BIOVALOREM

value imagination.

Clinical Research Coordinator I

Seeking individuals wanting to grow within the life science industries!

Role

Clinical Research Coordinator (CRC) I
USA (Home Based from IN)
Permanent Opportunity

Role Description

Biovalorem is actively recruiting for a Clinical Research Coordinator I to join our expanding l company in the USA as a permanent opportunity in Indianapolis. By working with Biovalorem you can further your career in a dynamic, fast-paced environment and you can be assured of rewarding benefits.

The Clinical Research Coordinator I will audit and monitor investigational sites, laboratories, and other entities for research studies to ensure compliance to the study protocol, Standard Operating Procedures (SOPs) , applicable regulations, and the principles of ICH-GCP and/or ISO standards. The CRC I will also be charged with ensuring the quality and integrity of data, and assessing the overall risk of the entities.

Responsibilities of the Clinical Research Associate I:

- Audit and Monitor clinical trials to ensure absolute adherence to Good Clinical Practice in accordance with ICH-GCP standards, Declaration of Helsinki, Federal Regulatory Requirements and study procedures;
- Site management review to ensure proper adherence to protocol, source data verification and assess CRF entries;
- Develop, review and edit clinical trial related documentation including but not limited to; Case Report Forms, Informed Consent Forms, study specific handbooks, guidelines and checklists;
- Assist with study protocol design, development and / or review, if required;
- Complete and compile all necessary research, documentation and information to gain appropriate regulatory and ethical committee approval where required;
- Assess and/or Perform pre-study initiation, interim monitoring and close out visits as required;
- Carry out drug formulation administration procedures and documentation records;
- Ensure adequacy of drug shipment and drug accountability;
- Liaise with the Medical Monitor, Principal Investigator, clinical operations staff and sponsor representatives as required;
- Organise / attend investigator meetings as required;
- Provide support to the Project Manager / Managing Partner with ad-hoc tasks as required

Essential Criteria:

- ✓ Bachelors degree, equivalent or higher qualification within Medicine, Biological Science, Pharmacology, Nursing or a relevant life sciences discipline;
- ✓ Clear understanding of the drug development process;

- ✓ Experience (1-2 years) in performing a Clinical Research Coordinator role;
- ✓ Work experience within either a hospital, medical / research centre environment, Contract Research Organization or Pharmaceutical company;
- ✓ Proven track record of adherence to ICH-GCP and applicable local regulatory requirements during the conduct of clinical trials;
- ✓ Ability to contribute to the development of clinical trial related documents and materials;
- ✓ Ability to independently perform pre-study initiation, interim monitoring and close out visits as required;
- ✓ Good communication skills including the ability to present complex information to both clinical and non-clinical disciplines;
- ✓ Excellent presentation skills including the ability to meet exacting standards and a keen attention to detail;
- ✓ Fluency in English language (both written and spoken) as well as a second language such as Spanish, Mandarin, Portuguese and/or French;
- ✓ Willingness and ability to travel;
- ✓ Willingness and ability to be home based in the USA;

Desirable Criteria:

- ✓ Auditing expertise and/or certification;
- ✓ Sharepoint 2010 know how;
- ✓ Experience across a wide range of clinical indications / therapeutic areas;
- ✓ Ability and experience to work with an electronic case report form (eCRF);
- ✓ Membership of local professional bodies or international clinical groups;
- ✓ Ability to learn and motivated to grow – self driven.

Biovalorem talent value imagination as they develop their expertise throughout their careers as well as the opportunity to be involved in every aspect of Clinical Trials across the full life-cycle of the drug development and manufacturing processes. We have strong partnerships with academia, government and industry. We welcome those seeking to challenge themselves!