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: Lead, China QA, Affiliate and Supply Chain QA
Department: Affiliate and Supply Chain QA
Line Manager: Head of East Asia QA
Location: Beijing/ Shanghai

Purpose and Scope

Responsible for leading and managing Affiliate Quality Assurance activities in China to ensure compliance with local regulations and Astellas global quality standards across wholesaler and MAH DRE operations.

Responsible for Acting as the primary quality point of contact, driving quality strategy, governance, and collaboration with internal and external stakeholders. Ensure an effective, compliant, and independent Quality Management System is established and maintained to safeguard product quality and patient safety.

Responsibilities and Accountabilities

QA Leadership, Strategy & Governance

- Lead and manage Affiliate Quality Assurance activities in China, acting as the primary point of contact for all quality-related matters

- Provide strategic QA leadership and direction to the Affiliate QA organization
- Ensure independence in QA decision-making within the Affiliate
- Ensure alignment with global QA governance, policies, and corporate quality standards
- Contribute to the development and execution of Global, Regional, and Local QA strategies and objectives
- Drive implementation of the Affiliate annual action plans align with global objectives
- Promote continuous improvement, risk mitigation initiatives, and quality culture within the Affiliate
- Participates in Astellas Quality meetings (local, regional and global) and communicates with appropriate QA personnel or key stakeholders regarding any product or compliance related risks

Quality Management System & Compliance

- Establish, implement, and maintain an effective and compliant Quality Management System
- Ensure alignment of local procedures with Global Policies and SOPs
- Ensure QMS is fit-for-purpose for GDP/GSP/GMP and oversea MAH Domestic Responsibility Entity (MAH DRE) responsibilities as the quality responsible person in legal entity.
- Lead management review process and ensure effectiveness of the QMS
- Manage the QMS as a responsible person in a legal entity in accordance with the local requirements
- Ensure all activities related to 3PL, Business Distribution Partner (BP), wholesaler and MAH DRE responsibilities comply with local regulations and Astellas requirements
- Oversee nonconformance, complaint, CAPA, change control, recall, and product quality review processes
- Ensure computerized systems used for GMP/GDP/GSP activities are appropriately validated
- Ensure inspection readiness and lead preparation, hosting, and response to regulatory inspections and internal audits， including coordination of Product Quality and GSP/GDP/MAH DRE.
- Support the inspection for the oversea MAH or manufacturing site. Support the inspection for local MAH.
- Ensure proper documentation management and audit-ready status of QA records

QA Operations, Risk Management & Technical Oversight

- Act as Qualified Person, GDP releasing to the Chinese Market
- Ensure supplier, customer, and third-party qualification, oversight, and audit programs are established and maintained

- Establish and maintain a Quality Risk Management process in line with global standards
- Ensure appropriate assessment and escalation of Significant Quality Issues (SQIs)
- Ensure decisions on critical quality matters are aligned with Sub-Region Lead and QA governance structures
- Support the vendor to import cells, reference standards etc. and purchase reagents and consumables for port QC testing
- Support communication and feedback related to port QC testing issues
- Ensure and support the new product launch or product diversity or product withdrawn in line with local regulation requirements, global requirements and project requirements
- Drive initiatives to improve efficiency, effectiveness, and compliance of QA processes
- Implement regional/global QA initiatives, tools, and systems locally

Stakeholder Engagement, Communication & Capability Building

- Represent the Affiliate in interactions with external stakeholders including authorities and industry associations
- Ensure timely and appropriate communication of quality issues and compliance matters to authorities and internal stakeholders
- Monitor local regulatory changes and ensure timely implementation within QA systems
- Collaborate with global, regional, and Affiliate stakeholders (e.g., QA, RA/PV, SCM, Manufacturing, 3PLs)
- Act as a key liaison between Affiliate and QA
- Ensure effective communication across internal and external stakeholders on quality-related matters
- Ensure implementation of QA training programs for Affiliate QAs and stakeholders
- Monitor training compliance and maintain training matrices
- Promote a strong quality culture and awareness of compliance requirements across the Affiliate
- Ensure adequate tools, systems, and support are available for QA
- Manage Affiliate QA resources, including budget

Required Qualifications

- Minimum 10 years of practical experience in drug production and quality management.
- Minimum 3 years of experience as people manager.
- Minimum 3 years in quality management for biological product or aseptic products

- Good understanding of the regulation on GMP, GDP and Chinese regulation of MAH DRE
- Science Graduate or equivalent professional qualification and/or proven expertise
- Proven compliance expertise; to understand and comply with industry laws and relevant regulations.
- Coaching and collaboration skills to interact with all levels of personnel to achieve shared goals.
- Proven ability to influence, (appropriately) challenge and engage diverse senior stakeholders.
- Fluent in written and verbal business English

Preferred Qualifications

- Experience in biological manufacturing or aseptic manufacturing.
- Experience in the supporting for oversea inspection by Chinese HA
- Licensed pharmacist