« *QA Specialist* » (M/F)

Promethera Biosciences is a global innovator in liver therapeutics whose mission is to enable patients to overcome acute and chronic liver diseases. 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, consider a collaboration with our fast-growing company. Promethera Biosciences is currently hiring a **Quality Assurance Specialist – Deputy QP**.

MAIN RESPONSIBILITIES

- Maintains and improves product quality and ensures continuous improvements by managing change controls, deviations, OOS, CAPA, Quality risk assessment
- Manages and reviews documents of Promethera quality system
- Participates in the reception and release process of raw materials and consumables
- Organizes and takes part to suppliers' and service providers' qualification / auditing
- Develops quality assurance plans by conducting hazard analyses; identifying critical control points and preventive measures; establishing monitoring procedures, corrective/preventive actions, and verification procedures
- Reviews batch records and qualification/validation reports
- Participates in the release and shipping processes of the finished product
- Participates in the process of reception/qualification/release of equipment
- Performs Annual Quality Reviews
- Is present on the ground for assisting day to day critical operations
- Performs internal audits
- Develops quality assurance in R&D department
- Develops quality system for Biobanking

QUALIFICATIONS/REQUIREMENTS

- Industrial pharmacist or relevant experience in a similar position in the sector of biotech/Pharma/cell therapy. Qualified Person certification is a real plus.
- Strong knowledge of cGMP
- Experience of minimum 4-5 years in Quality Assurance, preferably in a biopharmaceutical company
- Experience in cGMP audits
- Experience in cell therapy or quality control of human cells is a real plus
- Fluency in French and English professional proficiency

- Computer skills (Windows environment)
- Rigorous, passionate and dynamic
- Hands-on problem solving and proactive attitude

LOCATION

- At our headquarters in Mont-Saint-Guibert, Belgium / Gosselies

You may apply for this position by sending your CV and application letter to HR@promethera.com

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

For information, resumes and application letters received will be retained as long as the employment's offer is valid and will be destroyed as soon as the position is filled. We will contact you in case we wish to keep your CV after the recruitment period.