MA - USA

(Sr.) Scientist Viral Vacccine Process Development (Upstream)

Company Profile

My client is a biopharmaceutical product development services organization, based in The Netherlands and USA where it has R&D and GMP manufacturing capabilities, that actively develops and offers unique know-how and technologies aimed at bringing biopharmaceuticals to the market more rapidly and at lower cost.

The company is actively involved in major *global health initiatives* where it collaborates with funding organizations like BMGF, PATH, CEPI and IAVI and Developing Country Vaccine Manufacturers, helping to bring more affordable medicines to the market.

They have a specific focus on viral and vector-based vaccines and to support program expansion in this area it is seeking experienced people for its Woburn (MA) R&D site.

The position

We are looking for a **(Sr.) Scientist** experienced in Viral Vaccine Upstream Process Development to work in a small Upstream Process Development Team. The team collaborates closely with the Downstream Process Development and Analytical Development teams as well as QA. Processes developed by the team will be transferred either to the GMP manufacturing site in Leiden, The Netherlands or to Developing Country Vaccine Manufacturers, so good communication and documentation skills are required. Knowledge of bioreactor and cell culture techniques using cell lines including VERO, MRC-5 and HEK293 are essential.

In our startup culture, the ideal candidate will show entrepreneurial spirit, independence and ability to take strategic, calculated risks to guarantee efficient progression of the projects and help build the team and the US operations. This innovator will be motivated by assessing and implementing new manufacturing technologies to keep ahead of the competition. Agility, flexibility and will to contribute to projects that have a strong impact on global health are key components of the culture.

RESPONSIBILITIES:

- Technical leadership in the development of scalable, robust, high yielding, and economically viable cell culture processes using a range of adherent and suspension-based cell culture systems for the production of viral and vector-based vaccines. Processes will be developed at bench scale and scaled-up to clinical scale prior to tech transfer. Knowledge of process monitoring and control strategies, Design-of-Experiments experimental set up and different process types including perfusion will be necessary.
- Process documentation suitable to allow tech transfer to GMP manufacturing (within the company or to external manufacturer)
- Cost-of-Goods analysis using tools such as Biosolve.

- Collaboration and coordination with other teams including downstream process development, analytical development and formulation development.
- Manage, train, guide and coordinate activities of junior staff members
- Participates in and provide information to project team meetings
- The position may entail travel to other sites or tech transfer recipients

EDUCATION AND EXPERIENCE:

- B.S./M.S. or Ph.D.
- 10+ years (B.S./M.S.) or 6+ year (Ph.D.) of related experience working in biopharmaceutical industry focusing on viral vaccine or viral vector production.
- Significant experience in developing and optimizing scalable viral or vector-based vaccine processes including knowledge of upstream process development scale-up/scale-down, bioreactor set-up, operation and control strategies and aseptic bioprocessing.
- Experience operating in early and late stage clinical process development, ideally with experience of contract development and manufacturing.
- Ability to adapt to change and effectively deliver under pressure while maintaining a high level of work quality.
- Strong verbal and written communication skills and ability to communicate within the organization as well as externally. Strong process documentation skills.
- Ability to use DoE in Design Expert, or other for statistical experimental design, data analysis and knowledge of statistical process control, QbD, and PAT concepts. Ability to perform CoGs analysis using tools such as Biosolve.
- Familiarity with FDA guidance and quality systems.

You will join a stimulating and international team working in a highly collaborative environment within global consortia. As part of this group, personal as well as scientific growth are encouraged and developed. In this position, you will report to the Associate Director of Upstream Process Development.