Regulatory Affairs Technician

Mission

Responsible for the definition, support and implementation of the regulatory strategy for Advanced Therapy Medicines (MTA) under development by the BST, both own projects and in collaboration with other institutions, in order to facilitate and ensure that their progress is made in accordance with current regulatory requirements.

Main Duties and Responsibilities

• Collaborate in the definition of the regulatory strategy, in accordance with current regulations, of the MTAs developed at the BST (own or in collaboration with other research institutions).

• Coordinate and participate in the preparation, writing and presentation of documents and regulatory reports related to the MTAs.

Specifically:

- ✓ Product in Phase of Investigation (PEI)/Investigational Medicinal Product Dossier (IMPD)
- ✓ Investigator's Brochure (IB)
- ✓ Clinical trial authorization request

• Contact person with the drug regulatory agencies (AEMPS, EMA) in order to coordinate and implement all the necessary interactions for the development of MTAs in accordance with current regulations

• Coordinate, write and manage meetings with drug regulatory agencies related to scientific advice. Specifically:

- ✓ Identify those aspects related to the quality, the non-clinical development or the clinical development of the MTA susceptible to requests for scientific advice
- ✓ Drafting/revision of the corresponding "Briefing Packages" that support scientific advice
- ✓ Manage and participate in scientific advisory meetings

• Manage and maintain the regulatory authorizations related to the MTAs developed by the BST.

• Participate in regulatory inspections/audits related to the MTAs developed by the BST, together with the Quality Assurance manager and other BST professionals.

• Drafting and maintenance of the Standardized Work Procedures associated with the regulatory management of the MTAs at the BST.

• Comply with the functions established by the Prevention, Quality and Environment Manual

• Comply with all those responsibilities and functions inherent in the workplace.

Requirements

Degree or degree in health sciences (Medicine, Pharmacy, Biomedicine, Biology) or similar/equivalent training

Skills

Communication, Conflict Management, Knowledge Management, Change and Innovation Management, Results Orientation, Planning and Organization, Teamwork and Dedication to Service.

Merits to value

- Comprehensive knowledge of current regulatory regulations for medicines.
- One to three years of experience in the pharmaceutical, biotechnology, service companies or research centers as a regulatory affairs technician, preferably with MTA
- Knowledge of common IT tools (word processors, databases, etc.) and specific tools related to MTA regulatory requests (EudraCT, AEMPS "clinical trials" portal, REEC, CTIS, etc. .)
- Advanced English leve

We offer a job with the following characteristics:

• Job position: Regulatory Affairs Technician

• Banc de Sang i Teixits work center located at the Headquarters - Dr. Frederic Duran i Jordà Building (Barcelona)

• Details of the day:

• % Day: 100.00

• Specific Hours: 8:00 a.m. to 5:00 p.m.

• Remuneration: according to current legal regulations

Selection process

Verification of the adequacy of the requirements specified in the call.

Evaluation of knowledge merits and competency tests

Resolution and Communication

Interested people

Interested candidates must send a cover letter, updated CV and at least two reference letters to seleccio@bst.cat specifying the **REF. ID 15955 - Regulatory Affairs Technician**


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