

内部申请&内部推荐职位通知

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，成为阿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，欢迎符合条件的同事投递简历或推荐外部候选人。

职位：Drug Safety Associate

部门：PV Affiliate Management Dept.

直线经理：PV Team Lead, Greater China

工作地点：Beijing

Responsibilities and Accountabilities:

1、Individual Case Safety Report (ICSR) Management:

- Receive, triage and process initial and follow up adverse event reports from multiple sources (clinical trials, post-marketing, literature, regulatory authorities, etc.)
- Perform quality review of cases for completeness, consistency, and compliance.
- Ensure timely submission to PV Headquarter and Competent Authorities
- Conduct data entry in safety database.
- Perform reconciliation activities.
- Perform filing and archiving activities.

2、Establishment and enhancement of the ICSR management procedures:

- Support the optimization of ICSR management initiatives.
- Collaborate with vendor and Headquarter functions to ensure quality and compliance

and drive process efficiency.

- Conduct E2B(R3) and gateway management and transmission issue solutions.

3、Manage or support other affiliate PV activities including but not limited to:

- Self-assessment, audit, and inspection
- Aggregate reporting
- Business partner and PV agreement management
- Training
- Quality document management

Preferred Qualifications:

- 1、 Global database management experiences
- 2、 Project management experiences
- 3、 Vendor management experiences

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