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, CMC Lead China
Department: Project & Product Mgmt
Line Manager: Head, CMC PM PPM
Location: Beijing/Shanghai

Purpose and Scope

This role is a CMC Leader based in China accountable for assigned development and commercial product(s), acting as the primary CMC interface with China LT cross-functional team including commercial, R&D etc. This role will ensure that Chinese CMC development, registration, and manufacturing requirements are integrated in the global CMC strategy ensuring optimal formulation, manufacturability, supply reliability, and COGM for Chinese market. This position will also co-build and implement a China local commercial manufacturing roadmap balancing strategic options, risks, and business implications.

Responsibilities and Accountabilities

- Define and implement an integrated CMC strategy consistent with Clinical Development Plan and China product strategy, enabling accelerated new product development, registration, successful launch, post-approval manufacturing supply and regulatory product maintenance into China.
- Contribute to the China regulatory strategy and compliant submissions across the patient axis in

close collaboration with the Regulatory Lead and China LT cross-functional team.

- Co-lead with CMC Leads at AMT, the responses to the China CDE CMC RFI and ensures compliant submissions.
- Closely collaborate with the Clinical Supplies manager on CMC activities.
- In close collaboration with CMC Leads at the AMT, drive proactive lifecycle management for Chinese market including product innovation, process improvements and supply optimization.
- Co-build and implement a China local manufacturing roadmap
- Support assigned CMC Due Diligence activities, providing strategic and technical input to assess risks and value
- Participate in Joint Manufacturing Committee(s) with selected China based co-development partners.
- Co-own with CMC Leads at the AMT the COGM strategy including cost targets and optimization initiatives.
- Co-own with CMC Leads at AMT CMC risk management including global risk register and mitigation strategies.
- Drive effective communication with internal and external manufacturers as well as other relevant functions in PDM, to ensure that regulatory strategies for both new assets and marketed products are executed efficiently, ultimately supporting successful product registration and commercial supply
- Work with global cross-functional CMC matrix teams (EU, US, Japan, China) ensuring alignment and accountability across regions.
- Ensure delivery of CMC milestones, QC testing samples, method transfers, and supply readiness.
- Manage budgets and forecasts, optimizing trade-offs across cost, timelines, and risk maximizing value.
- Translate and effectively communicate strategy, risks, and value to senior stakeholders.

Required Qualifications

- Advanced degree in pharmaceutical sciences, chemistry, or engineering.
- 10–15 years proven CMC experience across early and late-stage development and commercial operations having successfully completed IND negotiations and NDA submissions with CDE.
- Strategic thinker able to translate strategy into tactics
- Experience leading global, cross-functional matrix teams.
- Deep understanding of the CDMO landscape in China

- Broad expertise in formulation, manufacturing, regulatory, and supply strategy.
- Experience with COGM optimization and lifecycle management.
- Strong business acumen including financial modelling and ROI evaluation.
- Knowledge of GMP and global regulatory requirements.

Preferred Qualifications

Demonstrated experience managing CDMOs and external partners, driving performance, ensuring compliance, and delivering against cost, timeline, and quality objectives.