking Puget Sound and our genomics team is growing quickly.

Interested applicants should send a resume and cover letter to:

careers@twinstrandbio.com

TwinStrand is an Equal Opportunity Employer