## Job Description - Clinical Development Director

Basic qualifications:
• Advanced degree in life sciences or allied field (PhD, PharmD, DDS, MPH, MS)
• 10+ years of experience in the pharmaceutical industry
• Experience in clinical program management, clinical development strategy and study design/trial management and reporting is a must
• Must have demonstrated experience with major regulatory submissions (NDA, BLA, MAA)
• Proven track record in leading multi-functional teams and ability to be an effective leader of global teams.

Preferred qualifications:
• Rare diseases experience is highly preferred
• Demonstrated scientific credibility, and ability to input and influence projects through scientific and operational expertise; proven ability to interpret complex clinical data
• Demonstrated excellence in stakeholder management. This role requires strategic thinking, solution-finding, and agility as evidenced by flexibility, adaptability to change, curiosity, and ability to lead and drive change.
• Excellent verbal and written communication skills are a must. Demonstrated skills in networking internally and externally and communicating in situations requiring special tact and diplomacy
• Possesses sound operational knowledge of the pharmaceutical industry and broader R&D processes including scientific activity impacting project work.
• Possesses detailed knowledge of Good Clinical Practice (GCP) and other regulations governing clinical research
• Demonstrates a proven ability to both independently complete and lead peers in completion in components of complex plans, i.e. draft protocols, selecting appropriate methodologies, measures, analytical plans and evaluation tools.

Details:
Responsible for oversight of development and execution of studies linked to worldwide clinical development plans for assigned programs in portfolio. Responsible for integrating clinical development objectives with global considerations into strategic business decisions. Ensures clinical, operational and medical governance excellence across all clinical development projects for assigned programs.

Key Accountabilities:
• Lead the delivery of clinical development activities for a clinical stage program in the Rare Diseases Unit and ensure consistency with clinical development strategy for regulatory approvals, reimbursable medicines, and successful lifecycle management.
• Lead multi-disciplinary clinical matrix team and major contributor to integrated clinical development strategy and Clinical Development Plans.
• Contribute to the medicine development strategy
• Assures clinical studies are conducted effectively in partnership with Local Operating Company, alliance partners and Clinical Operations colleagues and CRO as appropriate.
• Lead clinical study teams in development and conduct of clinical studies.
• Lead authoring of study protocols, CRF's and contribute to development of analytical plans through discussion with matrix team members. Reviews standard format data displays in protocols and CRF's to

assure consistency in data capture. Accountable for authoring of clinical study reports and Investigator Brochures. Assist in producing materials for Investigator meetings.
• Participate in data review discussions and contribute to data interpretation
• Lead the preparation of regulatory briefing documents and clinical elements of regulatory submission documents (IND, CTA, NDA, BLA, MAA)
• Assist with the writing of manuscripts and development of abstracts and presentation materials. This role may also contribute to individual studies and project level activities, as appropriate. This includes responsibility and accountability for the coordination, execution and delivery of one or more portfolios of studies and programs.