CMC PROJECT MANAGER BIOLOGICAL DRUGS

As a member of our team, you will play a key role in the development of innovative therapeutic solutions for European biotech companies.

Our goal is to reduce human suffering by accelerating patient access to life-changing therapies.

3BIOTECH provides innovative solutions and resources with extensive experience to support our clients throughout the CMC and other drug development processes. We operate at both the strategic and operational levels to secure the three pillars of drug development: safety, efficacy and manufacturability.

Contact us if you would like to help create hope for a healthy future in the lives of many people.

Your missions:

- For our clients, implement and monitor detailed execution plans and long term biologic drug development plans in the various areas of CMC and technical operations, including analytical development, process development, clinical batch production, supply chain and logistics.
- Anticipate technical and regulatory issues and recommend measures to mitigate emerging risks.
- Prepare for prospects and clients, with the support of other CMC experts, proposals and formalizations of services offered by 3Biotech, providing advisory support on CMC and regulatory aspects.
- Independently manage third party projects for the development and manufacturing of therapeutic proteins, at the clinical stage phase 1 to 3.
  - Organization and follow-up of meetings
  - Reporting
  - Planning (creation and follow-up of the Gantt Chart)
  - Budget follow-up
  - Quality
  - Regulatory
- Coordinate and monitor project activities with the various CDMOs.
  - CDMO services include process transfer, cell line and process development, scale-up, cGMP manufacturing, viral safety studies, fill and finish, quality control, ...
- Manage / write the documentation of the CMC regulatory strategy (protocols, reports, Master Batch Records, Quality agreement...),
- Identify/ contact/ and qualify service providers (CRO/ CDMO)

FROM SCIENCE TO FIRST IN HUMAN
3BIOTECH

Your Profile :

With a scientific background (Pharmacy, Master of Science in Biology, Ph.D.) with a specialization in BioProduction, you have at least 5 years of experience in the development and manufacturing of biological molecules (mAbs, ADC, Therapeutic proteins) for the Biotech/ pharmaceutical industry. You have significant experience in managing complex biological drug development projects. You have a good knowledge of GMP and of the regulatory environment related to the production of clinical batches of biological molecules (ICH, FDA and EMA guidelines).

- Excellent interpersonal skills, good communicator, customer focus
- Recognized leadership
- Organization and rigor
- Sense of detail
- Fluent English
- French speaking
- Mastery of cGMP and EMA/FDA regulations
- A strong interest in writing
- Mastery of Microsoft Project

Working Conditions:

Freelance

100% Remote work

Travel to client sites and CDMOs (Europe and USA)

Contact : job@3biotech.eu

Contractor

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Visit our web site: www.3Biotech.com