

## **Manager/ Director of CMC, Large Molecule**

### **Responsibility**

- 1) Create and implement the CMC development strategy through early development to production launch, and to post life cycle management.
- 2) Create and execute the CMC budget and timelines.
- 3) Oversee scientific, planning and execution of all aspects of biologic product CMC development, including but not limited to process development of drug substance and product, analytical method development, and establishment of spec., and manufacture of clinical trial material etc.
- 4) Manage project internal CMC team, CMO and CRO, and communicate with project team and management team effectively to ensure meet development timeline within budget.
- 5) Ensure the delivery of clinical and launch drug supplies in accordance with development plans.
- 6) Author, revise and review CMC regulatory documents and responses.
- 7) Ensure compliance of current GMP's, regulation and guidance of FDA and CFDA of all CMC related aspects.
- 8) Demonstrate behaviors consistent with the current Leadership Imperatives and cooperate culture.
- 9) Mentoring and coaching CMC Team Members to improve their skills and contributions to the organization in collaboration with line management.

### **Qualifications**

- 1) A Master's degree in life science or related field with at least 5 years of experience in pharmaceutical, biotechnology or a related industry OR a Ph.D. with at least 3 years of experience in pharmaceutical, biotechnology or a related industry is required
- 2) Large Molecule CMC experience is required; Experience in setting development and regulatory strategies for products in development is preferred.
- 3) Demonstrated capability to manage multiple projects.
- 4) Proficient in project and personnel management, excellent organizational skills and the ability to work on multiple projects with tight deadlines.
- 5) Excellent oral and written communication skills, auditing skills, and proven ability to work autonomously and manage effectively in a matrix environment.

### **Location**

Nanjing, China

Frontier Biotechnologies Inc.

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