

« Qualification and validation engineer » (M/F)

Promethera Biosciences is a global innovator in liver therapeutics whose mission is to bring 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 **Qualification and validation engineer**.

MAIN RESPONSIBILITIES

- Analyze projects in order to create the Validation Plan (VP)
- Make URS and risk analysis for all systems and components of an industrial project: HVAC, Clean rooms, EMS, Utilities, laboratory equipment, ...
- Write validation protocols for each step of the validation phase: DQ, IQ, OQ, PQ
- Help the project team to be prepared for the external audits
- Write/update checklist
- Write/update SOP
- Participate to preliminary testing
- Execute validation protocols: witness execution, control results and attest in a report to submit to the QA department
- Execute and follow the requalification plan for the equipment

QUALIFICATIONS/REQUIREMENTS

- Education: Master (chemistry, biochemistry, microbiology, pharmacy, civil engineer interested in the pharma industry), industrial engineer with significant experience in the pharmaceutical biotechnology industry;
- Skills: Good knowledge of MS Office Word/Excel/Access/PowerPoint.
- Languages: English/French very good, knowledge of other languages is an asset.
- Experience: at least 3 years
- Driver license B
- In addition to your sense of organization and method, you are rigorous in your work
- You are proactive

- Ability to participate effectively in team-based information sharing environment
- Ability to plan, prioritize and deliver tasks on time
- High client service orientation and initiative to solve problem, excellent analytical and communication skills
- Consistently approaches work with energy and positive, constructive attitude
- Affinity with technical issues

LOCATION

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

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.