



Head of CMC at Afyx Therapeutics A/S

Are you a highly motivated individual interested in a position as Head of CMC in a small, entrepreneurial company offering you a broad range of responsibilities?

Responsibilities

As Head of CMC you will be responsible for all Chemistry, Manufacturing, and Controls activities at Afyx from developing the CMC strategy, identifying tasks needed, selection of CMOs and oversight of CMOs. More specifically the following activities will be part of your job description:

- Identification, selection, and management of Contract Manufacturing Organizations (CMOs) for cGMP process optimization, manufacture, quality control, and supply of investigational medicinal products for clinical trials and commercial products
- Management of supply chain and logistics in support of clinical trials
- In coordination with Quality Assurance, implement appropriate analytical methods and protocols and ensure that all CMOs are using systems and processes in compliance with relevant regulatory standards and cGMP
- Implement and execute plans for the validation and registration of medicinal products and medical devices (and combination products) as required by cGMP, ICH, EMEA, and FDA regulations
- Writing and reviewing documents for IND/regulatory submissions; represent the company as the CMC expert to U.S. and European regulatory authorities
- Prepare, review, or edit cGMP batch records, specifications, validations reports, CMC regulatory documents, and other Quality documents
- Provide CMC input to development of pipeline products
- Actively contribute to key corporate strategic discussions and activities as a member of the Senior Management team

Preferred background

Educational background

- PhD or MSc in Pharmaceutical Science, Pharmaceutical Chemistry, or related scientific discipline

Professional experience

- At least 10 years of relevant experience in a pharmaceutical or biotechnology CMC/cGMP environment
- Solid experience with cGMP manufacturing, QC and/or QA
- Experience with IND, CTA, and NDA filings as well as thorough knowledge of relevant FDA and EMEA regulations
- Experience in managing international GMP CMOs for the manufacture and QC of API and Drug Product
- Experience in implementing technical, strategic, and operational plans
- Experience in supply chain management and/or combination products will be a benefit

Personal skills

- Good collaboration skills
- Leadership/project management skills



- Pro-active, result oriented, flexible
- Able to identify and resolve complex situations and critical issues
- Culture awareness
- Holistic mindset

The Head of CMC will report to COO, Lars Siim Madsen.

The position is based in Copenhagen, Denmark. Some travel activities will be 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 4116 3037 or email: hesk@afyxtx.com.

Please send your application and CV to Executive Manager, Tina Jensen, careers@afyxtx.com before August 15, 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.afyxtx.com