Our client is a biotechnology company based in Liège.

This human-sized structure provides innovative solutions to medical needs concerning infections, with the ambition of progressing towards the next clinical steps.

To support growth and join the team, we are actively looking for a (m/f):

Head of Regulatory Affairs (M/F)

RESPONSIBILITIES

As Head of Regulatory Affairs, you will be responsible for developing and executing **regulatory strategies** to support the advancement of the company's vaccine candidates from IND to late-stage clinical development (including plans for market approval). This role requires a strategic yet detailed-oriented leader with a solution-finding attitude and extensive experience in regulatory affairs within the biotech or pharmaceutical industry, particularly **in vaccines.**

Your main responsibilities are:

- **Regulatory Strategy Development:**
  - Develop and implement comprehensive regulatory strategies to ensure the development from early-stage up to EOP2, and beyond towards approval of strategic vaccine candidates.
  - Plan over a multi-year horizon, collaborating extensively within the company up to the VP level.
  - Ensure alignment of regulatory strategies with the company's overall business objectives.
- **Regulatory Submissions:**
  - Lead the preparation, submission and maintenance of regulatory documents, including INDs, BLAs, MAAs, and other relevant filings.
  - Ensure accurate, high-quality and timely submissions to regulatory authorities.
  - Reviews, comments, corrects and may sometimes write part of the files.
- **Documentation, Reporting and Regulatory Compliance:**
  - Oversee the preparation of regulatory documents, reports, and dossiers.
  - Maintain accurate and up-to-date records of all regulatory activities and submissions, making sure that the company's activities and records comply with all applicable regulatory requirements and guidelines, as well as with due diligence requirements from contemplated pharma partners.

- Monitor changes in regulatory requirements and communicate their implications to the company.

- **Liaison with Regulatory Authorities:**
  - Serve as the primary point of contact with regulatory agencies, including the FDA, EMA, and other global regulatory bodies.
  - Manage regulatory agency meetings, responses to inquiries, and inspection activities.

- **Cross-Functional Collaboration and Team Leadership:**
  - Collaborate with clinical, preclinical, CMC, and commercial teams to ensure alignment and integration of regulatory strategies.
  - Provide regulatory guidance and support to project teams throughout the development lifecycle.
  - Lead and mentor a focused regulatory affairs team which may include internal employees and external consultants, fostering a culture of excellence and continuous improvement.
  - Ensure effective interaction of RA teams with other stakeholders.

PROFILE

- Advanced degree in life sciences, pharmacy, or a related field (Ph.D., Pharm.D., M.D., or equivalent).
- Minimum of **10 years of regulatory affairs experience** in the biotech or pharmaceutical industry, **with a focus on vaccines**.
- Proven track record of successful regulatory submissions and approvals.
- Experience interacting with major regulatory agencies (FDA, EMA, etc.).
- Deep understanding of global regulatory requirements and guidelines for vaccine development.
- Extensive knowledge of IND, US, and EMA regulations for product development and licensure/post-licensure.
- Strong leadership and team management skills.
- Excellent written and verbal communication skills both in French and in English.
- Strong problem-solving attitude, as a Strategic thinker with the ability to influence and drive complex regulatory processes.
- Detail-oriented with strong organizational and project management skills.

OFFER

- The possibility to work both as a freelancer or as an employee with an attractive remuneration in line with your experience.
- The opportunity to make a real difference in a biotech company specializing in vaccine development.
- Join a fast-growing, supportive and collaborative international team.
- Flexible working hours and remote work options.

INTERESTED ?

Please send your CV together with an adapted cover letter to recruitment@pahrtners.be.

YOUR APPLICATION AND RELATED INFORMATION WILL REMAIN STRICTLY CONFIDENTIAL.

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