telomere therapeutics

JOB DESCRIPTION

Background: Telomere Therapeutics is a spin-off company from **Spanish National Cancer Research Center** (CNIO) and **Universitat Autònoma de Barcelona** (UAB). Telomere Tx is a gene therapy company developing disease modifying treatments for unmet medical needs, pioneering "telomere repair" to treat organ fibrosis and other telomere-dysfunction syndromes for which there is no curative treatment. The lead program focuses on an *in vivo* gene therapy based on the expression of the telomerase (**TERT**) gene using an AAV vector for **idiopathic pulmonary fibrosis**. Telomere Tx has an open position for a dedicated CMC & Regulatory Manager who fulfil the following requirements.

Job title	• **CMC & Regulatory Manager**
Role and functions	• Point of contact and proactive communication with regulatory authorities. • Guide and spearhead the company´s pre-clinical regulatory package in terms of its design and strategy in order to ensure it fulfills regulatory standards as the company approaches IND/IMPD submission. • Responsible of gathering information to draft company´s TPP. • Manage review applications to Regulatory Authorities including, IND/IMPD & CTA submissions, annual reports. • Development and review material for submission to the Regulatory Authorities, ensuring compliance with regulatory standards. • Coordinate activities and manage relationship amongst CMC supply chain, while ensuring CMC is aligned with regulatory endpoints. • Coordinate activities and manage multiple projects amongst research collaborators and CROs from a regulatory perspective, including regulatory affairs specialists for regulatory submission targets. • Ensures effective communication is maintained and project status reports and progress reports are provided both internally and externally. • Coordinate and lead regulatory-related meetings. • Ensures successful management and coordination of efforts assigned to all members of the project team, to support milestone achievement and overall project delivery. • Maintains and evaluates study progress, project timelines and budget reviews. • Data analysis, interpretation, and discussion with scientific team. Understands clinical and pre-clinical results and helps in its interpretation for regulatory purposes. • Good knowledge of clinical trial methodology in gene therapeutic space, CMC and gene therapy manufacturing, regulations and guidelines of drug development and approval. • Support the preparation and management of non-dilutive funding applications or ongoing projects at the national and international level, if needed. • Support in dissemination activities, if needed. • Support in the preparation of scientific and regulatory authority meetings.

Qualification required	• PhD in life sciences.
Qualification desirable	• Regulatory affairs master or equivalent experience,
Experience required	• Work in regulatory affairs & CMC manufacturing management and/or similar role for >3 years within CRO, biotech or pharma industry within the field of biologics or preferably gene therapies. • Experience in leading submissions from preclinical to clinical trials to Regulatory authorities, including IND/IMPD & CTA applications. • Experience in project management.
Desirable experience	• Experience working globally. • Experience in cell & gene therapy.
Key competencies	• Excellent organizational skills. • Excellent communication skills. • Problem-solving and analytical skills. • Results orientation and proactivity.
Languages	• Excellent English level (written and oral), preferably (CAE).
Special conditions	• <10% of time on travelling.

Salary	• In proportion to experience and track record.
Condition	• Permanent position (6 months evaluation period).
Location	• Remote work (within EU).
Application	• To apply please send your CV and motivation letter, including references, to: jacobo.lopez-abente@telomere-tx.com • Deadline for applications: 25th June 2023.