JOB DESCRIPTION

JOB TITLE: Sr. Clinical Trial Manager

GENERAL INFORMATION:

- **Location:** Basking Ridge, NJ (US office)
- **Position Type:** Full- Time
- **Direct Supervisor:** Project Director

GENERAL MISSIONS :

- Support Clinical Operations activities for assigned clinical studies including study planning (protocol designs), study start-up activities, protocol execution and study close-out as directed by and in collaboration with the Director Clinical Project Manager. Ensure global clinical studies are managed according to Good Clinical Practice, local regulations, guidelines, and SOPs.

MAIN ACTIVITIES :

- Ensure appropriate oversight and management of the CRO/service providers
    - Supervise service provider/CRO's country feasibility and site selection process in collaboration with Medical Affairs and Director clinical projects to identify and approve high quality investigators
    - Review and approve project plans developed by CRO/service providers (e.g., communication plans, risk management plans, project plans, safety management plans) in accordance with study objectives
    - Review status reports provided by CRO/service providers and highlight issues to facilitate decision making
    - Participate in meetings led by CRO/service providers, review minutes, and provide support to the Direct Supervisor so that CRO issues are proactively identified, communicated, and resolved in a timely manner
    - Over-see site payments to ensure timely payments by the CROs.
- Work cross-functionally, using clinical operations expertise to ensure effective contributions, execution, and delivery of study activities
    - Ensure common understanding of activities across all stakeholders/line functions
- Contribute to writing and updating of study documents such as: Protocol, Protocol amendments, Informed Consent Forms, Clinical Study Reports
    - Actively contribute, as needed to the preparation of clinical parts of IND/NDA/BLA/AMM/IMPD/DSUR dossiers
- Conduct co-monitoring visits to ensure proper adherence to study protocols, develop/enhance site relations as needed which may include travel to a limited number of sites

JOB DESCRIPTION

RESPONSIBILITIES (transversal and managerial):

N/A

INTERNAL AND EXTERNAL RELATIONS :

- Contribute to the supervision and assessment of protocol compliance/execution of clinical studies, in partnership with the DBV M.D. and external partners
- Contribute/participate to SOP updates and ensure compliance with the application of all company policies and procedures
- Collaboration with the Regulatory Department as needed to ensure clinical studies remain compliant with Health Authority regulations

REQUIRED SKILLS:

Technical / scientific skills:

- Good understanding of the drug development process and knowledge of Pharmaceutical Industry
- Knowledge and experience of GCP/ICH practice, and the regulatory and ethical environment of Clinical Studies
- Excellent organizational and management skills
- Scientific rigor, ability to analyze, interpret, write and report
- Good verbal and written communication skills
- Good computer literacy

REQUIRED EDUCATION :

- Minimum of B.S degree or higher degree (M.S., MPH, M.D., Pharm D, PhD etc)

REQUIRED EXPERIENCE :

- Minimum 10-12 years of experience in a Clinical Operations role working on international/global Clinical studies within the Pharmaceutical/Biotechnology Industries or with a CRO
- Experience in Pediatric Allergy, Asthma, Immunology, or Immunotherapy is a significant plus, but not mandatory. Pediatric experience in any therapeutic area is also a plus.
- Experience/track record of having worked effectively in a multi-cultural environment
- Experience working in a matrix/cross-functional corporate organizational

DVB-technologies Contact:

Hiring Manager: Saishree Ramalingam- saishree.ramalingam@dbv-technologies.com

Human Resources: Caroline Daniere – caroline.daniere@dbv-technologies.com