3x Regulatory Submissions Co-ordinators

Clinical Operations · Drugs & Devices · TGA & MEDSAFE

Our Client

Our client is a global, full-service Clinical Research Organization (CRO) specializing in a multitude of therapeutic areas and active in over 45 countries globally. Due to continual growth they are seeking a full time Regulatory Submissions Manager to join their operations based in Melbourne.

Our client has a culture of expertise that empowers teams to support their business partners. Their values are high, and recognition and advancement are incremental to their success. Their team is stable and long term, and their employees are valued. Just a few reasons why mexec careers choose to represent this employer.

The Opportunity

Due to continual growth our client is seeking 3 full time Regulatory Submissions Co-coordinators to join their operations based in Melbourne. Your role primarily will be responsible for:

- Perform required activities within the country that lead to activation of investigative sites in all phases of clinical trials
- Prepare, review, and submit to Regulatory Agencies (TGA / Medsafe)
- Communicate with global study teams and personnel on study progress
- Ability to effectively identify risks to site activations and mitigate as necessary
- Provide expertise and guidance to global study teams in ethics and regulatory submissions
- Review and finalize essential documents required for site activation
- Act as a main contact for Ethical and Regulatory submission-related activities
- Direct contact with investigative sites during the study start up and activation process
- Ensure submissions comply with applicable regulations and guidance documents
- Advise sponsors on changing regulations and compliance requirements
- Track submissions and ensure timely filing of documents.

Your Experience

- Bachelor's degree in the science field or equivalent combination of education and experience
- At least two year of relevant working experience at a CRO, Pharmaceutical Company, or an investigative site
- Experience in preparing and submitting TGA regulatory applications
- Excellent organization and communication skills
- Knowledge of Microsoft® Office
- Knowledge of ICH - GCP guidelines and regulatory guidelines in Australia and New Zealand.
- Hands-on experience preparing, reviewing, and submitting regulatory documentation to Ethics Committees and Regulatory Agencies; including formulating responses to queries.
- Proactive approach to role with ability and willingness to learn and be challenged.
- More than 5 years of experience in clinical research, preferably with a CRO
- Experience may include CRA or project management experience
- Regional experience will be highly advantageous
- Strong oral and written communication skills

Our Offer

We invite you to be a part of a company that is impacting millions of people around the globe while enjoying a competitive total compensation and benefits package and internal growth opportunities.
If you are interested in joining our client in this exciting new challenge, please call us for a confidential discussion and/or email your resume & cover letter. careers@mexeccareers.com. Confidential enquiries to Marilyn Jones on 61 40 100 3553