Associate Director / Director QA-GCP (m/f/d)

About Tubulis

The development of novel and effective and safe therapies for the treatment of cancer is one of the main challenges for modern medicine. We want to drive this process forward. The main goal of Tubulis is to become a leading company in the field of targeted therapeutics and antibody-drug conjugates (ADCs). With a strong team, our own technologies and innovative therapeutic concepts, we are ushering in a new era in the ongoing fight against cancer and share the vision of helping patients world-wide. Be part of a multidisciplinary and focused team, that works towards getting novel promising ADCs to patients with solid and hematological cancers.

Be part of our team

Tubulis is looking for an experienced QA-GCP professional to manage and execute QA oversight of our clinical service providers, clinical trial sites and internal GCP related systems and processes. By performing audits or managing contract auditors you assure that vendors and internal systems and processes are assessed for compliance with applicable regulations, guidelines and SOPs. You act as the central point of contact for and provide expert GCP advice and GCP training to Tubulis departments. The candidate will further implement and improve the internal GCP related quality management system. You will report to the VP Quality.

Responsibilities

- In close cooperation with VP Quality execute strategic plan for further implementation and improvement of clinical QMS
- Plan, conduct, report, follow-up audits of external CROs, laboratories analysing patients samples and clinical trial sites; preferred also of GLP vendors
- Manage external contract auditors
- Plan, conduct, report, follow-up audits of internal GCP systems, processes and documents
- Prepare, host, follow-up of authority inspections
- Prime contact partner for Clinical Operations and Clinical Development to provide compliance advice and guidance; train relevant Tubulis employees on GCP
- Represent QA-GCP in internal and external cross functional teams (e.g. trial team, vendor selection team etc.)
- Write, review relevant SOPs
- Provide QA support for Computerized System Validation (CSV) activities

Requirements

- Bachelors or master's degree in life science field or medical related discipline
- At least 10 years of QA GCP experience in biotech or pharma
- Experience in auditing GCP vendors including full service CROs, laboratories and clinical trial sites
- Experience in preparing and hosting of authority inspections
- Expert knowledge of GCP regulatory standards, laws and guidelines (US FDA and Europe/EMA, ICH)
- English fluent written and spoken
- Excellent writing and communication skills
- Experience in working in an international setting
- Experience in QA-GLP is a plus

We offer

Flat hierarchies and short decision-making processes, open corporate culture, 30 days vacation, strong team spirit, multicultural team and high level of collegiality, team events, EGYM Wellpass, mobility allowance.

We look forward to receiving your application, with details of your possible starting date and your salary expectations, at career@tubulis.com. For further information, please visit www.tubulis.com.