Senior/Principal Manufacturing Engineer

Location: Woburn, MA

Vaxess is a NIH and venture-funded company developing a pipeline of next-generation vaccines on the MIMIX platform. With only five minutes of wear-time on the skin, the self-applied MIMIX patch enables two weeks of sustained delivery. The platform combines high temperature stability with simplified application to dramatically alter the way that drugs are delivered. Vaxess is committed to enabling products that are not only more effective, but also more accessible to patients around the world.

Drug-Device Combination Product Development at Vaxess is cross-disciplinary, integrating mechanical, industrial, biomedical, and chemical engineering with chemistry, biology, and human factors to address important unmet medical needs. We are seeking a talented, collaborative, and highly motivated engineer with a proven track record in managing novel Process Development and Optimization to join our team of scientists and engineers. The Senior Process Engineer will report to the VP of Engineering and will collaborate closely with cross-functional teams. This role offers a unique opportunity to bring innovative technology to the global vaccine and therapeutic market.

Responsibilities

- Draft specifications for manufacturing equipment and manage outside equipment vendors.
- Develop and execute equipment and process qualification and validation protocols, draft manufacturing SOPs and contribute to implementing and maintaining the Quality System.
- Conduct root cause analysis and develop timely solutions for production problems that might arise.
- Develop & implement new or improved processes and controls to increase quality and throughput for Vaxess's drug-device combination products.
- Plan and execute process development studies and thoroughly document results in engineering reports and presentations.
- Train, supervise, and mentor other members of the process engineering and manufacturing team.
- Collaborate closely with cross-functional teams to support product development and manufacturing activities.

Qualifications

- BS or MS in Mechanical Engineering, Biomedical Engineering, or a related discipline, with at least 5 years of direct experience in manufacturing of combination products or medical devices. Title will be adjusted commensurate with qualifications.
- An understanding of phase-appropriate GxP requirements including batch records, equipment and process validation, and product specifications, and experience contributing to regulatory submissions
- Demonstrated expertise with Design of Experiments and statistical methods used to analyze manufacturing process performance.
- Experience working in clean room environments with bioburden controls.
- Excellent time and project management skills and proven ability to meet goals and deadlines.
- Demonstrated abilities to learn new skills and fields, creatively solve challenging technical problems, think independently, and work collaboratively in diverse multidisciplinary teams.
- Entrepreneurial spirit and drive to positively impact global human health.

Vaxess Technologies, Inc. www.vaxess.com
359 Allston St. Cambridge, MA 02139
11 Cummings Park Dr. Woburn, MA 01801

Vaxess is building a team of exceptional people to rapidly advance product development. We work closely as a team and thrive in a dynamic, exciting, and engaging work environment. If you're interested in joining the Vaxess team, please submit your CV/resume to careers@vaxess.com.

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