



CMC Specialist at Afyx Therapeutics A/S

Are you a highly motivated individual interested in a position as CMC Specialist in a small, entrepreneurial company with broad responsibility?

Responsibilities

As CMC Specialist you will among others be responsible for

- Support identification, selection and coordination of Contract Manufacturing Organizations (CMOs) for cGMP process optimization, manufacture, quality control, and supply of Drug Product
- In coordination with Quality Assurance, implement appropriate analytical methods and protocols and ensure that Afyx and all CMOs are using systems and processes in compliance with relevant regulatory standards and cGMP
- Design of project plans and protocols with internal and external stakeholders
- Prepare, review, or edit cGMP batch records, specifications, validations reports, CMC regulatory documents and other Quality documents
- Coordination of activities for clinical trial supply

Preferred background

Educational background

- MSc in Pharmaceutical Science, Pharmaceutical Chemistry, biochemistry, engineer, or related scientific discipline

Professional experience

- Minimum 5 years of experience from pharmaceutical industry in production, QA, QC, supply chain, regulatory and/or development
- Knowledge of GMP and regulatory requirements for development and production of pharmaceutical products for phase 3 and commercial phase
- Experience in working with international GMP CMOs for the manufacture and QC of API and Drug Products
- Experience in preparing and reviewing of cGMP batch records, stability records, validations reports, and other quality documents
- Experience from combination products (pharmaceutical product/medical device) will be a benefit

Personal skills

- Good collaboration skills
- Project management skills
- Pro-active, result oriented, flexible
- Cultural awareness
- Holistic mindset

The position as CMC Specialist will reports to Head of CMC.

The position is based in Copenhagen, Denmark. Some travel activities required.



Application and further information

We look forward to receiving your application and Curriculum Vitae (CV).

If you have any questions to the position, please contact Senior Consultant, Helle Skov, phone: +45 41163037 or email: hesk@afytx.com

Please send your application and CV to Executive Manager, Tina Jensen, careers@afytx.com before August 8, 2020.

***AFYX Therapeutics A/S** is a company developing a pipeline of patch products for treatment of diseases where available dosage forms provide inadequate treatment.*

Our proprietary Rivelin[®] patch is flexible, biodegradable, and adhesive to mucosal surfaces. Designed with electrospinning technology, it delivers a therapeutic directly to the site in need, without interfering with patients' daily activities.

For further information please visit our website: www.afytx.com