BIOVALOREM

value imagination.

Project Manager I

Seeking individuals wanting to grow within the life science industries!

Role: Project Manager I

Description

Biovalorem is actively recruiting for a Project Manager I to join our expanding team in the USA. This is a **permanent** opportunity **in Indianapolis, IN**. By working with Biovalorem, you can further your career in a dynamic, fast-paced environment and you can be assured of rewarding benefits.

The Project Manager I will manage activities regarding GXP audits and monitor investigational sites, laboratories, and other entities for research studies to ensure compliance to the study protocol, Standard Operating Procedures (SOPs) , applicable FDA regulations, the guidelines of ICH-GXP and/or ISO standards. The candidate will also be charged with ensuring the quality and integrity of data, and assessing the overall risk of the entities.

Responsibilities of the Project Manager I:

- Manage audit and remote verifications of 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;
- Schedule and monitor time driven activities;
- Manage and integrate quality within the processes;
- Control actual costs against budgets;
- Site 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;
- Monitor progress on 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;
- Liaise with the Medical Monitor, Principal Investigator, clinical operations staff and sponsor representatives as required;
- Organize / attend investigator meetings as required;
- Provide support to the Managing Partner with ad-hoc tasks as required.

Essential Criteria:

- Bachelor's degree, equivalent or higher qualification within Medicine, Biological Science, Pharmacology, Nursing or a relevant life sciences discipline;
- Clear understanding of the project management activities related drug development and manufacturing processes;
- Experience (1-2 years) in performing a PM support role;
- Experience within either a hospital, medical / research center 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;
- Willingness and ability to travel;
- Willingness and ability to be home based in the USA;
- Ability to learn and motivated to grow – self driven.

Desirable Criteria:

- PMP certification or in progress;
- Lean Six Sigma expertise;
- GXP auditing expertise and/or certification;
- Sharepoint 2010 know how;
- Experience across a wide range of clinical indications / therapeutic areas;
- Membership of local professional bodies or international clinical groups;
- Fluency in English language (both written and spoken) as well as a second language such as Spanish, Mandarin, Portuguese and/or French;

At Biovalorem, people value imagination while they increase their expertise in bringing safe and effective medicine to patients around the globe, whether in drug development and manufacturing processes, academia, government and industry. We seek those seeking challenges!