**Job Description – Clinical Regulatory Documentation Assistant**

* Preparation, handling, distribution, filing, and archiving of clinical trials documentation according to the scope of work and standard operating procedures
* Review of study files for accuracy, completeness and ensure TMF inspection ready
* Product dossiers preparation for registration submission
* Provide training and support to systems users (such as CTMS, eTMF)

Qualifications:

* At least 2 year of experience in similar position in well-established CRO,pharmaceutical, medical device company  – **significant advantage**
* At least 2 year of experience as Study coordinator in clinical site- – **significant advantage**
* Awareness of knowledge of applicable clinical research regulatory requirements; i.e., Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) guidelines, TMF RM – required
* BS/BA diploma or equivalent
* Knowledge of regulatory requirements in the EU, APAC, East-Europe and south-America regions

Skills and abilities:

* Computer skills including proficiency in use of Microsoft Word, Excel and PowerPoint
* Ability to prioritize, self-control and diligence in completing big demanding projects
* Strong written and verbal communication skills including good command of English language
* Effective time management and organizational skills
* Permanent attention to details, accuracy in work
* Ability to establish and maintain effective working relationships with coworkers, managers and vendors