开发创新疗法是科学领域中最具挑战性、最重要和最有个人价值的领域之一。在我们追求将创新科学转化为患者价值的过程中，成为安斯泰来的一员是一个令人兴奋的时刻！我们是一家拥有独特的合作和以患者为中心的文化的公司。

现对以下职位进行公开招聘，欢迎公司符合条件的同事投递简历或推荐外部候选人。

职位：临床质量与合规经理

部门：开发本部

直线经理：临床质量与合规总监

工作地点：北京

Job purpose:

Ensure clinical trials are conducted according to GCP requirement and global SOPs, and to ensure the quality of conduction.

Maintain the quality process (e.g., develop SOP, implement quality control scheme) to help identify any abnormalities / inconsistencies in clinical trials in accordance with Astellas quality system.

Responsibilities and Accountabilities:

Quality control of clinical trial

•Coordinate communication with global quality management team, develop and maintain clinical trial quality control system in line with global new standard and procedure, such as study risk-based monitoring.

•Review clinical study documents and conduct co-monitoring according to company requirement.

•Maintain verification process that will allow identification of abnormalities / inconsistencies with guidance of senior members.

SOP development /maintenance

•Join global SOPs development discussion, support the harmonization of local SOPs with global SOPs, ensure local standards and procedures are consolidated with global SOPs.

•Maintain SOP according to related laws, regulations and company requirement.

Training of China Development / CRO CRAs and relevant members.

•Support the maintaining of training system, provide training to new and existing staff to ensure their qualification.

•Support the training based on the inspection / audit results.

•Provide training according to GCP and company policy.

•Provide training of Chinese clinical trials related regulations

Supports of inspection/audit conducted by health

•Take note to new local regulations and industry standards, such as new GCP, self-inspection requirement etc., communicate with global team and industry organizations to assess the impact to clinical operation.

authority/internal auditor

•Support and ensure inspection/audit readiness, appropriate conduct and follow up, serve as the primary liaison with CQA/inspectors to control the activities during inspection/audit.

•Support the audit with China Development members based on internal CQA/health authority request.

•Support document preparation for Audit.

•Follow up CAPA and support the CAPA discussion

Required Qualifications:

Education

•Master’s/Bachelor’s degree in Medicine, Pharmacy, or related pharmaceutical sciences

Skills

•Demonstrated communication, negotiation/influencing, and social skills with a sense of diplomacy, relating to peers.

•Very good active and passive skills in English, leading and attending meetings, presenting and training.

•Working knowledge of China drug development processes.

•Understanding the impact of regulatory requirements and guidance / internal SOPs / PM concepts.

•Works effectively under pressure, accurate and patient.

•Proficient in utilizing and creating outputs using relevant software. Easily adapts to change

Experience

•5 years or above experiences in study and project management

•3 years and above quality management experiences

•Medical or pharmaceutical knowledge and background

•Teamwork, training arrangement and necessary computer skills.

简历接收邮箱: ACN_HR5@astellas.com (邮件主题：应聘岗位-姓名-地区)