**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**: Manufacturing Head

**Report line**: CEO

**Location**: Shanghai, China

**Responsibilities:**

* Supports to establish GMP manufacturing facility consisting of design, construction, validation of facility, and GMP operation system.
* Oversees the preparation and management of complex GMP manufacturing facility development plans, budgets, and long-range planning.
* Oversee daily operations in a multi-product GMP facility, manage and control production schedule; Ensures all manufacturing and process validation activities relating to drug substance and drug product are completed in accordance with quality and regulatory expectations to support relevant global regulatory submissions.
* Collaborate with QC&QA groups to ensure GMP compliance, manage deviation investigation and CAPA implementation, and support client auditing and agency inspections.
* Recruit, retain and develop talents, and provide leadership for a high performing team to meet our overall business objectives.
* Perform other duties as assigned based on business needs.

**Qualifications**

* A master or bachelor degree in biological science, chemistry or a related discipline with at least 7 years of industry experience or a bachelor’s degree with 10 years of industry experience.
* Technical knowledge and hands-on experience in GMP manufacturing of monoclonal antibodies or other protein therapeutics.
* Experience in GMP facility design and construction, equipment selection, qualification and validation.
* Experience in large-scale manufacturing operations with GMP requirements.
* Experience in CMC regulatory affairs for US FDA, cFDA and EMA is a plus.
* Direct management experience with successful track record of building, coaching and mentoring a high-performing team.
* Strong interpersonal, verbal, and written communication skills.
* Bi-lingual, fluent in Chinese and English reading, writing and conversation.

*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*