

Company Description

We are a Contract Development and Manufacturing Organization (CDMO) with over 20 biotech companies worldwide that have placed their trust in us. We develop and manufacture lentiviral vectors as a European leader working under both EMA and FDA standards. The lentiviral vectors produced by VIVEbiotech are used to treat a range of disorders, including haematological and solid cancers, and rare diseases. We are looking for you to be part of our Team!

Information

📅 Deadline: 2022-11-30
🏢 Category: Business
📍 Province: Gipuzkoa

🌐 Country: Basque Country
📍 City: Donostia - San Sebastián

Company

VIVEBIOTECH SL



Main functions, requisites & benefits

Main functions

We are looking for an Upstream Process Development Scientist to perform this key role reporting directly to the Head of USP Development of the Company. You will perform the scale-up of the lentiviral vector production bioprocess and carry out continuous improvement. You will also design and create new strategies to optimize the seed train production process, bioreactor cell growth, transfection and viral production. You will manage and organize internal and customer projects assigned to you: tech-transfer, execution and reporting. You will lead the manufacturing of customer and internal development batches, either manufactured within your own department or by other departments. You will identify and define improvement strategies for the USP process thanks to an in-depth knowledge of VIVEbiotech's lentiviral vector production process, actively participating in the definition of the necessary improvements of the manufacturing process with ideas, critical spirit and experimental design proposals. You will collaborate in the drafting of procedures, research, proposals, projects and improvements of the USP production process. You will actively participate in the manufacturing activities of the development batches always with a critical and objective view of the batch target. You will report any deviation of the development batches/experiments to the department manager. You will perform administrative tasks related to the process, for the correct development of the process: prepare manufacturing guides, material orders and sample management. You will prepare the necessary documentation for the registration of new materials and equipment: specifications, URS, internal files, working procedures, etc. You will organize the training of new recruits assigned to the department and accompany them in their training. You will work closely with the Area Manager for the development and implementation of improvements of the production platform and the strategic lines of the area; with the DSP Development Technicians to ensure the coordination of the activities; with the Production Team-Leaders for possible manufacturing of the USP development batches meeting all the milestones set or to test experimental hypotheses; with Logistics for material requisitioning; with Quality Assurance to ensure proper GMP compliance where applicable; with Quality Control to obtain analytical data; with R&D and CDS to ensure proper alignment of development lines. From time to time you will maintain relationships with suppliers of new materials, equipment and technologies as well as with Research Centers and Universities.

Requisites

You have a University Degree related to Biology, Biotechnology, Biochemistry or similar, with a solid background in Biotechnology, Molecular Biology, Cell Cultures and Bioreactors. Knowledge of Cell Cultures, Fermentation and Bioreactors and knowledge of GxP regulations is essential. Previous experience in the handling and use of bioreactors in the pharmaceutical industry or in a field related to life sciences or biotechnology is a must. Knowledge in PAT Technologies and Design of Experiments (DoE) and previous work in GMP environments is a plus. You possess excellent IT skills in MS Excel and other MS office tools (Word, PowerPoint). You work in an orderly and structured manner, with strong planning and organizational skills. You are a great team player. You are passionate about continuous learning, you are creative and like to solve problems showing a proactive attitude. You work with a strong results-oriented