TITLE: Vice President, Quality Management

LOCATION: Tianjin, China

REQ#: TJ002

Company Overview: Jecho Biopharmaceuticals Co., Ltd. is a biopharmaceutical company manufacturing innovative therapeutic biologics to address a broad range of infectious diseases as well as treatment of cancer. The company headquarter is located in Tianjin China.

Responsibilities:

- Take leadership on quality management of the company
- Responsible for setting up quality management system for the Tianjin facility. Responsible for implementation of quality assurances, final product releasing, from pre-clinical, clinical manufacturing, to commercial manufacturing and quality control.
- Responsible for all quality aspects on GMP facility including engineering designing, utility installation and qualification, facility commissioning, utility and production equipment validation, production process and analytical method validation.
- Responsible for quality operation. To solve comprehensive quality problems such as OOS, change control, inspection by regulatory agents. Arrange resources in aligning with company's priority.
- Organize a team of up to 100 technical staffs in several departments with responsibility of budgeting, timeline, senior level personnel training and evaluation.
- Provide updated regulatory guidance in the quality management to the executive committee and report to the CEO.
- Coordinate activities among departments on business operations, technical operations, regulatory affair, clinical management, GMP manufacturing, and engineering department.
- Organize company quality board meetings, coordinate all product quality and product safety related activities with all departments.
- Coordinate regulatory affair activities for DMF, IND and BLA/NDA submission.

Minimum Requirements:

- Ph.D. in bio-sciences, or Master in regulatory affair or related field. Minimum 15 years post-graduate degree biopharmaceutical experiences with ~8 years managerial responsibilities at a level of director of a department.
- Require extensive knowledge in microbial fermentation, mammalian cell culture, protein purification, product formulation, viral vector production and analytical method development and qualification. Large scale process experiences with GMP operation background.
- Extensive management experiences. Strong leadership, organization ability, Extensive GMP experiences. Professional communication skill with regulatory agents including FDA, EMA, or CFDA.
- Demonstrated track record in biopharmaceutical product development through IND submission and clinical manufacturing. BLA or NDA experiences are plus.

- Works within approved budget; Develops and implements cost saving measures. Contributes to potential profits and revenue; Conserves organizational resources.
- The candidate must be excellent with bilingual (English and Chinese) communication, professional writing and interpersonal skills.