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：亚太地区外部质量保证副总监

部门：CMC 产品 QA

直线经理：亚太地区外部质量保证负责人

工作地点：无锡

Purpose & Scope:

Responsible for managing the cGMP Quality Assurance requirements for drug substances, intermediates, and in-process and finished drug products, biologics and combination products manufactured for Astellas by Third Party Contract Manufacturing Organizations (CMOs). This position will support other CMO Managers with activities at CMOs or serve as the main point of contact between Astellas and external CMO’ s for quality matters. This position communicates potential risks to line manager for appropriate action in collaboration with colleagues and affiliates within the JAO region as well as global counterparts in US and EMEA.

Responsible for managing the following quality systems for Astellas CMO products: Deviation Management (including CAPA), Change Control, SQIM, Risk

Evaluation Committee, Audits, Stability, Annual Product Review, Complaints, Supplier Evaluation, batch acceptance, SAP/UPS release, Quality Business Review Meetings and Regulatory Intelligence

Appointed Delegate for Head of External Product QA JAO.

Required Qualifications:

Responsibilities and Accountabilities:

CMO QA Oversight:

- Provide onsite guidance and supervision of manufacturing processes and QMS to ensure compliance with regulatory standards, during the manufacture of Astellas batches at the CMO.
- Ensure harmonization of standards and effective alignment and integration between Astellas' and the CMO's Quality Management Systems (QMS).
- Comply with applicable procedures at the CMO when working on site at the CMO, eg Health and Safety, gowning etc.
- Perform regular audits of CMO's QMS to verify ongoing compliance with legal requirements.
- Perform audits of material suppliers and QC laboratories, supplying the CMO or performing subcontracted activities, respectively, where required.
- Maintain oversight of the testing process.

- Maintain oversight of incoming materials, including spot checks of incoming test results.
- Maintain oversight of contamination control measures and the effective implementation of such.
- Perform quarterly risk assessments to enhance the QMS of the CMO.
- Periodically review the QMS and production management processes to ensure appropriate for the Product.
- Provide on-site guidance and supervision of manufacturing processes and QMS to ensure compliance with regulatory standards.
- Support the sampling and testing of primary raw materials, intermediate and finished product, both routinely and in case of deviations or substantial change controls.
- Act as Qualified Person, releasing batches to the Chinese Market.
- Establish and maintain procedures to support release to market, including review of QC results, batch records and deviation review.
- Oversees the cGMP activities and processes for Astellas commercial drug substances, intermediates, and in-process and finished drug products manufactured for Astellas by low risk CMOs, supported by the Head External Product QA JAO.

- Provides QA oversight for technology transfers of commercial products to and between CMOs.
- Provide QA support for regulatory agency inspections at CMOs as necessary.
- Participate in CMO Business Review Meetings.
- Assists CMO QA managers with oversight of CMOs

Assessment of the effectiveness/compliance of the Quality System in CMOs

- Facilitates the resolution of all deviations, non-conformances and other batch related quality issues with the CMO to ensure product compliance.
- Employs a Risk Management approach to evaluate Quality issues to ensure that drug substances, intermediates, and in-process and finished drug products manufactured for Astellas by CMOs conform to all regulatory and Astellas product specifications.
- Participates in the CMO Evaluation Program for CMO products as required. Develops and distributes formal reports in a collaborative manner. Cooperates with Supply Chain, Purchasing, and Quality Systems groups to maintain a list of approved CMOs.

- Identifies and communicates major cGMP compliance issues to Head of External Product QA JAO. Participates in formal corrective/preventive action plans using a Risk Based approach.
- If required may support in the audit and inspection of CMOs by Health Authorities, external consultant and Global Quality Systems. Support special audit of the plants and contract manufacturer, as required.

Compliance:

- Embed Compliance Culture across all Regions of the business ensuring Integrity in Action is actively applied in all initiatives.
- Ensure the CMC Product QA Function strictly adopts a culture of ethics and compliance; leading by example and appropriately challenging non-compliance.
- Ensure adherence to Astellas policies relating to Ethics and Compliance standards and interactions with Healthcare Professionals (HCPs), Healthcare Organizations (HCOs) and Patient Organizations (POs).

Surveillance of Significant Quality Issues (SQIs) and resultant investigations in the JAO Region.

- Assures CMO compliance with Astellas corporate policies, Global Procedures and Guidelines, SOPs and regulatory agency standards.
- Manages assessments of SQIs and REC activities.
- Maintains related records and tracking systems.
- Support the coordination of recalls, as well as notifications to regulatory agencies.

QA Activities

- Supports the Continuous Improvement program. Develops and maintains effective relationships with internal and external stakeholders which may include regional Astellas entities.
- Authors, revises, and performs maintenance and administration of departmental controlled documents (i.e., SOPs, WPDs, Forms, etc.) as necessary
- Monitoring and periodical review of CMO Management Quality System and participation in Management Review activities.
- Supports the Regional and Local product quality review.
- 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.
- Other such duties as may be reasonably required by the business.

Required Qualifications:

- Minimum 5 years of practical experience in drug production and quality management.
- Minimum 3 years' experience in sterile or aseptic manufacture.
- Science Graduate or equivalent professional qualification and/or proven expertise
- Pharma sector experience
- 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:

- Previous experience in pharmaceutical Quality Assurance, and CMO oversight or in-plant GMP pharmaceutical manufacturing

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