BIOPHYTIS *(www.biophytis.com) is a Euronext and Nasdaq listed clinical-stage biotech company specialized in the development of therapeutics that are aimed at slowing the degenerative processes associated with aging and improving functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19.*

In order to sustain our development, the company is now opening the following position:

COVA Project Leader

Organization : Clinical-Medical, reporting to the Chief Medical Officer

Team : Clinical Development

Position overview:

The project Leader represents a key member in Biophytis Clinical-Medical Organization and He/She will be leading the project in all its dimensions and through the entire life cycle of the medication, from early development, to commercialization. He / She will be the interface between the Clinical-Medical organization, Research, Operations and other organizations teams contributing to the COVA project.

The Project leader will be accountable to prepare the project related documentation (e.g. target product profile, project plan and clinical development plan) and will coordinate across departments the members of the core project team (representing the clinical, medical, regulatory, pre-clinical, operations departments as well as support functions) for achieving the milestones and success of the project.

The position is located in Paris, France and provides a global coverage. The Project Leader reports to the Chief Medical Officer and works in close links with the Clinical Operations director, Regulatory and Medical directors and with the relevant functions in research and support functions. A relatively significant amount of travel is also required (in USA and Europe).

Key Responsibilities:

- Lead the Project Team including the core project team
- Responsible for the transverse management of the project, setting and meeting project goals, timeline, budget and resource allocations – under the guidance of the Chief Medical and Chief Operations Officers and the Executive Committee
- Responsible for ascertaining the input from and implementation by all members involved in the project, including external service providers, for reaching project goals and successful execution of project plans and work – maintaining a seamless and cross-functional interactions under the project team
- Define and write the target product profile (TPP) – with the project team
- Writes the Investigator's Brochure – with the members of the project team.
- Providing input to writing clinical documents (clinical development plans, study protocols) – under the lead of the clinical development team
- Provides input to writing product documents (e.g. IMPD) – under the lead of the operations team
- Involved in setting up the regulatory strategy and a part of the regulatory response team – under the lead of the regulatory team

- Involved in building the scientific dissemination plan and greatly contributing to scientific dissemination of the project through publications and presentations in scientific events – under the lead of the medical team
- Involved in identifying appropriate contacts with all stakeholders for the success of the project – under the lead of the medical team
- Lead all translational research through strong interactions with research and operations teams inside the company

Qualifications:

- A master or PhD in life-sciences or engineering
- Experience of at least 10 years in the pharmaceutical industry – in clinical or drug-product development
    - Experience in project management – of projects with a budget of ≥5MM Euros
    - Experience in late-stage development, regulatory filing (NDA and MAA) and pre-launch/launch activities
- An excellent knowledge in some of the following areas: drug development, clinical development, regulatory affairs, CMC or manufacturing
    - Knowledge in quality assurance, management and control is an advantage
- A significant experience in management of teams – especially virtual and matrix based
- An excellent knowledge of usage of electronic planning and project management tools

Skills:

- Strong synthesis & analytical capacity
- Good communication, coordination and organizational skills, mostly for planning
- Excellent oral and written English communication skills (Fluency in Spanish will be considered an advantage).
- 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.
- Knowledge of the French culture will be an advantage.

Compensation:

- +/- 60K€ + bonus

Contact:

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