Job Description

# Director of Quality Assurance – In Vitro Diagnostics

MBio Diagnostics of Boulder, CO (www.mbiodx.com) is seeking to fill the position of Director of Quality Assurance (QA), or Director of Regulatory Affairs / Quality Assurance (RA/QA), depending on applicant background. MBio is technology development company focused on next generation products for medical, food safety, and environmental applications. MBio is developing products for the human clinical *in vitro* diagnostics (IVD) market, and we are seeking a Quality professional to manage MBio's Quality System per FDA Quality Systems Regulations (21 CFR 820) and ISO 13485:2016.

**Job Duties:**

The first task of the Director of QA will be to streamline MBio's Quality Management System procedures and lead the company through ISO 13485:2016 recertification with a notified body. The Director of QA will be a key member of the MBio development team responsible for the QA activities linked to the company's FDA QSR-compliant design, development, and manufacturing operations. Demonstrated background in guiding teams through current Good Manufacturing Practice (GMP) development is required. The ideal candidate will have demonstrated QA background in organizations developing point-of-care diagnostics and CLIA-waived devices. This will be a "hands on" position – MBio has document control staff support, but this position will be expected to draft SOPs and perform many QA department functions as the company grows. The position will report to the Executive Vice President or CEO, depending on the candidate's background.

**Expectations:**

- Work with MBio Management and Quality consultants to review, revise, and streamline MBio's Quality Management System (QMS) standard operating procedures.
- Work closely and effectively with MBio R&D and Manufacturing teams to create an effective and compliant QMS for an early stage (< 50 employees) IVD developer.
- Lead the company's notified body audit preparation and certification process.
- Ideal candidate will have a background in FDA *in vitro* diagnostics product development, and demonstrated skills working with and guiding development teams under Design Control.
- Candidate will have outstanding communications skills and will be able to facilitate discussions between Senior Management, R&D, Engineering, and Manufacturing.
- Candidate will evaluate, recommend, and implement quality management software packages for document control, training records, and potentially other QMS functions.
- ISO 13485 auditor or lead auditor certifications will be considered favorably.

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

- Prior experience developing Quality Management Systems from the ground up, or significant revisions of systems.
- Prior experience in a small company setting, and related experience with “right-sizing” the QMS.
- Experience and skill with managing QA programs that include software development under IEC 62304.
- Experience and skill implementing Change Control processes.
- Management and documentation of training.
- IVD or medical device manufacturing experience.
- CLIA-waived device development background.

**Education and Experience:**

- Bachelor’s or higher degree in life sciences field.
- A minimum of 7 years IVD / medical device industry experience with a minimum of 5 years in quality assurance.

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.