Job Description

Quality Engineer

MBio Diagnostics of Boulder, CO (www.mbiodx.com) seeks a Quality Engineer to support ISO 13485-compliant operations. MBio is leading a new era in rapid, on-the-spot sample testing for diverse applications including human clinical diagnostics, food safety, and veterinary applications. MBio's core technology is a patent-protected planar waveguide system developed for fluorescence immunoassays, molecular diagnostics, and cell-based assays. The successful candidate will join a growing, fast-moving, multidisciplinary team focused on operational scale up to deliver instruments and related consumables to various partnerships and direct sales. This is an outstanding opportunity that offers the right person upside potential.

Position Summary:
The Quality Engineer (QE) position will, under limited supervision, perform complex quality work of a broad nature. The QE will apply knowledge of applicable regulations, standards, principles, theories, and concepts to ensure compliance of MBio's quality system procedures and processes. This position will support QMS SOP development for effective, efficient compliance and in support of high-quality product. This position reports to the Director of Quality Assurance.

Job Duties:

- **QMS** – support on-going efforts to implement and maintain SOPs for compliance to ISO 13485:2016 and other applicable standards and regulation.
- **Management Review** – Supply data for Management Review meetings and other KPI assessments as requested.
- **CAPA** – issue Corrective Action / Preventive Action (CAPA) for systemic issues, complaints, etc. Drive root cause investigations and completion according to target implementation date and without undue delay.
- **NCMR** – issue Non-Conforming Material Reports (NCMRs) for out of specification parts, sub-assemblies, and assemblies. Support and monitor timely disposition of materials.
- **Internal Audits** – support Internal Audit program, review and address results as appropriate
- **Test Method Development and Inspections** – Use knowledge of inspection methodologies to design and perform incoming, in-process, and final inspections.
- **Document and Record Control** – work with engineering and production teams to develop DMR, DHF, and DHR documentation.
- **Design and Development** – ensure quality objectives and deliverables are achieved during design and development efforts.
- **Risk Management** – host risk management sessions, such as hazard analyses or FMEAs. Ensure risk management efforts are occurring to plan.
- **Supplier Controls** – conduct supplier audits, assess supplier performance.
- **Production Controls** – work with production team to implement and maintain production controls.
- **Process Validation** – define process validation protocols, participate in execution of protocols, and report on results.
- **Equipment PM and Cal** – Work with other QA team members to ensure equipment program is compliant.

- **Training and Competence** – provide training on QMS topics, ensure training programs are established and executed.
- **Post Market Surveillance** – participate in Post Market Surveillance planning and execution.
- **Regulatory** – Support of regulatory submissions and interactions.

No single candidate is expected to have demonstrated skill in all functions listed below, but candidates should highlight relevant experience in a brief cover letter.

- Proven working experience
  - As a quality engineer, preferably within the IVD or medical device industry
- Working knowledge of ISO 13485:2016 standard
- Working knowledge of FDA and EU IVD regulations
- Success in 3rd party audits
- Tangible examples of where you had an impact on a process resulting in improved product quality
- Experience related to the above listed Job Duty categories
- Proficient and experienced in spreadsheets, MS Office, statistical software, and other QMS software applications
- Outstanding technical writing and communication skills

Education and Experience

- Bachelor's Degree in engineering, science, or other related technical field
- 3+ years of quality assurance experience, preferably in IVD or medical device industry
- Or equivalent combination of education and experience
- Recognized quality certification (e.g., CQE) preferred, but not essential

Applicant must have authorization to work in the U.S. Resumes must be accompanied by a cover letter explaining how the applicant meets the job requirements and desired skills**. Please email cover letter and resumes to jobs@mbiodx.com with applicant name and the job title listing in the subject line.** No phone calls, please.

MBio Diagnostics, Inc. is an Equal Opportunity Employer.