Director of Process Development
Location: Woburn, MA

Vaxess is an 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 weeks of sustained delivery in the skin. 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 engineering, biomedical engineering, chemical engineering, biomaterials, chemistry, biology, and human factors to address important unmet medical needs. We are seeking a talented, collaborative, and highly motivated individual with a proven track record in process development to lead our team of engineers, and scientists. The Director of Process Development will report to the VP of Device Development and will manage a team of engineers and scientists and collaborate closely with cross-functional teams to drive innovation to develop a platform technology. The ideal candidate for this position is hands-on, and has a strong background in chemical engineering, process development and/or process engineering within a pharmaceutical or combination product environment, with an eye toward continuous improvement.

This role offers a unique opportunity to take Vaxess through initial clinical trials, a monumental step in bringing innovative technology to the global vaccine market, while also leading long-term platform strategy.

Responsibilities

● Work under the VP Device Development, in collaboration with cross-functional partners and stakeholders, to define critical process and formulation parameters for model formulations to advance the MIMIX platform.
● Develop and test models for assessing the impact of critical formulation parameters on microneedle printing and drying.
● Create a framework to develop microneedle formulations, establish formulation production processes and scale up from early-stage R&D through pilot production.
● Develop test methods, specifications, protocol & report writing, in support of continuous improvement of the platform.
● Communicate highly complex ideas and projects to internal executive team, board, and external stakeholders.
● Manage, train, supervise, and mentor team members.

Qualifications

● BS in Chemical Engineering, Bioengineering/bioprocess, or related field with 10+ years OR MS/MA with 8+ years OR PhD with 4+ years of aforementioned experience
● Excellent communication and organizational skills
● Strong interpersonal skills to drive the team’s performance and communicate project needs to all stakeholders.
● Understanding of material & test specs generation, protocol & report writing, process & test development, DOE/SPC process optimization & validation (IQ, OQ, PQ), FMEA.
● Experience in the development of regulated medical devices, pharma, or combination products is strongly preferred.
● Solid understanding of fluid mechanics. Experience in drying of complex formulations is highly desired.
● Experience setting up, executing, and analyzing results from designed experiments.
● Background in biologics (protein, mRNA, vaccine) early-stage process development would be helpful.
● Ability to read, analyze, and interpret professional journals, technical procedures, and governmental regulations.
● Collaborative problem solving, risk assessment, and risk management skills.
● Proven time and project management skills and proven ability to provide accurate timeline estimates and then 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.
● Commitment to fostering an inclusive environment with experience in developing peers or junior employees.

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.

Vaxess aims to recruit, employ, train, compensate and promote regardless of race, religion, color, national origin, sex, gender identity or expression, sexual orientation, disability, age, or veteran status.

If you’re interested in joining the Vaxess team, please submit your CV/resume to careers@vaxess.com.