Position	Regulatory Affairs & Market Access Officer
About us	PEP-Therapy is a clinical-stage biotechnology company developing first-in-class peptides as targeted therapies in oncology. PEP-010, our lead product, is in Phase Ia/b clinical trials for the treatment of advanced solid tumors and in particular platinum-resistant ovarian cancer and pancreatic ductal adenocarcinoma. PEP-Therapy was founded in 2014 and builds on research results from Institut Curie and Sorbonne University. The company is backed by international investors. For further information: www.pep-therapy.com
Mission	You will support the design and implementation of a **strategic market access roadmap** in compliance with health and safety rules and regulations, including budgets and deadlines. In interaction with our R&D and corporate management teams as well as our CMO, your work will contribute to strategic decisions for the company. In particular, your primary responsibilities will be to: ▪ **Regulatory Strategy Development:** Develop and implement regulatory strategies aligned with business objectives to facilitate timely approvals for drug development and commercialization. It includes the redaction of a Target Product Profile and its update. ▪ **Market Access Planning:** Lead market access assessments and develop strategies to optimize future reimbursement, pricing, and access to the drug candidate in the US and European markets. ▪ **Regulatory Submissions:** Participate in the preparation, submission, and maintenance of regulatory filings, including INDs, CTA, ODD, …, ensuring accuracy and completeness of documentation. ▪ **Participate in the management** of outsourced studies with CROs or academic partners. You will also be involved in: ▪ **Cross-functional Collaboration:** Collaborate closely with cross-functional teams, including R&D, clinical development and corporate management teams, to integrate regulatory and market access as well as quality assurance and legal considerations into product development. ▪ **Regulatory Intelligence:** Stay abreast of evolving regulatory and market access requirements, guidelines, and trends in the pharmaceutical industry, providing insights and recommendations to internal stakeholders. ▪ **Risk Management:** Identify regulatory and market access risks and develop mitigation strategies to address potential challenges or obstacles to product approval and market access.
Experience	▪ 1 to 3 years' experience in the market access and regulatory field in a biotech or pharmaceutical company or in a consulting firm. ▪ A previous experience in oncology therapeutic area will be a plus.

Education	▪ MSc degree in Pharmacy or Biology. ▪ Post degree qualification in Regulatory Affairs, Health Economics and Market Access or Healthcare Management.
Skills	▪ In-depth knowledge of regulatory requirements and processes in the US (FDA) and Europe (EMA), with experience navigating regulatory submissions and interactions. ▪ Understanding of the global healthcare, policy, market access principles, pricing and reimbursement mechanisms in the US and Europe. ▪ Fluent speaking and writing in English. ▪ Ability to work with multidisciplinary teams. ▪ Rigour with analytical spirit, organization, autonomy, proactivity. ▪ Thorough interest in a young biotech company work environment, taste for innovation.
Duration	Fixed-term contract, 6-months contract, starting as soon as possible
Salary and benefits	Fixed salary commensurate with experience + performance bonus based on achievements of objectives + luncheon vouchers.
Location	111, Avenue de France, 75013 Paris, France, and home office.
Application	Send CV and cover letter to application@pep-therapy.com. Please clearly indicate "Market Access" in the subject line, and your possible start date in your email.