Position: Quality Assurance Lead *

Location: Remote (UK/Ireland) - travel / meetings, as required

About SynOx Therapeutics

SynOx Therapeutics is a privately owned innovative, late-stage biopharmaceutical company. It was established in November 2020 following the licensing from Roche exclusive worldwide rights to Emactuzumab, a potentially best-in-class CSF-1R monoclonal antibody. Emactuzumab has a well-tolerated safety profile and has shown promising efficacy in patients suffering from TGCT, a rare and debilitating disease that causes significant pain and disability.

Our mission is to establish Emactuzumab as a best-in-class drug of choice to address unmet needs and improve the quality of life of as many patients as possible. By connecting our industry-leading knowledge and experience with passion and dedication, we initially aim to provide life-improving options to address the unmet clinical needs of people living with tenosynovial giant cell tumors (TGCT) and other macrophage-mediated diseases.

SynOx is led by an experienced team of industry professionals with a successful track record of developing and bringing products to commercialisation. It is backed by a strong syndicate of premier life sciences investors.

Position Overview

The Quality Assurance Lead in collaboration with the SVP, Operations and Finance, Global Clinical Study Senior Director, Quality Consultant and other key stakeholders has overall responsibility for leading the day-to-day management and oversight of the quality management system (QMS), including GMP, GLP and GCP in support of clinical, commercial and regulatory requirements, through commercialization. This will include making recommendations to senior management and continuous improvement of the quality function and processes.

This is an excellent opportunity for an experienced quality professional to provide strategic and operational leadership to the quality function whilst retaining a strong hands-on element. In this impactful and visible position, the role holder will add value to SynOx during a critical time of its evolution as well as making a difference to patients.

The Ideal Candidate

- BSc or MSc degree in a science area coupled with solid QA experience in pharmaceutical/biotechnology industry, preferably in a start-up environment.

- Knowledge of GMP/ GCP/ICH requirements and inspection readiness with GCP experience being an essential requirement
- Up to date knowledge of clinical trial regulations and guidelines.
- Experience in sourcing, implementing and managing QMS systems to ensure GxP compliance.
- A working knowledge of regulatory requirements that specifically apply for the manufacture and/or testing of ATMP products (experience with therapies essentials, preferably with biologics/ monoclonal antibodies).
- Experience in planning, managing and executing vendor and site GCP audits, auditing key raw material suppliers as to GMP compliance.
- Responsible for follow up of audit and issue CAPA's.
- Experience of partnering with different contract manufacturing companies as well as other vendors.
- Experience with continuous improvement or implementing new policies and processes.
- Documentation and data quality review to ensure compliance.
- 'Self-starter', highly organised, proactive and efficient. Whilst we are a highly experienced team with cross functional experience, there will be a high level of autonomy in this role.
- Enjoy working in a small start-up team.

What is on offer?

- Competitive package, remote working (preferably in the UK or Ireland) with a monthly all teams meeting and the option to work from or meet at 'rented' offices.
- We are happy to discuss any flexible working preferences and consider part-time candidates.
- We are an Equal Opportunity Employer.

** Title to be confirmed: Manager/Senior Manager/Associate Director, in line with experience*

For more information, a confidential conversation or to send your CV please contact:
recruitment@synoxtherapeutics.com