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。

Position：Medical Lead

Department：Development Division-Development Medical Dept.

Line Manager：Head of Development Medical Dept.

Location：Beijing/Shanghai

Job purpose

Provide medical & scientific inputs to the current/new drug development strategy, CDP, protocol and CSR. Supervise junior medical science manager. Working as medical lead by Therapeutic Area. Take on new or early stage projects and work on China development strategy. Bring more projects to China if feasible. Take on other projects when people turnover.

Responsibilities and Accountabilities:

1.People management

Working as TA lead by medical, recruit medical manager, coach and supervise them, support Department head to build up good team culture.

2.Be expert on the related therapeutic areas of the new pipeline for ACN and headquarter

- Acknowledging the guideline, academic progress and trends of the related therapeutic area, reading related reference/documents，attending academic conference
- Reading internal data, grasp the pipeline information
- Effective communication with KOL, understanding Chinese clinical practice and clinical requirements
- Discussing and drafting CDP of new pipeline

3.Reviewing/Composing clinical study protocol based on development strategy of headquarter and requirements of Chinese registration and clinical practice

- Closely consulting with headquarter, acknowledging the development strategy of headquarter
- Understanding the details of the protocol, confirming reasonable protocol design after communicating with development department (Development Regulatory Affairs, Development Clinical Department, Data Management and Statistician, Development Strategy & Management Manager), PV & QA Department, RA & Supply & Sales management Department, external experts (Clinical Experts, Statisticians, Pharmaceutical Experts) and CDE reviewers
- Working closely with project team members, draft review process and timeline of the protocol
- Reviewing/Composing clinical study protocol

4.Medical monitoring and giving scientific medical support for ongoing clinical studies

- Composing and executing medical monitor plan with discussing among project members based on project requirement
- Familiar with clinical study process, conducting regular medical review on clinical data cooperating with project members
- Solving medical questions of the protocol (e.g. medicine background, inclusion/exclusion criteria, combination medication, dosage adjustment of the study drug and discontinuation criteria et al.)
- Working closely with project team members, discussing and reviewing clinical study related documents and timeline

5.Reviewing and composing CSR and giving medical support for disclosure and publication of the clinical study results

- Familiar with the requirement of the clinical CSR, Scientific analyzing and discussing for the clinical data, reviewing/composing clinical CSR
- Working closely with project team members, discussing and drafting review process and timeline of the clinical CSR
- Giving medical support and comments to the disclosure and publication of the clinical study data

6.Supportive for IND and NDA

- Drafting CDP and giving medical support with discussing among project members for the submitting and approval of the IND and NDA
- Working closely with Development Regulatory Affairs, answering medical questions from CDE reviewers, and preparing medical documents and solving medical issues for the CDE consult meeting

7.Others

Based on the work arrangement

Preferred Qualifications:

Education:

Master’s degree in Medicine or higher.

Knowledge: ICH/Chinese GCP

Compliance and Pharmacovigilance

Pharmaceutical industry environment

Clinical development process

Skills

Fluency in English

Excellent in oral presentation both in English and Chinese

Be good at communication and coaching

Excellent negotiation skill

Experience

Training/experience of Medical Monitor or Project Physician in clinical development in the pharmaceutical industry or CRO, people management experience.

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