Job Description

Automation / Facilities Process Engineer – Cartridge Manufacturing

MBio Diagnostics of Boulder, CO (www.mbiodx.com) is seeking to fill the position of Automation/Facilities Process Engineer for the Cartridge Manufacturing (CMFG) area. 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. Primary responsibilities: Support of future CMFG automation and facilities integration as well as ongoing upkeep of CMFG equipment and facilities.

Job Duties:
This position reports to the Director of CMFG and will be responsible for both day-to-day and forward-looking process engineering support of our production areas. Job duties include managing current facilities to specifications; defining and implementing facilities enhancements and improvements; defining, scoping, and procuring automation to support increasing volumes.

Expectations:

- Serve as the CMFG engineering project manager for current facilities. Identify and support future facilities fit up including Cleanroom definition, installation, and certification. Author SOPs to support facilities and infrastructure processes.
- Experience with the automation concepts required to transition manual CMFG processes into automated work cells. Serve as program manager interfacing with external automations suppliers to define process requirements, manage budgets, and oversee installation.
- Knowledge relating to process maturation from lab-based procedures to automated continuous-mechanical-assembly (CMA)
- Experience transitioning new products through milestones and process development gates.
- Skilled in authoring manufacturing Standard Operating Procedures (SOPs) and detailed work instructions. Proven skills with respect to equipment qualifications and succinct IQ, OQ, PQ procedures.
- Demonstrated ability to work in a self-sufficient and detail-oriented manner and adhere to manufacturing schedules and deadlines
- Excellent verbal and written communication skills

Desired Skills:
Strong preference will be given to candidates with the following skills and experience. No single candidate is expected to have demonstrated all the desired skills listed below. Applicants should highlight relevant experience in any of these areas in a brief cover letter.

- Proven automation work cell implementations
- Manufacturing or other production environment background - preferably for medical equipment, including cleanroom protocols.
- Direct manufacturing and/or engineering experience with disposable medical devices
- Candidate should be familiar with Quality Management Systems with previous work in a regulated environment, under QMS requirements (ISO 13485/ cGMP)
- Ability to interpret product drawings. Familiarity with SolidWorks.
- Competency with Microsoft Word and Excel.

Education and Experience:

- Bachelor's or higher degree in engineering, computer science, biochemistry, or a related field from an accredited university
- At least 7 years' experience in an R&D or production scale-up environment preferred, 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 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.