

## « Regulatory Affairs Associate» (M/F)

Promethera Biosciences is a global innovator in liver therapeutics whose mission is to bring patients life-saving treatments to reduce the need for liver transplantation. Our lead clinical program, derived from our patented cell technology platform HepaStem, is designed to benefit from its immune-modulatory and anti-fibrotic properties. In addition to our cell-based pipeline we develop antibody technologies, such as the anti-TNF-R1 antibody Atrosimab, to complement and diversify our therapeutic options. We are a team of international experts operating out of facilities in Mont-Saint-Guibert, Belgium, Durham, NC, USA, Tokyo, Japan and Basel, Switzerland.

If you are sharing our vision of becoming the world leader in regenerative medicine in the liver space by developing innovative advanced therapies for acquired liver diseases and if you are looking for new challenges amongst a dynamic and international team of more than 100 people, consider a collaboration with our fast-growing company. Promethera Biosciences is currently hiring a **Regulatory Affairs Associate**.

### DESCRIPTION OF THE POSITION

- Report directly to the Regulatory Affairs Sr. Manager (RA)
- Be dynamic member of the RA department
- Support Regulatory team in meetings including agenda, minutes and logistics
- Support RA team in various activities, communications and documentation as needed, including documentation research and writing
- Under the supervision of the RA Manager, ensure adherence to applicable requirements, accuracy, consistency, completeness of regulatory documents
- Under the supervision of the RA Manager, participate to the editing, publishing, assembly, quality, and tracking documentation to help the planned regulatory submissions
- Establish and maintain Regulatory documentation (submission planning tools and trackers, archive correspondence, etc)
- Writing of Regulatory affairs SOPs
- Promethera Biosciences is offering a good opportunity to jump into RA and to acquire global RA knowledge in a dynamic biotechnology environment

### EDUCATION & EXPERIENCE

- Relevant scientific knowledge
- Ability to gathering information
- Excellent English written and verbal communication,
- Excellent organizational skills,
- Flexibility, professionalism and good interpersonal skills (within the RA field and across all the departments of the Company),
- Solution and results oriented
- Team player who can work independently

## QUALIFICATIONS

- Master's in sciences (Pharmaceutical Sciences, Life Sciences or equivalent), a PhD is a plus. A strong candidate with a relevant BSc will be considered if has some relevant industry experience
- Strong interest for RA is mandatory
- Interest for cell therapy is a plus
- Basic knowledge of GXPS and/or clinical trials is a plus.

## LOCATION

- At our headquarters in Mont-Saint-Guibert, Belgium.

You may apply for this position by sending your CV and application letter to [hr@promethera.com](mailto:hr@promethera.com)

Please note that, due to the high number of applications we receive, only retained candidates for interview will be contacted.