Job #: 02-253

Job Title: Manager/Sr. Manager, GMP QA (Drug Substance & Packaging & Labeling)

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 offer an outstanding culture focused on:

- Providing a collaborative and energized work environment
- A diverse and multi-disciplinary workforce
- Dedicated and talented people who are passionate about achieving excellence in all they do
- A commitment to the patients we serve

We are seeking a **Manager/Sr. Manager GMP/GDP Quality Assurance (DS & P & L)** to provide expertise for the development and commercialization of Deciphera's products in compliance with relevant US, EU and ICH requirements. The primary responsibility of this position will be to ensure proper QA oversight and collaboration with Deciphera's Drug Substance (DS) and Packaging & Labeling (P&L) partners.
This position will report to the **Director, GMDP & GLP Quality** and be located in the Waltham, MA office.

Key Responsibilities:

- Assure compliance (internally and externally) with 21 CFR 210/211, 312, EudraLex Vol. 4 (including relevant parts and annexes) and ICH.
- Provide GMP oversight and management of daily quality related tasks and priorities of the clinical and commercial DS and P&L partners.
- Review and Approve Master Batch Production & Packaging Records and Executed Batch Production & Packaging Records.
- Responsible for all DS and P&L material disposition.

- Internal Quality lead for DS and P&L partner change controls, deviations, and investigations.
- Collaborate and support with internal stakeholders, along with DS and P&L partners on validation and technology transfer activities.
- Establish and maintain strategic business partnerships to ensure corporate deliverables are met.
- Create organizational procedures and processes for clinical and commercial programs.
- Develop, review and approve relevant Technical Quality Agreements.
- Assist in internal audit program and regulatory inspections.
- Support QP release activities.
- Review pertinent CMC sections of regulatory submissions.

Required Qualifications:

- B.S. degree in life sciences, chemistry or equivalent.
- 5+ years of GMP Quality experience, with at least 3 years managing external partners.
- Ability to manage multiple projects in a dynamic environment.
- Experience working with drug substance and packaging partners.
- A well organized, self-motivated and independent work style with the ability to initiate and follow through on expected duties.
- Excellent interpersonal skill with knowledge of basic negotiation, influencing and conflict management to assure effective interactions within and across departments.
- A strong team player is required with the ability to effectively communicate sound Quality advice cross-functionally based on experience, regulations and business needs.
- Proven track-record of leadership and building relationships with internal and external partners.
- Experience with using risk-based principles and decision making to ensure compliance at all stages of development.
- Ability to travel ~15% domestically and internationally.
- Must be authorized to work in the US.

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.