CMC PROJECT DIRECTOR LARGE MOLECULES AND/OR CELL & GENE THERAPIES

2 Bridge company

2 Bridge is a Belgian-based consultancy company that provides advice and support on all key disciplines of healthcare product development (discovery, pre-clinical, clinical and product development, registration and life-cycle management). We work globally with startups, biotech, medtech, pharma, and investors. 2 Bridge typically operates via flexible and cross-functional teams, aligned to the project need. Our broad and multidisciplinary expertise allows to address the most complex and challenging tasks during development. For more information, please visit: www.2Bridge.be.

Job description

Are you interested to make a difference and contribute to realize our growth plans? We are looking for an experienced CM&C project director with experience in early phase large molecule development (proteins/antibodies) and/or cell & gene therapies to strengthen the CM&C team of 2 Bridge. You will work in a non-hierarchical environment that highly values teamwork and where you will have the freedom to shape your role. You will report to and work closely with the Head of CM&C of 2 Bridge.

The required expertise for the CM&C project director includes:

- Technical knowledge of biologics up and downstream process development and/or GMP production.
- Ability to create and implement biological and/or ATMP development strategies.
- Ability to develop and implement a regulatory strategy for biologics and/or cell & gene therapy products and authoring of regulatory documents.
- Ability to select and work with C(D)MOs for project execution.

Projects within the CM&C group can vary but usually fall within the following scope:

- Act as CM&C project lead in drug development team for large molecules/ATMP projects and support development projects within Chemistry and/or Pharmaceutical product development.
- Preparation of Scientific and Technical documentation within the area of CM&C.
- Preparation of Module 3 registration dossiers based on Chemistry and Pharmaceutical source documentation. Dossiers may be supportive of clinical trials (e.g. IMPD/IND), product registrations (e.g. MAA/BLA) or life-cycle management support projects (e.g. post-approval variations).
- Preparation of risk management strategies.
- Project management within commercial GMP environment.

Desired profile

- MSc/PhD in Bio-medical sciences, Bio-engineering, Biology, Industrial Pharmacy, Chemistry, or equivalent.
- At least 5-10 years of experience within CM&C product development, registration and/or within a GMP production environment of large molecules and or cell/gene therapies.
- Proven track record of successful authoring and contribution to delivering CMC sections of investigational medicinal products for new biological and/or cell and gene therapy compounds.
- Experience in physicochemical analysis of biologicals and knowledge of different analytical techniques used for release and stability testing.

- Knowledge and interest in pharmaceutical legislation (ICH/GMP/ATMP,…).
- Team-player with the ability to work independently.
  Analytical, pro-active, flexible and with an eye for detail.
- Interest in the overall process of health care development is a must.
- Interested in working in a multidisciplinary team.
- Enthusiasm with a keen interest to learn new things.
- Good communication skills.
- Fluency in English is a must.

What we offer

- You will be contributing to our ambitious growth plans.
- You will be part of an enthusiastic team where human interactions, teamwork and bringing together different perspectives are highly valued.
- You will work in a small, but growing organization with an informal and non-hierarchical way of working.

How to apply

CV, motivation letter where you:

1. Introduce yourself
2. Explain why you are interested in the job
3. Outline why you think you are the right candidate

Interested? Please send your motivation letter and CV to info@2bridge.be before April 15, 2021.