Bismarckallee 2a / D 79098 Freiburg / Tel. 0761-29615-0 / Fax 0761-29615-25 /
e-mail: info@pp-pharma-planing.de / www.pp-pharma-planing.de

Our client is a Biotech company, founded in 2000 in Heidelberg (German Cancer Research Center, DKFZ). Today, the company has a pipeline with two clinical-stage product candidates. A third clinical-stage product candidate is being developed.
The company's mission is to develop breakthrough cancer therapies. The approach is to direct the immune system to eliminate tumor cells. Its next generation tetravalent, multi-specific antibodies engage two of the most potent cytotoxic cells of the immune defense arsenal (T cells or natural killer (NK) cells) and link them with high affinity and precision to a tumor cell, thus triggering an attack by the immune cell that ultimately results in the destruction of the tumor cell.

To lead the overall regulatory strategy of the company and ensure its operational implementation we are looking for our a client for a

Senior Regulatory Affairs Manager (m/f)

Main responsibilities:

- Full accountability for the preparation and compilation of the Common Technical Document (CTD) for dossier submission according to regulatory requirements of different regions (e.g. EU, USA, Canada, Japan)
- Lead and coordinate the dossier submission process
- Identify the required documentation for submissions based on a deep knowledge / understanding of the respective regulatory environment and negotiate the required documents in accordance with the program timelines
- Review and write high-quality Regulatory Affairs documentation during product development and registration based on agreed regulatory strategies
- Assure technical congruence and regulatory compliance
- Meet agreed timelines and publishing requirements
- Build and maintain a sustained relationship with Regulatory Authorities
- Lead the preparation and conduct of Regulatory Authority meetings in close collaboration with the program team(s)
- Develop regulatory strategies for the submission of new programs as well as provide input on general development concepts
- Prepare responses to health authority questions during development and registration

Profile:

- PhD in natural sciences or equivalent education
- 5 or more years of Regulatory Affairs experience in drug development in the biotechnology or pharmaceutical industry environment
- Excellent understanding of regulatory requirements and guidelines (all Regulatory Modules) for filings worldwide and critical evaluation of emerging requirements and guidelines for new drugs
- Excellent communication and presentation skills
- Potential to take leadership as Head of Regulatory

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Do you feel attracted by this position? We kindly ask you to apply in full confidentiality in English, with resumee and list of key competences.

PP PHARMA PLANING
International Executive Search & Specialist Recruitment Healthcare
Dr. Bergauer + Partner GmbH
Frau Doris Messing, Managing Partner, CMC (BDU)
Bismarckallee 2a D-79098 Freiburg im Breisgau
Telefon: +49 761 2 9615-0 oder Direktwahl: +49 761 2 96 15-15
Email: d.messing@pp-pharma-planing.de
www.pp-pharma-planing.de www.pharma-career-box.com

Your application will be treated with strict confidentiality.