CMC DIRECTOR EARLY DEVELOPMENT

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

We are looking for a CM&C Director with experience in early development of small and/or large molecules and/or ATMPs to strengthen the CM&C team of 2 Bridge.

The CM&C Director will demonstrate leadership regarding the development and execution of CMC development programs.

As CMC representative in the Development Teams of our clients, you will supervise and manage the CMC programs covering oversight on Drug Substance, Drug Product and Clinical Supply Management.

Key activities will include:

- Lead multiple cross-functional CM&C teams end-to-end
- Oversight on selection and management of GMP C(D)MOs
- Oversight on authoring of regulatory CM&C documentation
- Development of CM&C strategy in line with overall program development strategy;
- Management and mitigation of CM&C risks;
- Management of CM&C budget and timelines;
- Oversight of delivery of clinical and launch drug supplies in accordance with development plans;

You will work in a non-hierarchical environment that highly values teamwork and where you will have the freedom to shape your role.

Qualifications/desired profile

- MSc/PhD in Bio-medical sciences, Bio-engineering, Biology, Industrial Pharmacy, Chemistry, or equivalent.
- At least 10 years' experience within CM&C drug development, registration or GMP production.
- Experience with chemical/biological process development and/or formulation development.
- Experience in physico-chemical characterisation of biologicals/chemicals and knowledge of different analytical techniques used for release and stability testing.
- Experience with preparation of Scientific, Technical and Regulatory documentation within the area of CM&C.
- Knowledge and/or interest in pharmaceutical legislation (ICH/GMP,…).

- 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.
- Good communication skills.
- Fluency in English (especially in writing) is a must.
- App 20% Travelling expected with focus on Europe

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 hr@2bridge.be.