Job #: 02-268

Job Title: Associate Director/Director, Drug Product 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. We have used our proprietary drug discovery platform to develop a diverse pipeline of drug candidates designed to improve outcomes for patients with cancer by enhancing the quality, rate and/or durability of their responses to treatment. We currently retain global development and commercialization rights to our drug candidates, including three programs in clinical development. Deciphera (NASDAQ: DCPH) is a publicly traded company headquartered just outside Boston in Waltham, Massachusetts. Our state-of-the-art research facility is located near the University of Kansas School of Pharmacy in Lawrence, Kansas.

We offer an outstanding culture and opportunity for personal and professional growth based on these key principles:

- providing a collaborative, energized and fun work environment where people are empowered and supported in the achievement of their career goals
- a diverse and multi-disciplinary workforce
- dedicated and talented people who are passionate about achieving excellence in all they do
- a work environment that allows you to balance your priorities
- above all else, a commitment to the patients we serve

We are seeking an **Associate Director/Director, Drug Product Manufacturing Science and Technology (MS&T)**, who will have responsibility for leading and managing late-stage development, validation and commercial manufacturing activities for drug product and packaging. The scope of the role encompasses late stage process development, scale-up, Process Performance Qualification (PPQ), routine commercial manufacturing, technical transfer and Continued Process Verification. Operating within a virtual (100% outsourced) business model, the incumbent will have accountability for CDMO oversight, and the development of strong and enduring business partnerships. The successful candidate will also assume a key role in the development, review and approval of Module 3 sections of

CTD regulatory submissions, pre-approval inspections (PAIs) and written responses to regulatory authorities.

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 validation 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 **Sr. Director, MS&T** and be located in the Waltham, MA office.

Key Responsibilities:

- Lead and manage cross-functional teams engaged in external cGMP manufacturing of bulk drug product and finished goods.
- Lead and manage process transfers, associated site implementation and PPQ 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.
- Play a key role in the selection of drug product 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.
- Review/approve technical reports, controlled GMP documents and CMC content for Module 3 CTDs.
- Potentially represent the Technical Operations organization in meetings with FDA, EMA and related regulatory authorities.

Required Qualifications:

- A B.S./M.S. degree in chemical engineering, pharmaceutics, chemistry, or related life sciences discipline with at least 10 years of hands-on experience in small-molecule pharmaceutical product development and commercialization.
- Track record of success in leading and managing small-molecule drug product MS&T program through validation in a 100% outsourced environment.
- Thorough knowledge of current global regulatory expectations and industry best practice for Process Performance Qualification , Continued Process Verifications and implementation of Quality by design (QbD) principles.
- 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.
- 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 influence others, negotiate during situational conflict, and establish the best forward path in the face of competing points of view.
- 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.