At Astellas, we believe that nurturing exceptional relationships with our employees delivers exceptional business results.

Everyone at Astellas has a responsibility for creating a brighter future for patients around the world. From the first moment, Astellas will inspire you to put this ethos into practice – with a positive, agile company culture and with well-defined ethical principles, values, and systems.

Everything we do is led by our company values of integrity, being patient centric, taking ownership, delivering results, and communicating openly. These values are essential to Astellas' relationship with its employees and now is an exciting time to join us as we continue to evolve as a cutting-edge, value driven life sciences innovator.

Position: Clinical Trial Manager II
Department: Development Clinical Department
Line Manager: Clinical Operation Lead
Location: Shanghai

Purpose and Scope

- The position is to manage new clinical study day to day in compliance with GCP/ICH-guidelines and other regulatory requirements.
- To insure the clinical study conducted in a high speed, good quality and insure budget managed appropriately.

Responsibilities and Accountabilities

- Clinical study management. Manage and lead the day-to-day operations of assigned studies to ensure completion per established project team goals and objectives in compliance with applicable GCP/ICH guidelines and other regulatory requirements.
- Lead development of study plans and system set-up; participate in preparation and ensure operational excellence of protocol, CRF, CSR and other key study team deliverables
- Participate in process improvement and quality-related initiatives associated with study execution

and deliverables; participate in establishment of best-in-class processes and standards for study conduct

Required Qualifications

Minimum of 5 years working experience in the pharmaceutical industry or healthcare discipline including 3 years in a Clinical Research Associate (or equivalent/parallel) role and 2 years in project management

- Must have strong knowledge of ICH/GCP guidelines and regulatory requirements.
- Must have strong knowledge of protocol and clinical drug development processes, clinical study design, study planning and management, and monitoring.
- Requires proven project management skills and study leadership ability.
- Must have excellent interpersonal, written and verbal communication skills, administrative skills and computer ability.
- Fluent in English. Moderate (25%) travel required.

Preferred Qualifications

- CRA management experiences in MNC