BIOPHYTIS (www.biophytis.com) is a pioneering biotechnology company developing transformative therapies that impact longevity

To support our growth, we are recruiting:

Clinical Operations Manager

Reporting line

Medical & Clinical Operations Department, reporting to the Chief Clinical Operations Officer.

Position overview:

The Clinical Operations Manager (COM) represents a key member in Biophytis Clinical Operations Organization. The COM takes part in the interface between Biophytis, Clinical Research organizations (CRO) and governance bodies to successfully and efficiently conduct clinical trials.

The COM is the main contributor for the clinical trial timelines and objectives from start-up activities to Clinical Study Report. He/She is a key contributor for the preparation and/or the timelines of numerous clinical study documentation (Clinical development plan; Clinical trial design / synopsis; Monitoring Plan). He/She is also contributor for the clinical trial governance bodies management, and responsible for the budget and site contracts negotiation. He/She is the main contributor for the CRO selection as well as the country selection.

The position is located in Ivry-sur Seine, France and provides a global coverage. The COM reports to the Chief Clinical Operations Officer and works in close links with the Program Director, Regulatory and Medical Directors and with the relevant functions in Research and Development and Pharmaceutical Operations.

Key Responsibilities:

- Responsible for Clinical Study management, setting and meeting goals, timeline, budget and resource allocations, under the guidance of the Chief Clinical Operations, Chief Medical Officers
- Contribute to updating Biophytis' internal Standard Operating Procedures (SOPs) to ensure studies are conducted in compliance with ICH Good Clinical Practice.
- Establish strong interactions for responding to questions and issues raised by sites, suppliers, monitors, and consultants as regard clinical operations.
- Strong contribution in Database lock and Data cleaning
- Responsible for CRO selection under the guidance of the Chief Clinical Operations Officer
- Contribution in clinical trials governance body management (DSMB/DMC; Steering committee).
- Review/providing input to clinical documents (clinical development plans, study protocols; Monitoring plan, Drug development plan, the scientific communication plan etc...)
- Participate in—and, if necessary, oversee—the development of tools required for study monitoring and the maintenance of Trial Master Files; participate in the development of informed consent forms and the design of electronic Case Report Forms, etc….
- Review the following documents (Clinical development plan, etc…)

- Contribute to the analysis, summary, and reporting of clinical data of the study.
- Maintain professional expertise regarding clinical documentation and scientific literature.
- Involved in identifying appropriate contacts with all stakeholders for the success of the trial.
- Maintains professional expertise through familiarity with therapeutic area and clinical research literature.

Qualifications:

- A Master's degree, Pharm D or PhD in life-sciences
- Experience of at least 5/7 years in the pharmaceutical industry – in clinical or drug-product development
- At least 5/7 years' experience as a Clinical Research Associate (CRA) in the pharmaceutical industry, (biotech company or CRO).
- Knowledge in some of the following areas: drug development, clinical development, regulatory affairs, CMC or Knowledge in quality assurance in a plus
- A thorough knowledge of GCP, ICH guidelines and regulatory requirements for clinical trial management, with an up-to-date certification, from the last 3 years.
- Experience with multicenter, international trials, ideally Phase II/III.
- Experience in CRO oversight

Skills:

- Strong synthesis & analytical capacity
- Good communication, coordination and organizational skills, mostly for planning
- Ability to influence and negotiate effectively.
- Ability to work well in a dynamic and constantly changing environment, with flexibility and agility.
- Ability to combine a strong scientific knowledge and understanding of medical challenges, with focused and value-adding delivery of tasks and commitments.
- Ability to work with internal and external stakeholders in a multicultural and diverse environment with respect and patience.
- Excellent oral and written English communication skills.

Contact:

Write to Marie-Paule Julienne: rh@biophytis.com with motivation letter & resume