

JD – Director of Regulatory Affairs

The position is accountable for biopharmaceutical products of various stages in Jecho Biopharmaceutical Co. Ltd... This includes remain current with regard to food and drug laws, regulations, guidelines, policy and pharmaceutical issues and anticipate changes in the US, China and international regions which may impact Jecho and recommend appropriate action to protect Company's interests. The incumbent is expected to lead by influence within teams to ensure alignment of the agreed upon IND/NDA filing strategy.

Responsibilities:

- Strategically planning in IND filling, NDA strategy interacting with regulatory agents including FDA, EMA and CFDA;
- Supporting QA and Other Department for GMP auditing;
- Supporting CMC team for product development and manufacturing;
- Supporting clinical development in dealing with regulatory agents;

Minimum Requirements:

- Ph.D. from an accredited institute or equivalent training in related field with six (6) years' experience OR Master Degree from an accredited institute with eight (8) years' experience OR Bachelor degree with ten (10) years of technical experience in chemical disciplines within chemical research, analytical research, quality control, production formulation development or product development
- Record of accomplishment of regulatory approvals and demonstrated success in working with regulatory authorities
- Experienced in supporting in CMC staged and Clinical development in biopharmaceutical industry
- Exceptional analytical and problem solving skills; extensive medical, scientific and /or technical knowledge pertaining to pharmaceutical development or operations good judgment; exceptional interpersonal skills with emphasis on diplomacy, negotiation and ability to work in a team-based setting; effective communication skills; flexibility; self-confidence, achievement oriented with appropriate concern for quality are highly desirable soft skills
- Exceptional written and verbal communication skills including ability to acquire buy-inbehaviour from stakeholders (internal and external)
- Outstanding inter-personal skill