Job Description

Manufacturing Process Engineer / Production Manager

MBio Diagnostics of Boulder, CO (www.mbiodx.com) is seeking a uniquely capable Manufacturing Process Engineer and Production Manager for our disposable cartridge manufacturing line. The ideal candidate will be looking to grow an operation from pilot production to scale, within the dynamic environment of an emerging growth company. MBio is a technology development company focused on next generation products for human clinical diagnostics, veterinary, and environmental applications. MBio products consist of a disposable plastic cartridge and portable reader used for a diverse set of biological assays. The right candidate will have demonstrated problem solving skills, the ability to develop test methodologies/protocols, and a track record of successful technical accomplishments.

Job Duties:
This position is responsible for day-to-day operation of MBio's plastic cartridge device manufacturing line. Duties will include manufacturing equipment and method process development, running and maintaining automated processing equipment, and performing mechanical assembly of injection molded subcomponents. Overseeing quality control and quality assurance procedures, under ISO 13485, will be part of the job function, as are scheduling and inventory management. Job responsibilities also include the implementation of streamlined manufacturing processes, as well as assisting with improvements to assay protocols and cartridge fluidics. The candidate should be familiar with Quality Management System requirements and will preferably have a solid statistical experiment design background.

This position reports to the MBio CTO and will have direct interactions with the MBio Executive Management team. The Production Manager will work closely with MBio design engineers and assay scientists and will serve as a key interface between groups.

Expectations:

- Manage cartridge production line, moving builds through the floor
- Develop and implement improvements to cartridge manufacturing processes under Design Control documentation
- Supervise and mentor manufacturing staff
- Implement and maintain manufacturing documentation per ISO 13485 and FDA QSR regulations
- Manage inventory and supply chain, and maintain relationships with key vendors
- Design statistical sampling plans for design verification and validation
- Control biological reagent (e.g., antibodies, recombinant proteins) handling and lyophilization

Desired Skills:
No single candidate is expected to have demonstrated all the desired skills listed below. But candidates should highlight relevant experience in any of these areas in a brief cover letter.

- Direct manufacturing and/or engineering experience with disposable medical devices, particularly in vitro diagnostics
- Demonstrated statistics background, particularly design of experiments (DOE) or statistical experiment design (SED)
- Hands-on experience with microfluidic devices or low volume liquid systems, especially with blood or other biological samples, including microfluidic devices, lateral flow systems, and/or microarray construction and processing
- Experience handling biological reagents, particularly antibodies, recombinant proteins, and oligonucleotides
- Background with biological reagent lyophilization
- Demonstrated skill with manufacturing equipment IQ/OQ/PQ
- Experience with internationally recognized Acceptable Quality Limit (AQL) quality control methodologies
- Experience with production scale surface chemistries – both liquid-phase and gas-phase.
- Experience with ultra-low volume dispensing printers for biological reagents
- Experience with molecular biology techniques, especially as relating to diagnostic and/or detection assays, including but not limited to immunoassays (e.g. ELISA), nucleic acid techniques including PCR, fluorescence microscopy, and fluorescence imaging
- Biological safety and bloodborne pathogen training

Education and Experience:

- Bachelor's or higher degree in an engineering discipline (preferably biomedical, chemical, or mechanical), chemistry, biochemistry, or a related field from an accredited university.
- At least 4 years' experience in an R&D or production scale-up environment with project successes directly attributed to the candidate.

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.