EG 427
PINPOINT
GENE THERAPY

Job description

EG 427, a French biotechnology company that pioneers a new approach in gene therapy called pinpoint gene therapy, is looking for its:

CMC Project Manager

Full time position
Paris, France

Overview

EG427 is a gene therapy biotechnology company leveraging non-replicating HSV-1 based viral vectors to develop a novel class of innovative therapeutics. Our initial focus on peripheral nervous system (PNS) disorders is based on the unmet need coupled with the high potential of HSV-1 vectors in order to provide major clinical benefit in these areas. With our headquarter and R&D Laboratory in Paris, our global footprint gives us the prospect to partner with leading organizations around the world, allowing us to deepen our understanding of disease mechanisms and progression.

Our team was built with deep expertise in gene therapy development, allowing us to efficiently advance our programs from pre-clinical to clinical development. Our experience in viral vector design, optimization and gene therapy manufacturing of herpesvirus viral vectors give us an alternative approach to develop gene therapies. Additionally, we are developing proprietary technology to potentially enable innovative gene therapy treatments in a variety of indications.

Due to continued growth of our program, we are currently seeking a highly motivated and talented CMC Project Manager who have demonstrated success in developing emerging medicines and in particular gene therapy product.

You will work with internal and external partners to develop and execute CMC and manufacturing operations of our gene therapy portfolio of multimodality compounds in development (including cell lines). The candidate is expected to be adept with all areas of CMC (process, analytics, quality and supply), all stages development (research interface, early and late stages) and agnostic of modality.

Key responsibilities

The CMC Project Manager:

- Will oversee a range of CMC activities including process development (USP/DSP), process robustness assessment, GMP lot manufacturing, analytical development, quality control, comparability studies and supply activities
- Will manage day-to-day interaction with CDMOs and CROs activities in the CMC field including identification, selection, contracting, management and troubleshooting
- Will be responsible for implementing manufacturing strategy and tactical plans for non-GLP, GLP and GMP materials aligned with overall development strategy
- Will lead and manage CMC activities of multimodality compounds in development
- Will work with internal and external stakeholders to establish development paradigms for portfolio
- Will be responsible for knowledge, GLP/GMP materials and documentation to help advance programs

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- Will work with cross functional team members to support the preparation of timeline and budget aligned with overall development strategy
- Will manage CMC processes to ensure successful knowledge transfer, monitoring, continuous process improvements, and on-site technical support
- Will collaborate with stakeholders (CMO, CRO, internal teams, consultants, regulatory agencies) in preparing CMC review and CMC regulatory documents
- Will identify and enable new technologies and new processes to help in efficient development of advanced CMC processes

Requirements

- Advanced degree in biomanufacturing, bioengineering, or related field
- 5+ years relevant industry experience in a CMC position as project manager
- Hands-on experience in cell and gene therapy manufacturing. Knowledge in HSV-1 vector production and cell line development (Vero cell, HEK cell) is a strong asset
- Strong GxP knowledge in the pharmaceutical industry
- Proven record of participating to regulatory dossiers generation such as INDs, IMPDs, CTAa and/or BLAs
- Comfortable with standard modality and emerging modalities
- Strong organizational skills and attention to detail
- Self-motivated, self-disciplined and able to function independently as well as part of a team
- Strategic agility, strong critical and logical thinking with ability to analyze problems
- Strong ability to prioritize in a fast moving environment
- Must be fluent in English (both spoken and written), French fluency is a plus.

Complementary information

We’re looking forward to receiving your application (as a single PDF file) including:

- Cover letter
- Resume
- Contact details of referees
- Miscellaneous documents (if any) to support your application

Please send your application to info@eg427.com

EG427 is an equal opportunity employer and values diversity within our company. We do not discriminate in any way. We make hiring decisions based solely on your experience and skills.