Director of Regulatory Affairs (M/F) – Permanent contract

Apply at recrutement@ose-immuno.com

The role is based in our Paris office (10 Place de Catalogne, 14th arrondissement) with flexible home-office.

Who are we? OSE Immunotherapeutics is a French clinical-stage biotechnology company (6 clinical assets, over 60 employees), specialising in the development of innovative immunotherapies for the activation and/or regulation of the immune system in different areas of expertise: vaccination against T-cell epitopes, monoclonal antibodies (agonists, antagonists, bispecifics) and RNA therapeutics for the treatment of cancers, autoimmune diseases and chronic inflammatory diseases.

We have a dynamic, cutting-edge team at two sites in Nantes (Research) and Paris (Development), responsible for optimizing research activities, clinical development and the industrialization of programs, to take our projects through to the clinical registration phase. The company is listed on Euronext Paris and has the scale and ability to leverage its assets through industrial and academic partnerships.

The position is reported to the Chief Clinical and Medical Research Officer. The Director will operate internationally and cover the following missions:

- Provide, develop, also with the advice of external experts, and lead global regulatory strategies, for the success of OSE portfolio, from pre-IND status to post marketing approval commitments
- Lead relationships and negotiations with Authorities such as the EMA and the FDA
- Direct point of contact with health authorities, supervises and validates all communications with Authorities, leads and manages FDA/EMA meetings
- Provide tactical guidance to relevant cross-functional team members and ensure the regulatory strategy is updated and executed
- Coordinate, monitor and review the compilation of regulatory dossiers from start of clinical study until result (CSR) for quality and contents
- Ensures compliance of submissions to the current international regulatory guidelines, and coordinating with third-party vendors to any local regulations
- Accountable for Authorities' submissions (through CTIS platform for Europe) and tracking of approvals of project(s) of responsibility
- Ensure project team colleagues, line management, and key stakeholders are informed of any developments that may impact regulatory success, and provide input to the project team for project planning
- Anticipate risks and be responsible for developing solutions to identified risks and discussing with team, management, and portfolio review committee or other relevant
- Supervise the storage and archiving of regulatory dossiers and approval documents
- Select service providers for regulatory affairs and coordinate closely their activities
- Keep abreast of the evolving regulatory landscape, monitor and anticipate trends that impact both the regulatory and access environments
- Participate in Regulatory Affairs conferences
- Propose and manage the function budget
- Depending on the development of OSE's portfolio, manage an operational regulatory team
- Expertise in immunotherapeutic and biologics in Oncology and I&I, CMC and Companion Diagnostics regulatory aspects will be pluses.

The candidate we are looking for has a 5-year higher education in Science (minimum), ideally a PhD in Pharmacy. He or she has a solid experience in pharmaceutical regulatory affairs (at least 7 years), with a good grasp of regulatory issues in Europe, the United States and other countries. He or she is fluent in English and has excellent communication skills.

The successful candidate also has the following qualities:

- Thoroughness and commitment
- Adaptability and intellectual agility
- Solution Driven
- Structure and organisation
- Ability to take ownership of the company's challenges.

Our commitment

OSE Immunotherapeutics is committed to the equal treatment of all candidates during recruitment procedures, regardless of age, gender or gender expression, ethnic origin, skin colour, nationality, disability, marital status, sexual orientation, pregnancy and maternity, religion or belief, and any other category protected by law.

Protection of personal data

The data collected during the examination of your application is processed by the Human Resources department to enable it to manage the recruitment process for its future employees. It is kept for the time required to complete the recruitment process.

Your file is treated as confidential. The only people with access to the personal data contained in your file are the managers of the departments interested in your application (recruitment officers, managers, etc.).

You have the right to access your personal data. You have the right to rectify and delete this data, as well as the right to object to its processing. If you have any questions about the protection of your data or wish to exercise your rights, you can contact OSE Immunotherapeutics' Data Protection Officer (DPO) at the following address: data-privacy@ose-immuno.com.