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: Statistical Science Lead (China, Non-Clinical, CMC, Biomarker)
Department: Evidence Generation and Advanced Analytics
Line Manager: Head, Early and Exploratory Statistical Science
Location: Beijing/ Shanghai

Purpose and Scope

The Statistical Science Lead within the Early and Exploratory Statistical Science group provides strategic and technical leadership across nonclinical and early development activities, with a strong focus on nonclinical study design, CMC, and early biomarker research. This role ensures rigorous statistical analysis, including robust study design, data analysis, and interpretation for preclinical and translational studies, while supporting CMC activities such as process and bioassay development. The Statistical Science Lead also advances biomarker strategies that link non-clinical insights to clinical development and partners closely with Research, CMC, and Translational Scientists to enable high-quality, data-driven decisions.

Responsibilities and Accountabilities

Provides best in class Quantitative Sciences and Evidence Generation (QSEG) support to Astellas drug development programs by providing high quality statistical leadership across non-

clinical, CMC, and biomarker activities ensuring all required analyses, interpretations, and deliverables are executed with rigor, consistency, and timeliness.

- Provide strategic and technical leadership for nonclinical toxicology, safety, and pharmacology studies (in vivo, in vitro, including New Approach Methodologies), ensuring rigorous study design, analysis, and interpretation aligned with regulatory expectations.
- Perform and lead end-to-end statistical analyses for nonclinical and translational data (e.g., dose-response, longitudinal, safety endpoints), including hypothesis formulation, experimental design, statistical analysis planning, data cleaning, execution, and reporting. Ensure analyses are robust, reproducible, and suitable for regulatory use, with clear and scientifically sound interpretation.
- Provide statistical leadership for CMC development across the lifecycle, including process characterization, DoE, analytical method development/validation, stability, and comparability, and contribute to defining critical quality attributes (CQAs) and critical process parameters (CPPs). Develop statistical tools to streamline process development, QC testing and troubleshooting.
- Drive the development and statistical evaluation of biomarkers across discovery through lifecycle development, applying rigorous methods to assess performance, variability, and clinical/translational relevance, and enabling linkage of nonclinical findings to clinical outcomes.
- Contribute to and review regulatory submissions (IND, IMPD, BLA/MAA), ensuring statistical approaches are well-documented, traceable, and compliant with GxP standards; support health authority interactions.
- Act as a strategic and scientific partner to Research, Toxicology, Pharmacology, CMC, and Translational leaders, shaping quantitative strategy and enabling high-quality, data-driven decisions.
- Continuously develop expertise in emerging statistical methodologies, technologies, and analytical tools, applying innovative approaches to address evolving scientific and regulatory challenges

Mentorship and Capability Development

- Mentor statisticians and analytic professionals, supporting both scientific development and career growth
- Share knowledge and best practices within QSEG and cross-functional project teams
- Contribute to internal training and methodology development
- Lead or contribute to internal initiatives, including standardization efforts, methodology forums, and innovation network

Required Qualifications

- PhD (or MS with equivalent experience) in Biostatistics, Statistics, or a related quantitative discipline.
- Minimum of 6 years (9+ years for MS) of experience in pharmaceutical or related industry in nonclinical, CMC, and/or biomarker development with proven leadership in statistical and ML strategy.
- Strong understanding of the drug development lifecycle, regulatory requirements, and evidence generation
- Ability to lead and influence cross-functional, global teams within a matrix environment.
- Strong communication, collaboration, and stakeholder engagement skills across both technical and non-technical audiences.
- Advance and broad knowledge of classical and modern statistical methodology, including Bayesian methods, ML algorithms, and simulation tools, along with understanding of industry best practices related to analysis of non-clinical, CMC, and biomarker data.
- Knowledge and proficiency in implementing statistical software (e.g., SAS, JMP, R, Python)
- Self-starting performer with the demonstrated capacity to operate both independently and collaboratively in a fast-paced, team-oriented setting
- Strong written and verbal English communication skills; Chinese language proficiency as required by local role expectations

Preferred Qualifications

- Experience with CMC activities for cell and gene therapies, including process characterization, analytical methods, and product quality assessment.
- Experience supporting regulatory submissions, including authoring or reviewing nonclinical, CMC, or biomarker sections
- Strong knowledge of regulatory expectations for non-clinical and CMC, including quality-by-design (QbD) principles and data integrity standards
- Scientific contributions through publications, presentations, or participation in industry/regulatory working groups