Clinical Regulatory Affairs & Medical Writing Associate

Location: Singapore (608531)
Salary: $SGD COMPETITIVE
Job type: Permanent
Company: The CLINICAL TRIAL Company (ASIA) Pte Ltd

An exciting opportunity has arisen for an experienced Clinical Regulatory Affairs & Medical Writing Associate to join The CLINICAL TRIAL Company (ASIA) Pte Ltd (TCTC), a fast-growing global, full-service clinical research organisation (CRO).

The role offers the opportunity to work on exciting, cutting edge studies with innovative medical device and pharma companies at the forefront of clinical research across different therapeutic areas, within a dynamic, international CRO. This varied and exciting role allows the successful candidate the opportunity to develop and grow within our expanding company, supported by an enthusiastic and knowledgeable team.

ROLE OVERVIEW
The role will require to consistently produce high quality regulatory documents, medical education and communications materials for the pharmaceutical and medical device industries across a wide range of therapeutic areas. In addition to project managing sponsor Clinical and Regulatory projects to applicable regulatory guidelines and Good Clinical Practice (ICH GCP) standards, within agreed timelines and stated budgets, under the supervision of the Regulatory Affairs and Medical Writing Manager.

Essential duties and responsibilities include, but are not limited to the following:

- Development of clinical trial investigation plan and other trial documentation including CRF, informed consent forms and patient information leaflets, MDD/MDR & IVDD/IVDR compliance
- Design and Development Support, Verification and Validation support, Technical File/Design Dossier review, Pre-Submission meetings, PMA/510(k) review, Post Market Surveillance, and International Registrations
- Development and preparation of regulatory documents, trial submissions, medical information publications and educational materials including Clinical Study Reports (CSR), CTD and scientific publications in line with regulatory requirements and internal document standards
- Preparation and oversight of competent authority, ethics committee, HRA and R&D submissions including amendments
- Liaise with pharmaceutical and medical device industry key contacts, healthcare professionals and other external service providers
- Check printer's proofs (text, layout, colour, specification) and sign-off for print/production and provide direction for the development of creative designs
- Assists in the development and documentation of TCTC processes
- Provision of regulatory support for clients and internally
- Ensure that all TCTC studies conducted are in accordance with GCP guidelines and are completed on time and within the stated budget
- Generate project plans and oversee adherence to ensure business objectives and key deliverables are met
- Contribute to the clinical trial design and the identification of potential study sites where necessary
- Oversee and manage the development and approval of clinical trial documentation
- Develop ongoing relationships and define project milestones as the primary contact with the sponsor
- On-going evaluation of project strengths, weaknesses and potential areas for improvement, including: internal processes, additional training, support or educational needs of staff,

timelines for individual project activities and identification of potential problems, activities that could improve overall project impact and results and overall project profitability
- Build effective relationships internally at TCTC and externally with the Sponsor/Contractors
- Maintain a high level of professional expertise through familiarity with clinical literature and project team meetings
- Where necessary, visit sites to initiate, supervise and coordinate clinical activities
- Assist team members:
    - Providing appropriate support and guidance to team members;
    - Setting achievable objectives for team and draw up training plans;
    - Keep line manager fully informed about progress and problems;
    - Act as a mentor;
    - Train staff in standard operating procedures
- Mentor other members of staff
- Prioritize and Implement department objectives
- Approval of Site/Investigator selection
- Coordinate data management and statistical activities where applicable and participate as assigned in the review of data listings, summaries and final study reports
- Develop and maintain Regulatory Standard Operating Procedures (SOPs) as necessary. Oversee adherence to SOPs, Good Clinical Practice and FDA regulations
- Additional duties as identified

ROLE REQUIREMENTS

The role will require you to hold a life science degree in a scientific field with a minimum of two years' clinical trial regulatory affairs experience, within a CRO or pharmaceutical company. You will have a clear understanding of the requirements and responsibilities for safety reporting in International Pharmaceutical Trials and will have had exposure to Protocol Development and Writing and Clinical Study Report preparation. GMP and Marketing Authorisation experience would be helpful. Medical Device experience is essential.

ABOUT THE CLINICAL TRIAL COMPANY™ LTD (TCTC)

TCTC has offices in the UK, Canada, Australia, Singapore and the USA. We operate throughout Europe, North America, South America, India, China, Africa and Australasia. Our expanding company provides clinical trial services and support to the pharmaceutical and medical device sector. TCTC offers the opportunity to work on clinical trials of real scientific merit, genuinely working in partnership with our Clients. Working within a highly motivated team, you can make an impact and see your talents rewarded.

BENEFITS

This is an exceptional opportunity to join TCTC. Our employees are vital to our success and we are seeking candidates to join our company and grow with us. As a progressive organisation embracing the work/life balance, we offer fantastic opportunities for personal development and advancement as well as competitive salaries and group health insurance.

PRIVACY NOTICE

We want to reassure you that we take our data protection responsibilities very seriously. By applying for this role you are agreeing to our Job Applicant Privacy Policy and this can be viewed here: https://www.tctcgroup.com/copy-of-privacy-notice-1.

Any offer of employment will be subject to the successful candidate holding the right to work in Singapore.

For further information please contact Amanda Harrison, Group HR Manager on T: +44 (0)1565 732 003 or email HR@TCTCGroup.com or visit our website: https://www.tctcgroup.com/

Clinical Regulatory Affairs & Medical Writing Associate

Ref: Clinical Regulatory Affairs/Medical Writing Associate (Singapore)

WE ARE SORRY BUT WE DO NOT ACCEPT APPLICATIONS FROM RECRUITMENT COMPANIES