

CMC Product Support Manager

Y-mAbs Therapeutics is expanding its CMC activities and the CMC Development Team is supporting both early- and late-stage CMC development together with product support for commercialized products.

With this position we seek to strengthen our resources and competencies within product support to our commercial products and their product life cycle management.

The position will be part of our late-stage CMC Development Team and have a close collaboration with especially Regulatory Affairs (RA) and external alliance partners. The position will be located in Hørsholm, DK.

The CMC Product Support Manager will be responsible for coordinating global regulatory communication related to CMC and will have support from several Subject Matter Experts (SMEs) within the CMC Development Team and dedicated CMC specialist in RA.

It is important that our new colleague is self-driven and can drive multiple tasks based on both own CMC and RA skills and via management skills to bring the right people together to complete the task efficiently.

The person must be able to work independently and be strong at SME communication and interdisciplinary collaboration.

Preferred qualifications:

- Strong project management and coordination skills
- Good at structuring multiple work task, and keep focus on the important details
- Strong in SME communication and interdisciplinary collaboration
- Experience in working according to quality management systems and GMP compliance
- Experience with CMC support and life cycle management of commercial biopharmaceutical product
- Some experience in eCTD module 3 documentation is required together with basic knowledge within regulatory workflow
- Basic knowledge of manufacturing processes for biopharmaceutical products like monoclonal antibodies or similar

For more details about the job or our company, please contact Tore Søderblom, Senior Director, CMC Development on +45 5388 0988. Please note that all applications must be submitted in English and will be treated confidentially.

You can apply for the position by sending an email to HR@ymabs.com no later than 14th November 2021. Please mark your application with **Job ID no. 1064**. We will initiate interviews in a rolling manner as applications are received.

Y-mAbs Therapeutics A/S is a Danish affiliate of Y-mAbs Therapeutics Inc., which is located in Hørsholm, Denmark. Our mission is to discover, develop and deliver novel antibody therapeutics for the treatment of both pediatric and adult cancer patients.

Please access the company web site www.ymabs.com for more information regarding the company and our development projects.