

## « Quality Control Associate »

Promethera Biosciences is an international biotech company with headquarters in Belgium and US operations in North Carolina, developing innovative therapies for the treatment of liver diseases. Its proprietary cell-based technology platforms are based on mature hepatocytes and allogenic progenitor cells isolated from healthy adult human liver donors. Promethera Biosciences is today in clinical stage with HepaStem and in pre-clinical stage with H2Stem.

If you are sharing our vision of the world leader in regenerative medicine in the liver space by developing innovative advanced therapies for inborn and acquired liver diseases and if you are looking for new challenges amongst a dynamic and international team of more than 80 people, consider joining our fast growing company. Promethera Biosciences LLC in Durham NC is currently hiring a Quality Control Associate.

### MAIN RESPONSIBILITIES

- Maintain laboratory inventory
  - Create purchase order forms as needed
  - Remove any expired materials from laboratory area
- Materials Management
  - Accept packages and assign internal lot number
  - Receive supplies and move materials to quarantine
  - Quality Control inspection of materials according to specifications
  - Ship materials to contract labs as needed for raw materials testing
- Environmental Monitoring
  - Monitor manufacturing cleanroom suite (must be gowning validated)
  - Off-test environmental monitoring plates
  - Ship isolates for identification
  - Initiate deviations for action level excursions
  - Enter all EM results into database
  - Growth promotion testing
- Donor Blood Processing
  - Prepare and aliquot blood as appropriate for different product lines
  - Contact Donor Develop Manager to acquire additional blood as needed
- Facility Maintenance
  - Clean Laboratory and Workspace
  - Maintain, clean, calibrate and qualify equipment in QC, EM and Assay Development workspaces
- Release and Stability Testing
  - Execute testing procedures for all liver cell batches produced
  - Data entry for all results
- Author, review and revise protocols, reports and SOPs
- Data entry for all special projects
- Some weekends on call for QC functions
  - EM and blood processing
- Other duties as assigned

### QUALIFICATIONS/REQUIREMENTS

- Associates or B.S. in Biology or Chemical Sciences or equivalent experience.
- At least 1 year of relevant experience in the GMP biotech/pharmaceutical industry.
- Working knowledge of requirements for aseptic manufacturing. Basic knowledge of cell biology.
- Ability to work collaboratively in matrix organizations and teams
- Must have strong organizational skills and be able to manage and prioritize multiple projects or assignments at one time, including the ability to follow assignments through to completion and meet deadlines.

- Effective communication (verbal and written) skills required.
- Rigorous, passionate and dynamic
- Hands-on problem solving and proactive attitude
- Experience with Cell culture a plus
- Experience working in a cleanroom environment a plus

## **LOCATION**

- At our US GMP manufacturing site in Durham, North Carolina

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

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