Regor Therapeutics Group

Regor Therapeutics Group was formed in 2018 as an independent, private biotech company. At Regor, we are dedicated to developing new small molecule-based therapeutics to improve human life. We use the latest scientific knowledge and apply novel approaches to discover new ways of treating disease. We encourage cooperation and support a high level of scientific freedom to find the best answers to biological questions.

Position: Process Chemistry Director/Associate Director

Location: Shanghai, China

RESPONSIBILITIES:

Lead Process Chemistry

Develop synthetic route: Scale up reactions to develop synthetic routes for large-scale clinical and commercial use, that is cost-effective and complies with regulations established by government organizations.

Improve existing processes: Analyze existing processes and look for indicators of problems with system performance. Recommend various actions to improve environmental safety, lower costs, and maximize production.

Conduct environmental research: Conduct environmental research and audits to determine how pollutants are distributed and the ways in which industrial effluents can be reduced and controlled.

Design experiments: Design experiments to determine how process changes and variable manipulation will impact final products. Monitor reaction processes and then identify ranges for operational parameters.

Manage API Supplies

API program outsourcing: Craft and distribute request-for-proposals to CDMOs to access intermediates and API supplies to enable the pipeline. Evaluate proposals, select supplier and award contract. Manage day-today interactions with CDMOs to ensure that deliverables are completed as contracted.

Supply Management: Establish detailed plans to guide project chemical development activities from pre-clinical to commercialization, ensuring all quality and regulatory requirements are proactively satisfied. Design and implement a comprehensive API supply strategy for specific projects. Drive forecast planning and inventory management of project intermediates and APIs to meet near-term and long-term goals. Incorporate risk-mitigation

strategies. Lead the collection of relevant data and reports from suppliers and contribute to drafting of INDs, NDAs, and associated amendments.

QUALIFICATIONS:

- An MS/Ph.D in Chemistry or Chemical Engineering or related technical field.
- 10+ years relevant experience in CMC operational roles, preferably in an MNC or bio-tech environment.
- A successful history of hands-on chemical development and scale-up.
- A successful track record in the RFP/contracting process along with detailed technical oversight of third-party contractors.
- Experience with management of all stages of API development and manufacturing.
- Comprehensive working knowledge of Good Manufacturing Practices (cGMPs) and regulatory guidance documents as they relate to manufacture and quality testing of pharmaceutical products.
- Demonstrated experience in inventory management and forecasting.
- Ability to effectively prioritize and deliver on tight timelines.
- Outstanding problem-solving abilities.
- Detail-oriented, with good organizational and project management skills
- Strong leadership, project planning, negotiation and presentation skills.
- Significant experience in communicating/presenting complex information to senior management and regulatory agencies.
- Ability to multi-task and manage several projects in parallel, paying attention to detail.
- Ability to forge cross-functional working relationships with internal and external project partners.
- Ability to be proactive in identifying issues and hurdles that may hinder the effective progression of an asset and resolve the issues in a timely and creative fashion.

ORGANIZATION AND REPORTING RELATIONSHIPS:

- Reports to Head of Pharmaceutical Science