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:

VP Head of Regulatory Affairs

General:

The HRA works at the interface between Biophytis and the regulatory authorities, through the entire life cycle of the medication, from early development, to commercialization. He/She has an up-to-date knowledge of the regulatory guidelines, a good understanding of the decision-making process in the regulatory authorities and is able to identify trends and directions that influence this process.

The HRA serves as the contact person of Biophytis with the regulatory authorities and is managing the documentation required for all steps of development and commercialization. The HRA is also a 'center of excellence', for knowledge and advice, to inform and direct the development and commercialization plans.

The position is located in Paris, France, and provides a global coverage. The HRA reports to the Chief medical officer (CMO) and works in close links with the clinical and medical directors, as well as Project Leaders and with the relevant functions throughout the organization. A relatively significant amount of travel is also required (+/-30%).

Key responsibilities:

- With the project lead, build the regulatory strategy and plans for the project in the Biophytis pipeline
- Provide leadership in implementing registration strategy across relevant groups, including Clinical Development, Preclinical Development, Marketing and CMC
- Lead and work closely with relevant clinical development, operations and research personnel to ensure regulatory compliance and consistency with regulatory registration strategy
- Manage interactions and build positive relationships with all relevant Health Authorities to facilitate timely and compliant submissions and approvals
- Work closely with consultants and contractors to coordinate publishing, and other submission activities including eCTD preparation
- Advise senior management on regulatory pathways and options
- With the relevant functions, coordinates and manages the preparation of documents such as IB and IMPD
- Participates in the safety team and coordinates the preparation and submission of periodic safety reports
- With the medical director, reviews material for communications with external stakeholders, including, promotional materials, press-releases, study ads and relevant media for regulatory compliance

- With the quality lead ascertains the compliance of production with ICH-GCP guidelines and other relevant specifications and regulatory guidance
- Identification and management of external consultants – ascertains the utilization of external advice to cover knowledge gaps
- 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:

- At least 10 years of experience in the pharmaceutical / biotech industry and 2 years in regulatory affairs (US or global)
- BSc or higher academic degree, including MD and Pharm D
- Specific experience in late-stage development, filing of NDA/MAA and launch readiness
- Experience in working with FDA (including preparation of NDA, IND, EoPII, NDA, SNDA, BTD / fast track, ODD, regulatory advice meetings and other relevant regulatory submissions) and EMA (including CTA, NTA, ODD, PRIME, scientific advice and other relevant regulatory submissions)
- Experience in the mutual assessment and EUnetHTA will be an advantage
- Experience in identification and management of external consultants
- 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
- 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:

- +/- 130K€ + bonus

Contact:

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