TauRx Therapeutics Ltd

Vacancy

Head of EU Regulatory Affairs

TauRx are seeking to recruit a Head of EU Regulatory Affairs

Role Purpose:

- Take leadership responsibility for successful submissions to appropriate authorities through the approval process.
- Line manage and mentor internal European regulatory team and support their own personal development.
- Develop and maintain appropriate QA policies for the department's operations.
- Select and manage external regulatory affairs personnel (CROs) and ensure that SOPs provided by these CROs are consistent with the organisation's policies.
- Implement the EU elements of the company's global regulatory strategy, taking the lead in writing and reviewing submissions to European regulatory authorities.
- Maintain strong relationships with European competent authorities while advocating the company's position.
- Monitor national and international regulations and their impact relative to drug regulation.
- Provide advice and information on the legislation, regulation and guidance applying to the company's R&D activities to internal and external stakeholders.
- Act as a role model for the company and its ethos.
- Work as a team player with a "can do" attitude.
- Assist in the contracting, design and oversight of Phase I, II, III and IV clinical trials.

Experience:

- Considerable background in pharmaceutical R&D.
- Significant and accomplished career in drug regulatory affairs.
- Direct line management experience.
- Degree level qualification in a scientific subject (post-graduate scientific qualifications highly desirable).

- Direct contact and negotiation experience with the EMA and MHRA is a must have. FDA, Health Canada, BfArM, PEI, MPA and other regulatory authorities are highly desirable.
- Up to date and able to provide hands-on support with European filings.
- High degree of written and verbal communication skill.
- Experience in leading Quality, Nonclinical and Clinical development desirable with knowledge of GxP disciplines.
- Recent hands-on experience of CTA/IND and registration MAA/NDA/BLA phases of regulatory submissions.
- Broad drug development experience across relevant therapeutic areas desirable.
- Experience of different dosage forms, drug/device combinations, Orphan and paediatric drug expertise also desirable.

This is a full-time position based in our Aberdeen office.

Applications should me be made in writing by forwarding a covering letter and CV to HR@taurx.com