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:

Director of Medical Affairs (DMA)

General :

The DMA is a physician that integrates specific therapy area knowledge and industry experience and serves as a 'center of excellence' for disease area, medical and scientific knowledge, combined with clinical trial experience. As such, the DRA is signing of on safety, efficacy and benefit – risk assessments and interpretation of the clinical data pertaining to Biophytis products.

The DMA is also responsible for planning and creation of content for scientific and medical communications with external stakeholders, especially care providers and patients.

The position is located in Boston, MA, USA and provides a global coverage. The DMA reports to the Chief Medical Officer (CMO) and works in close links with the clinical and regulatory directors and with the relevant functions in research and operations. A significant amount of travel is also required (50%, including Europe).

Key responsibilities :

- With the project lead, build the scientific communications strategy and plans for the project in the Biophytis pipeline.
- With the project lead, build the real-world evidence, observational and epidemiology study plans for the project in the Biophytis pipeline.
- Responsible for patient safety and risk management, including signing of on AE / SAE reporting, narratives and safety assessments, periodic safety reports and the patient's safety sections in clinical trial reports and regulatory documentation.
- Responsible for the assessment of efficacy and benefit - risk interpretation based on data from the clinical trial and real-word data.
- Responsible for the writing and signing of on publications related to the relevant project.
- Represents clinical study data in symposia, congresses and other public interactions.
- With the regulatory director, reviews study ads and relevant media for regulatory compliance.
- With the Medical Science Liaison, reviews investigator initiated / sponsored trials (IST / IIT) and research grants proposals.
- Leads the planning and executions of advisory boards
- Maintain high ethical standards and a strong knowledge and understanding of rules, regulations and guidelines – relevant to clinical research, scientific scrutiny and level of evidence and engagement with stakeholders.
- Attends training lectures, symposia and conferences in order to maintain up-to-date level of knowledge and expertise.

Qualifications:

- MD degree
- Therapy area knowledge in infectious diseases / virology / acute respiratory care is an advantage
- Specific knowledge about conducting clinical research in pediatric or elderly populations, with significant regulatory insights
- 10 years' experience in the pharmaceutical / biotech / medical device / healthcare industry, in clinical development or medical affairs. Late stage development/pre-launch experience will be a plus
- Knowledge and experience in epidemiology, HEOR or pharmacovigilance will be an advantage
- Experience in identification and management of external consultants.
- Experience in writing and publication, and making scientific presentation.
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- Up-to-date ICH-GCP certification
- Fluent English. Knowledge of French will be an advantage

Skills:

- 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 from business & investment perspectives.
- 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:

- +/- 150K€ + bonus

Contact:

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