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: Product Safety Officer - China
Department: Global Medical Safety
Line Manager: China Medical Safety Team Lead
Location: Beijing

Purpose and Scope

This position is to fulfil execution of medical safety tasks and activities in China including supporting IND and NDA phase and post-marketing phase.

Responsibilities and Accountabilities

- Responsible for supporting the Global MS or China MS Team Lead with regards to the design and successful implementation of medical safety strategies for drug products within the China MS, by authoring and reviewing medical-scientific reports, safety analyses and evaluations and ensuring cross-functional implementation and follow-up with the appropriate stakeholders in and outside China MS and the PV organization.
- Responsible and accountable for conducting medical safety activities including supporting IND/NDA submission activities in leading LRMP development in close collaboration and communication with relevant stakeholders including Global Safety Officer (GSO), Risk

Management (RM) and Astellas China Investment (ACI) clinical project team. Additional responsibilities and accountabilities include review of clinical safety related dossier, maintaining/updating local risk management plan for marketed products in China, Chinese case review for Astellas marketed products in China, developing aggregate safety report for IDL (imported drug licence) renewal etc.

Required Qualifications

- Master's degree in clinical medicine or clinical pharmacology required.

Preferred Qualifications

- Advanced degree in clinical medicine strongly preferred, or scientific, health-related field.
- Minimum of 2 years of experience in the pharmaceutical industry and 1 year of clinical experience preferred.
- Direct exposure to pharmacovigilance functions, additional regulatory and/or clinical development experience is a plus.
- Understanding of safety regulations for both marketed and investigational products, and knowledge of regional and global authority requirements, including ICH, and other applicable requirements, able to influence decisions relating to patient safety and assessment of benefit-risk.
- Sound medical scientific knowledge to evaluate and interpret clinical and scientific data and to communicate with both internal and external stakeholders.
- Specific working knowledge and experience in medical safety functions, including risk, signal management and periodic reports.
- Excellent communication and presentation skills in English (both written and spoken)