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：Manager, Quality Assurance (CQA)

Department:：Clinical QA, R&D QA

Line Manager：Head, Quality Assurance, CQA Asia/Japan Project Support

Location：Beijing/Shanghai

Job purpose

• This position is responsible for the development and maintenance of excellence in Clinical QA (CQA)

activities for Astellas sponsored programs. This position works in partnership with Medical and Development

and other business units in support of global and local drug development, registration and marketing for

assigned projects across Therapeutic Area(s) (TAs) for all stages of drug development.

• Collaborates with relevant QA members and Medical and Development for alignment with company-wide

standards. Supports CQA assets and/or non-asset activities to ensure that Medical and Development

processes and clinical trials (Phase I-IV) are executed in compliance with the international requirements for

Good Clinical Practice (GCP) and other relevant (inter)national regulations. Responsible for managing,

conducting and/or participating in regional/global audits. Manages external (contract) QA resources and

provides technical expertise to identify and resolve quality issues.

• Reports to the Senior Director/Director/Associate Director, CQA and contributes to the development,

implementation and successful execution of the QA mission, objectives and 3-5 years strategic plan.

Responsibilities and Accountabilities:

• Lead or support regulatory inspection preparation at Astellas entities and/or partners across the region and

global. Analyze the risks, defines the strategy for inspection readiness and manage the roll out of the

inspection readiness program across departments and territories ensuring a harmonized approach

Position Title: Manager, Quality Assurance (CQA)

Position Reports to (Title): Head, Quality Assurance, CQA Asia/Japan Project Support

Job Level: Level 2

Area of Accountability: Professional

Job Family: Product Safety

Pay Grade: GG16 Today’ s Date: 21/Aug/2025

Functional Unit: Quality Assurance Department: Clinical QA, R&D QA

Complete following section to initiate Recruitment and Activate Requisition:

Primary Location: China (Beijing or Shanghai) Other Locations:

Will position be posted in one region/country or multiple? ☒ One Region ☐ Multiple Regions

Will position be posted internally only? ☐ Internal Only ☒ Internal & External

Comments:

• It is urgent to have backfill for this position in CQA China.

• When posting this position for the external job seekers, please use the legacy job title, "Senior Manager",

instead of "Manager" for their easy understanding about the job level of this position. If it is not allowed, please

explain the external job seekers and the recruiters that "Manager" of this position is equivalent with Senior

Manager (GG16).

Complete following section where required Approved and Endorsed by:

Management Name/Title: Yoko Amada, CQA, R&D QA e-Signature

HRBP Name/Title: e-Signature

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• Manage or support GCP inspections. This includes communication with Regulatory Authorities' inspectors,

inspection preparation, inspection hosting, support of CAPA generation and monitoring of follow up to ensure

that any risk / inspection findings as identified by inspectors is adequately addressed and mitigated

• Perform multiple regional, cross regional and/or global audit programs. This includes the independently

scheduling, scoping definition, planning, conducting and reporting of audits, liaising with stakeholders on

audit findings and the follow up thereof. It also incorporates interpretation of findings, providing trending

information, root cause analyses and identifying lessons learned for the continuous improvement of the

Astellas organization. Manages and follows up on findings and improvement areas.

• Be represent CQA as a Global Quality Lead (GQL) or Regional Quality Lead (RQL) for Medical and

Development assets across Therapeutic Areas. Provides support and consultation to other QA functional

areas as needed

• Provide unsupervised GCP expert advice to key personnel. This includes and is not limited to:

✓ Developing training materials and providing GCP training internally and externally to both small and

large professional organizations. It also encompasses coaching of CQA colleagues and other functions

on CQA related processes

✓ In case of regulatory agency inspections review of responses from operations before sending to CQA

management for their final review and approval

✓ Interpreting regulatory authorities' requirements and advising in the implementation across the Astellas

organization

• Support the development, improvement and maintenance of the Astellas Quality System by identifying root

causes to non-conformances related to the processes and/or systems, and by addressing observed gaps in

these processes and systems. This includes research of the Pharma Market Place / QA organizations,

Regulatory developments and Inspection reports to ensure Astellas meets its strategic objectives in terms of

Quality, Business Model and Effectiveness

• Manage quality issues related to critical nonconformances, suspicion of scientific misconduct and/or potential

fraud. Lead proper corrective and preventive actions identification and rolls out and ensures follow up with

effectiveness measures

Required Qualifications:

• Bachelor’ s degree
• Minimum of 5 years in pharmaceutical, biotechnology, or related industry
• Minimum of 2 years significant experience in Clinical Quality Assurance
• Minimum of 2 years project management experience, preferably in a highly matrixed, multicultural global setting,
requiring facilitation, negotiation, problem-solving, and conflict resolution skills
• In-depth understanding of GCP requirements for both marketed and investigational products
• Practical experience and understanding of clinical quality assurance as applied throughout the entire
pharmaceutical compound/product life cycle
• Effective oral and written communication and presentation skills in English

• Solid understanding of QA processes
• Proficiency in Microsoft Office
• Domestic and international travel at 10-25% as required

Preferred Qualifications:

• Advanced degree in related disciplines
• Addition to GCP knowledge, other GxP knowledge would be preferred (for example, GVP, GCLP)
• Person who is not afraid of failure, who can think by her/himself, propose solutions, and act on her/his own.

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