Associate Director, PV QA

**Join a visionary company on their exciting journey and make your mark on a newly established function**

Y-mAbs is a fast-paced, growing company in the process of expanding its organization to support the

continuous growth on commercial activities as well as the exciting clinical pipeline with

activities in both early and late-stage clinical development.

**As Associate Director, Quality Assurance in the area of Pharmacovigilance (PV) at Y-mAbs** you will be part of a team of highly qualified and motivated colleagues in the QA department. You will be the QA PV partner and be a defining part of the newly established function. Further, you will establish QA processes to contribute to Good Pharmacovigilance Practice (GVP) compliance of the company operations.

**With direct report** to Senior Director Quality Assurance.

**Your main tasks are:**

* Contribute to development of the company Quality Management System and provide guidance in local and global requirements, as applicable to Pharmacovigilance
* Maintain Quality oversight of Pharmacovigilance System Master File, pharmacovigilance SOPs, Safety Management Plans, Pharmacovigilance Agreements, and other relevant documents
* Sustain Quality oversight of the company PV operations, including case processing, risk management, health authority reporting, and relevant IT system validation and maintenance
* Conduct audits of vendors relevant to PV areas as well as internal audits in these areas
* Lead preparation activities for and facilitate PV regulatory inspections
* Handle deviations, quality investigations and CAPA relevant to PV
* Train employees and business partners in GVP

**Your qualifications involve** 7+ years of relevant experience in pharma/biotech industry within QA

and/or PV and thorough knowledge of US, EU and global requirements in the area of PV. Further,

you have extensive experience and training as an auditor.

**Other qulifications are:**

* Knowledge of part 11 compliance requirements to computerized systems, specifically to PV/Safety data bases
* Record of successful collaboration with license partners, affiliates, etc.
* Experience in hosting of regulatory inspections
* Proficiency in English, written and orally
* Experience with EDMS (knowledge of Veeva Vault is an advantage)
* Experience in Clinical Drug Safety is an advantage

**You have a MSc/BSc** in pharmaceutical sciences, biological sciences or similar.

**You are a person with** good collaboration skills, both internally an with external partners. You must

be able to work independently, withmultiple tasks, and under ambitious timelines.

**Y-mAbs** offers an exciting work environment with opportunities for professional development. The position is newly established with a unique opportunity to make an impact in a global fast-growing oncology focused company that strives for becoming the world leader in developing antibody-based cancer products that address clear unmet needs.

Travelling: Up to 30 days per year.

Domicile: Great office location in Hørsholm at DTU Science Park including canteen scheme and easy

parking.

Unique Human Capital is handling the recruitment. For more details about the job or the company,

please contact Senior Research Consultant Jeanne Dederding, Unique Human Capital on M: +45 28

74 58 71. All applications must be submitted in English and are treated confidentially.

You can apply directly via this link:

<https://uhc.dk/ledige-stillinger/associate-director-pv-qa/>

*Y-mAbs Therapeutics is a late-stage clinical biopharmaceutical company focused on the development*

*and commercialization of novel, antibody-based therapeutic products for the treatment of cancer.*

*The company has a broad and advanced product pipeline, including 1 FDA approved and 1 pivotal-*

*stage product candidate – naxitamab and omburtamab – which target tumors that express GD2 and*

*B7-H3, respectively.*

*Y-mAbs’ mission is to become the world leader in developing antibody-based cancer products that address clear unmet needs in pediatric oncology. With the right partnerships and collaboration, they envision expanding their capabilities to treat adults – changing the course of cancer care and its outcomes. Currently, there are 100+ permanent employees in Y-mAbs.*

*Read more at:* [*www.ymabs.com*](http://www.ymabs.com)*.*