Jecho Laboratories Job Opportunity

TITLE: Director of Global Regulatory Affairs

REQ#: 23-006

The position is responsible for providing regulatory guidance and preparing submission for the approval of biologic products and/or biosimilars. The Director will ensure compliance with current regulations, guidelines and policies including USA, China and other international regions. The Director is expected to lead a RA team in Jecho Biopharmaceutical Co. Ltd. located in China with flexible remote working schedule.

Responsibilities:

- Strategically plan and lead the regulatory submissions (IND/BLA/NDA) to regulatory agencies including FDA, EMA and NMPA.
- Oversee industry-specific practices and ensure the organization complies with applicable government and company regulations.
- Establish and implement regulatory policies and strategies within the company.
- Recruit, train and support RA staff in regulatory filing.
- Interpret existing and new regulatory requirements as they relate to company products and procedures, clinical studies, testing or records keeping.
- Act as a liaison with regulatory authorities.
- Review, analyze and provide feedback to technical data generated by Development and Testing, as well as manufacturing changes.
- Work closely with QA and other Departments on CMC strategies.
- Support clinical development in dealing with regulatory agencies.
- Provide strategic input to the company's product development and commercialization.

Minimum Requirements:

- A Ph.D. or master's degree in scientific discipline is required, including but not limited to chemistry, biochemistry, microbiology, pharmacology.
- Candidates holding Ph.D. degree must have ten (10) years industrial experience with a minimum of five (5) years of RA practice and 5 years of management experience. Candidates holding a master's degree must have fifteen (15) years of industrial experience with a minimum of eight (8) years regulatory practice and 5 years of management experience. Experience in research and development, quality, lab sciences, engineering, clinical research and pharmacy is a plus.
- A track record of regulatory approvals and a demonstrated history of success in working with regulatory authorities.
- Experience in supporting CMC and Clinical development in the biopharmaceutical industry.
- Exceptional analytical and problem-solving skills, along with extensive medical, scientific and/or technical knowledge pertaining to pharmaceutical development with good judgment.
- Exceptional written and verbal communication skills including English and Chinese.
- Outstanding interpersonal skills and ability to work cross-functionally.
- This position is predominantly onsite at our office in Maryland and may involve remote

work to support other sites overseas. Occasionally, this role may require international travel to other company sites. The ability and willingness to travel internationally is a key aspect of this position.

Compensation

- Jecho offers a competitive salary and excellent benefits package, including but not limited to health insurance, dental/vision insurance, short-term and long-term disability insurance, and 401(k) retirement plan.

Disclaimer

- Jecho is an equal opportunity employer. We celebrate diversity and are committed to creating an inclusive environment for all employees.
- This job description may not be inclusive of all assigned duties, responsibilities, or aspects of the job described, and the employee may be required to perform additional functions.
- The job description is subject to change by the employer as the organizational needs and requirements of the job change.