

Supply Chain Manager / QA, 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 Supply Chain Manager / QA who will manage Amniotics supply chain and participate in QA activities for GMP manufacturing of cells under aseptic conditions. Areas of responsibility could also include preparing and reviewing CMC related documents for clinical trial applications as well as having contact with suppliers of facility and other services.

The candidate will help improve processes for material and services supply as well as supplier handling to ensure clinical and commercial supply. The position will report to the COO.

Responsibilities

- Manage all aspects of supply chain including purchasing and shipping
- Establish and manage strategic sourcing of raw materials and production supplies, including materials of biological origin.
- Manage all purchasing, warehousing activities, receiving, shipping, storage and inventory control while adhering to cGMP regulations
- Develop KPI (Key Performance Indicators) to monitor performance
- Manage vendor oversight, relationships and selection related to supplies and raw materials
- Work closely with the engineering and production teams to clearly understand technical requirements and sensitivities as they relate to manufacturing
- Identify and mitigate areas of risk with supplier and vendors
- Work closely with R&D to source new materials for future and current projects.
- QA responsibilities as part of the QA team (e.g. QMS maintenance, quality assurance tasks related to deviations, CAPAs, change control)

Qualifications

- Minimum BS degree in biological sciences, biochemistry, chemical engineering, bioengineering, or related technical field, or equivalent industry experience.

- Experience in procurement of biological raw and starting materials for biopharmaceutical based GMP manufacturing operations a must.
- Experience with supplier qualification
- Experience with Quality Assurance
- Experience with CMC activities
- Experience in equipment procurement, maintenance and validation 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:

Sidonie Karlsson, Production Manager, +46-73 545 8018, sk@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 2021.