« Regulatory Affairs Director » (M/F)

Bone Therapeutics SA is a biotechnology company specializing in the development of cell therapy products for bone fracture repair and fracture prevention. At the forefront of science and medicine and leader in its field, the Company is developing innovative regenerative products, containing bone-forming cells, using its proprietary stem cell-based technology platform. With its strong portfolio of clinical programs (Phase II and Phase III) and preclinical programs, Bone Therapeutics is organized as a "mini-pharma", with departments for preclinical research, clinical studies, production, quality control, quality assurance, regulation and administration.

To strengthen our growing organization, Bone Therapeutics is looking for a **« Regulatory Affairs Director » (M/F).** You will be in charge of the development, coordination, follow-up and strategic and operational management of all regulatory activities associated with our activities (clinical trials, human biological materials, scientific advice, marketing authorization application, centralized procedures, etc.), at both national and international levels. This position requires collaborating and interacting with the different departments within the Company (preclinical, production, quality assurance, clinical and management).

You will be in charge of:

Regulatory activities:

- Provide regulatory expertise and guidance for new product development and help develop regulatory strategy for EU and US;
- Responsible for Regulatory submissions including preparation and/or review of CTAs/briefing documents, IMPD, IND, clinical protocol, except for CMC matters, for various projects including ATMP;
- Prepare and distribute regulatory agency contact reports and meeting minutes;
- With oversight, conduct QC and QC checks of materials prepared by the regulatory unit, project team or external on regulatory compliance;
- Ensure completeness of regulatory information to be included in clinical trial.gov and EudraCT form with clinical study manager;
- Direct the preparation and submission of regulatory agency applications, reports, or correspondence;

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- Support preparation of tracker in order to define the list of potential issues raised by Agencies during clinical trials and scientific advice to allow to define the optimal strategy by Regulatory lead;
- Develop regulatory strategies and implementation plans for the development as well as preparation and submission of regulatory documents;
- Develop relationships with state or federal environmental regulatory agencies to learn about and analyze the potential impacts on Bone Therapeutics projects and internal policy.

Regulatory team activities:

- Arrange meetings of project teams for regulatory matters except for CMC or regulatory agency;
- Increase knowledge of regulations and guidelines, communicate regulatory information to multiple departments and ensure that information is interpreted correctly;
- Assist with project management, and other tasks as required by regulatory team members;
- Attend regular meeting including project team with all stakeholders and disciplines from R&D and management;
- Prepare Regulatory Risk mitigation for regulatory disciplines except CMC;
- Train staff in regulatory policies or procedures;
- Develop and maintain standard operating procedures or local working practices;
- Establish regulatory priorities or budgets and allocate resources and workloads ;
- Contribute to the development or implementation of business unit strategic and operating plans;
- Monitor regulatory affairs activities to ensure that they are aligned with corporate sustainability or green initiatives;
- Line management with growing of regulatory department;
- Ensure that resources estimate is accurate to allow recruitment in due time.

Expected experience:

- Master/PhD in Biomedical Sciences or Pharmacy or equivalent ;
- Minimum of the 7 years experience in Regulatory Affairs environment ;

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- A knowledge in ATMP regulation is an added value;
- Good knowledge of international guidance and regulatory requirements ;
- Applying domain knowledge: Merely possessing knowledge is not the key. Knowing how to apply domain knowledge in the field of regulatory framework development is very important;
- Project management skills: Product development life cycle in a complex project;
- Understanding of drug development process, quality systems, clinical trials, and scientific issues in cell therapy and other innovative products.

Soft skills:

- Strong interpersonal and communication skills ;
- Excellent verbal and written communication and presentation skills in both English and French;
- Able to work within a small but quickly growing structure ;
- Problem Solving: You should be able to resolve the most complicated problems that may arise in the course of product development ;
- Analytical skills: You should know how to take decisions based on facts and figures rather than on assumptions;
- Well organized ;
- Priority settings ;
- Team player ;
- Able to work in multicultural environment ;
- Flexible ;
- Resistant to stress and changes in strategy ;
- Able to travel based on business needs ;
- Fluent in English (oral and written) Medical writing skills is an asset.

Offer:

- Immediate start ;
- Full-time ;
- Long-term contract (CDI) ;
- Position based in Gosselies (Wallonia).

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This opportunity to join a dynamic quickly growing company sounds appealing to you? You want to be involved in the development of innovative research products with medical applications? Then, do not hesitate further, and send your detailed CV and an application letter to Mrs. Roels: hr@bonetherapeutics.com

Notice to Agency and Search Firm Representatives

Bone Therapeutics is not accepting unsolicited resumes from agencies and/or search firms for this job posting. Resumes submitted to any Bone Therapeutics employee by a third party agency and/or search firm without a valid written & signed search agreement, will become the sole property of Bone Therapeutics. No fee will be paid if a candidate is hired for this position as a result of an unsolicited agency or search firm referral. Thank you.

Si vous publiez vos données personnelles en tant que demandeur d'emploi, vos Données Personnelles seront utilisées pour:

- le recrutement et l'emploi;
- à des fins de référence et de correspondance des profils en vue de pourvoir les postes vacants;
- vous informer des futures opportunités d'emploi.

Veuillez noter que Bone Therapeutics traitera vos données en conformité avec les lois applicables sur les données privées. À moins que vous ne demandiez à le supprimer plus tôt, vos données seront stockées dans notre système de recrutement pour une durée maximale de neuf mois, jusqu'à trois ans si vous avez été invité à un entretien par Bone Therapeutics ou l'une de ses sociétés affiliées. Vos données seront stockées dans notre système de recrutement et pourront être transférées via un système intranet sécurisé, et conformément aux lois applicables sur les données privées, à toute société affiliée à Bone Therapeutics. Si votre demande est acceptée, vos données seront traitées et incluses dans votre dossier d'emploi. Bone Therapeutics peut transmettre vos Données Personnelles à des Tiers se situant hors de l'Europe; toutefois, Bone Therapeutics prendra toutes les mesures nécessaires pour assurer la confidentialité de vos données personnelles et de votre traitement, conformément à la présente politique et aux lois applicables en matière de confidentialité des données. Bone Therapeutics peut également devoir divulguer vos données personnelles si cela est requis par les lois applicables, les ordonnances judiciaires ou la réglementation gouvernementale. Il vous appartient de mettre à jour vos données personnelles contenues dans le système de Bone Therapeutics. Toutefois, Bone Therapeutics peut de temps en temps vous demander de mettre à jour vos données. Vous avez le droit, sans coût, d'accéder, de modifier ou de demander la suppression de vos données à tout moment en nous contactant par e-mail: dataprivacy@bonetherapeutics.com.

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