Quality Control Scientist, ATMP and Stem Cells

Amniotics AB
Lund, Sweden

Are you ready to join a team committed to move cell therapies into clinical and commercial settings by supplying high quality neonatal amniotic GMP MSCs for cell therapy use? Amniotics is at the start of an exciting journey, and we are looking for passionate individuals to join us on this important mission.

Amniotics is a stem cell company, dedicated to developing and commercializing novel treatments for the benefit of patients suffering from rare and life-threatening diseases, and to function as a CMO for other companies wishing to produce their ATMP in a GMP licensed facility. All in all, Amniotics envisions to be a team of about 16-20 people from spring 2021.

Amniotics is seeking a Quality Control Scientist who will also be part of the R&D team and participate in development of processes for GMP manufacturing of cells under aseptic conditions. Areas of responsibility will also include running QC testing of finished product.

This position will provide technical expertise in the areas of cell culture, flow cytometry and quantitative PCR. The candidate will help improve processes for drug product manufacturing and participate in the day to day drug product quality control operation to ensure clinical and commercial supply. The position will report to the QC Manager.

Responsibilities

- Support activities related to the transfer and validation of analytical methods.
- Perform routine in-process and release QC testing of cell products.
- Perform routine environmental monitoring.
- Execute analytical method qualifications, validations and transfers including drafting technical protocols, reports and troubleshooting.
- Maintain, calibrate and operate equipment and instruments supporting Flow Cytometry.
- Track and test products according to stability protocols.
- Complete routine record review of test data and related documents for in-process testing, drug substance and drug product release.
- Perform QC lab duties and R&D technical projects as required.

Qualifications

- Minimum BS degree in biological sciences, biochemistry, chemical engineering, bioengineering, or related technical field, or equivalent industry experience.
- Experience in a number of analytical techniques, including but not limited to, Flow Cytometry, Real Time PCR, ELISA, Cell Viability measurement, Environmental monitoring etc.
- Preferred:

- Experience in performing analytical method validation and supporting method transfer activities.
- Experience in QC department in the biotech and/or pharmaceutical industry.
- Knowledge of GMP, SOP's and quality control process.
- Excellent oral and written communication skills. Strong technical writing ability.
- Experience with cell therapy manufacturing a plus.

Please note this job description is not an exhaustive listing of activities, duties or responsibilities for this job. Duties, responsibilities and activities may change over time. This is a permanent position with a 6-month trial period.

For further information regarding the position, please contact:
Lisbeth Svensson, QC Manager, +46-73 507 0769, lsv@amniotics.com or
Jan Talts, COO, +46-72 327 8530, jt@amniotics.com

You are welcome to send your application with CV to one of the above e-mail addresses. Applications are evaluated on an ongoing basis. The expected starting date is early spring 2021.