Job #: 04-210

Job Title: Associate Director/Director, Analytical Development

Location: Lawrence, Kansas

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

Position Summary:
We are seeking an Associate Director/ Director, Analytical Development to have overall responsibility for leading and managing early-stage CMC development activities related to analytical characterization of products/processes and the development, qualification, transfer and validation of analytical methods for QC release and stability testing of small-molecule drug substance, drug product, intermediates, starting materials, excipients, and packaging materials and components. Operating within a virtual (100% outsourced) business model, the incumbent will have accountability for analytical CRO/CDMO selection and oversight. 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.

This position will report to the **Vice President, Chemical and Pharmaceutical Development** and be located in the Lawrence, KS office.

Key Responsibilities:

- Working through CDMOs, Lead and manage analytical activities for GMP and non-GMP manufacture of drug substance and drug product, including method development/transfer, method validation, release testing, reference standard characterization, investigations for OOS.OOT results, etc.
- Oversee stability operations and reference standard management for early clinical assets.
- Develop and maintain strong relationships with CRO/CDMO business partners.
- Review/approve technical reports, controlled GMP documents (e.g., analytical methods and associated validation protocols, specifications, change controls, LIRs, SOPs, etc.) and incorporate CMC content for Module 3 CTDs.
- As needed, Represent the Technical Operations organization in meetings with FDA, EMA and related regulatory authorities.

Required Qualifications:

- A B.S./M.S. degree in analytical chemistry or related life sciences discipline with at least 10 years of experience in small-molecule pharmaceutical product development or commercialization (or) a PhD with 5 + years of relevant experience.
- Experience and in depth understanding of routine instrumental methods: HPLC, GC, Mass Spec
- 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 IND/IMPD filings. Track record of authoring and defending Module 3 CTD content.
- 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 travel (10%) to CRO/CDMO domestic and international sites.

Preferred Qualifications:

- Prior experience leading and managing small-molecule analytical development in a 100% outsourced environment preferred.

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.