Job #: 02-231

Job Title: Associate Director, Quality Control

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 an **Associate Director, Quality Control**, who will have responsibility for leading and managing the pharmaceutical GMP quality control activities associated with development and commercialization of the company's small-molecule assets. Operating within a virtual (100% outsourced) business model, the incumbent will be responsible for site implementation of IPC and QC methods for drug substance, drug product, intermediates, starting materials, excipients, and packaging materials and components, review/approval of protocols, methods, reports, batch records and related GMP source documents, oversight of stability operations and reference standard management, and transfer/site implementation of analytical methods to support future supply chain expansion.

The successful candidate will also work collaboratively with Quality Assurance to assess laboratory conformance with cGMPs, and with CMC Regulatory Affairs to ensure the translational accuracy and integrity of data incorporated into Module 3 sections of CTD regulatory submissions and written responses to regulatory authorities.

This position will report to the **Senior Director, Analytical Development and MS&T** and be located in the Waltham, MA office.

Key Responsibilities:

- Manage/oversee qualification and site implementation of IPC and QC methods for drug substance, drug product, intermediates, starting materials, excipients, and packaging materials and components.
- Manage/oversee analytical method transfers and site implementation to support supply chain expansion activities and post-approval continuous improvement initiatives.
- Manage/oversee stability operations and reference standard program.
- Participate in the selection of analytical CROs/CDMOs based upon core capabilities and regulatory compliance.
- Review/approve controlled GMP documents, e.g., analytical methods and associated validation protocols, specifications, change controls, LIRs, etc.
- Review/approve development reports for data integrity and regulatory compliance; review/approve CMC content incorporated into Module 3 sections of CTD regulatory submissions for translational accuracy.
- Support cGMP audits of CDMO laboratories.
- Author and/or review standard operating procedures (SOPs) relating to analytical development and quality control.
- Maintain effective communication with CDMOs and deliver QC objectives in accordance with project timelines and budgets.

Required Qualifications:

- B.S./M.S. degree in analytical chemistry or related life sciences discipline with at least 10 years of quality control experience in pharmaceutical product development.
- In-depth understanding of CMC regulatory requirements for product registration and cGMP compliance requirements for pharmaceutical quality control laboratories.
- Strong vendor/supplier management and cross-functional collaboration skills.
- Ability to work successfully in a team/matrix environment and independently, as required.
- Ability to meet deadlines, demonstrate efficient and effective use of time, and handle multiple assignments simultaneously.
- Ability to convey both written and verbal information effectively and efficiently.
- Ability to follow procedures and perform assignments with a high degree of accuracy and careful attention to detail.
- Ability to travel (15%) to CRO/CDMO domestic and international sites.

Preferred Qualifications:

- Experience in developing and commercializing drugs for oncology and/or orphan diseases is desirable.
- Significant work experience in a virtual (100% outsourced) biopharmaceutical development business model is strongly 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.