**ZhenGe Biotech**

Established in 2017, Shanghai ZhenGe Biotechnology Co., Ltd. (ZhenGe Biotech) is a premier high-tech enterprise registered in the China Pilot Free Trade Zone (Shanghai). ZhenGe Biotech has Development Centers in Shanghai and Innovation Center in Maryland USA, as well as cGMP and commercial manufacturing sites in Shanghai. The core business of ZhenGe Biotech is to provide CDMO services to both biotech and pharmaceutical companies.

Our integrated CDMO services starting from pre-clinical research to commercial manufacturing, as well as customized cell culture media development, enable and accelerate the R&D and commercialization of innovative biologics for biotech and pharmaceutical companies worldwide.

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**Position**: CMC Head

**Report line**: CEO

**Location**: Shanghai, China

**Responsibilities:**

* Lead and build Process Development groups for small-scale, pilot-scale, scale-up, tech transfer, process characterization activities for biologics dev projects. Oversee this process development team management, project delivery and new technology development.
* Serve as CMC leader and alliance key contact for critical projects and clients. Coordinate efforts and facilitate communication to ensure alignment between ZhenGe Biotech and clients. Provide leadership in development and manufacturing alliance management, product development and manufacturing strategy for selected projects.
* Represent process dev functions in the CMC management review committee, tech transfer oversight committee (TTOC), project progress review committee. Collaborate with CMC functional areas to ensure successful execution of various CMC projects, and delivery of results on time and within budget.
* Recruit, train and retain high performance teams to ensure best quality services and leadership in process development functions worldwide.
* Develop and manage operational budgets and supervise teams to ensure IP and EHS compliance.
* Assist or lead (if necessary) in BD efforts, especially on areas related to process development. Enhance current service offering and develop new clients.
* Establish solid documentation systems within the organization, to record and document all studies to support regulatory filings and inspections, as well as business development and financing projects.
* Adopt and/or develop new technologies for improvement of quality, speed, and/or cost effectiveness.
* Other projects and tasks to be assigned.

**Qualifications**

* A Ph.D. degree in biological sciences, biochemistry, or bioengineering with at least 15+ years or MS with 20+ years of related technical and managerial experiences in the biotech or biopharma industry.
* Excellent communication skills and be bilingual for both English and Mandarin Chinese (proficient in both written and verbal aspects).
* Strong expertise in biologics process and product development, one and/or many aspects of CMC activities, with proven track record in international biologics development community and accomplishments
* Be familiar with various FDA and ICH, NMPA guidelines with regard to the development of biologics for therapeutic indications. Experience in cGMP manufacturing of biologics and/or technical support, cross-functional biological CMC support and support for IND or BLA filing preferred
* Be goal-oriented and resourceful, capable of serving as a role model of the corporate culture emphasizing on quality, speed and innovation.
* Proven track record in building, leading and managing a large group, including personnel management, budget planning/management, resource management etc.

*Company provides competitive compensation package, including stock options.*

*For more information, please visit* [*https://zgbiotech.com/en/*](https://zgbiotech.com/en/)*, or contact us at* [*hr@zgbiotech.com*](mailto:hr@zgbiotech.com)

*Date: April 10, 2022*