At DBV Technologies, we celebrate full expression of our four core values and their associated professional behaviors. Also known as the 4Cs, these values - Curiosity, Courage, Collaboration and Credibility - are rooted in the DNA of our company.

With roots in France, and a strong American and Australian presence, our ambition is global. Do you want to join an ambitious biotech company where employees are passionate about science and innovation?

Join us at DBV Technologies!

## TITLE: Clinical Trial Manager

DBV Technologies is recruiting a Clinical Trial Manager (Full-Time) under the direction of the Director, Clinical Project Manager. This position is based in the US Basking Ridge NJ office.

## 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.

## RESPONSABILITES:

- 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
- Work cross-functionally, using clinical operations expertise to ensure effective contributions, execution, and delivery of study activities o 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

## REQUIRED 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

## PROFILE :

- Minimum of B.A or B.S degree or higher degree (M.S., MPH, M.D., Pharm D, PhD etc)
- Minimum 5-years-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

## CONTACT : rh@dbv-technologies.com

DBV Technologies is committed to reviewing all applications with the utmost care and without discrimination.