Job #: 02-239

Job Title: Senior Director, Drug Substance Manufacturing Science & Technology (MS&T)

Location: Waltham, MA

Role Summary:

Deciphera Pharmaceuticals is a clinical-stage biopharmaceutical company focused on improving the lives of cancer patients by tackling key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. Our small molecule drug candidates are directed against an important family of enzymes called kinases, known to be directly involved in the growth and spread of many cancers. We use our deep understanding of kinase biology together with a proprietary chemistry library to purposefully design compounds that maintain kinases in a "switched off' or inactivated conformation. These therapies comprise tumor-targeted agents designed to address therapeutic resistance causing mutations and immuno-targeted agents designed to control the activation of immunokinases that suppress critical immune system regulators, such as macrophages. We have used our platform to develop a diverse pipeline of tumor-targeted and immuno-targeted drug candidates designed to improve outcomes for patients with cancer by improving the quality, rate and/or durability of their response to treatment.

We are seeking a **Senior Director, Drug Substance MS&T**, who will have overall responsibility for leading and managing late-stage development and commercial manufacturing activities for drug substance, DS intermediates and starting materials. The scope of the role encompasses process development, scale-up, and characterization/design space mapping, process performance qualification (PPQ), routine commercial manufacturing, technical transfer and process/operational improvement initiatives. Operating within a virtual (100% outsourced) business model, the incumbent will have accountability for CDMO selection and oversight, and the development of strong and enduring business partnerships. The successful candidate will also assume a key leadership role in the development, review and approval of Module 3 sections of CTD regulatory submissions, written responses to regulatory authorities, and TPP/QTPPs, and will support strategic partnerships relating to potential in-licensing and/or out-licensing opportunities and external collaboration agreements.

The successful candidate will have significant experience in CMC development and commercialization of small molecules and an in-depth understanding of critical-path activities and interdisciplinary connections associated with product registration and commercial launch. S/he will possess strong leadership, management and

communication skills, ensuring that external business partners understand and respect program goals, objectives, priorities, and timelines.

This position will report to the **Chief Technical Officer** and be located in the Waltham, MA office.

Key Responsibilities:

- Lead and manage cross-functional teams engaged in external cGMP manufacturing of drug substance, DS intermediates, and starting materials.
- Lead and manage process transfers and associated site implementation to support supply chain expansion activities and post-approval continuous improvement initiatives.
- Monitor, track and trend process performance. Develop and implement data analytics to support investigations and provide historical baseline for future operational and process-related improvements.
- Support investigations, root cause identification and CAPA implementation associated with manufacturing deviations and associated quality events.
- Work closely with internal Quality Assurance, Regulatory CMC, Supply Chain and Commercial functions and external manufacturing operations to ensure operational excellence with respect to timelines, budgets, and attainment of technical, regulatory and business goals/milestones.
- Lead the selection of drug substance CDMOs based upon core capabilities, capacity and track record of regulatory compliance; establish KPIs to monitor site technical, quality and business performance.
- Develop and maintain strong relationships with CDMO business partners and participate in quarterly Joint Steering Committees across the supply chain.
- Review/approve technical reports, controlled GMP documents and CMC content for Module 3 CTDs.
- Develop and manage scope, milestones, interdependencies, budgets and timelines associated with drug substance program deliverables.
- Continuously monitor external business and regulatory environments; identify risks and establish mitigation plans and/or best practices to proactively address CMC and supply chain risk.
- Serve as an integral member of the Technical Operations Leadership Team, ensuring cross-functional alignment of drug substance program deliverables with overall program strategy.
- Represent the Technical Operations organization in meetings with FDA, EMA and related regulatory authorities.

Required Qualifications:

- A B.S./M.S. degree in chemistry, chemical engineering or related life sciences discipline with at least 15 years of experience in small-molecule pharmaceutical product development and commercialization.
- Track record of success in leading and managing small-molecule drug substance MS&T programs in a 100% outsourced environment.
- Strong vendor/supplier management skills and excellent communication and cross-functional collaboration skills.
- Competency in developing, implementing and delivering CMC project plans (milestones, timelines, resources, etc.) to successful endpoints.
- Strong decision-making skills and ability to influence internal and external stakeholders.
- Thorough knowledge of the drug development process and ICH requirements for NDA and MAA registration. Extensive experience in working with regulatory authorities. Track record of authoring and defending Module 3 CTD content through regulatory approval and commercialization.
- Ability to articulate complex issues and ideas with clarity to enable understanding and decision making.
- Ability to work successfully in a team/matrix environment and independently, as required.
- Ability to influence cross-functionally to enable improvements and enhance performance across CMC development, MS&T and supply chain functions.
- Pragmatic, solution-oriented thinker who possesses a “can do” and ”whatever it takes” attitude, coupled with excellent organizational and communication skills.
- Strong interpersonal skills with the ability to motivate and influence others, negotiate during situational conflict, and establish the best forward path in the face of competing points of view.
- Understanding of industry trends, practices, techniques and standards, and associated impact on program strategy and execution.
- Ability to travel (20%) to CDMO domestic and international sites.
- Fluency with standard computer software packages (MS Word, Excel, PowerPoint, and Project) and JMP (or similar statistical tools).

Preferred Qualifications:

- Experience in developing and commercializing drugs for oncology and/or orphan diseases is strongly preferred.
- A Ph.D. degree in an engineering or life sciences discipline or M.B.A. in operations management is highly desired.

Deciphera offers competitive compensation, including equity-based compensation, and a comprehensive benefits package that includes medical, dental, vision, 401(k) retirement plan, life insurance and a flexible spending account for either health care and/or dependent care.