Job #: 02-251

Job Title: Manager/Senior Manager, Clinical Quality Assurance

Location: Waltham, Massachusetts

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 a Manager/Senior Manager, Clinical Quality Assurance to be responsible for the development, maintenance and oversight of GCP activities related to the Clinical Trial activities sponsored by Deciphera. The primary responsibilities will be to ensure that both quality and compliance of Deciphera sponsored clinical trials with respect to Standard Operating Procedures, applicable regulatory requirements (US FDA, ICH, and country specific), along with current industry standards and practices.

This position will report to the **Associate Director, Quality Assurance** and be located in the Waltham, MA office.

Key Responsibilities:

- Draft, review or revise Clinical SOPs to assess consistency and compliance with regulatory requirements/internal standards
- Attend cross-functional team meetings and provide guidance to clinical operations staff based on interpretation of current regulations to ensure best practices including risk-based management
- Work closely with Clinical Operations to ensure/coordinate appropriate and complete resolution of findings/non-compliant issues, quality investigations, etc. in a timely manner, including approval of corrective action and preventative action (CAPA) plans, as necessary
- Conduct and/or assist in internal audits (systems, processes, vendors, computer system validation)
- Work directly with CRO's and other external contractors and collaborators, managing the chain of communication related to GCP compliance
- Interact with contract auditors in the scheduling process, kick-off meetings with auditors and internal groups, assist in the drafting of audit plans, confirmation letters and agendas, etc.
- Identify the need for, conduct and/or assist in external audits (includes, but is not limited to, investigator sites, central IRBs, CROs and clinical labs)
- Oversee the audit response process for the Investigator Site and Contract Research Organization (CRO) audits/inspections and ensure acceptability of actions to address findings through the CAPA process
- Provide Quality Control (QC) review of clinical protocols, amendments, Informed Consent Forms, Clinical Study Reports and other clinical trial related documents
- Assist and advise with training QA and clinical staff as necessary for GCP
- Identify potential systemic gaps and coordinate with the appropriate stakeholder to ensure timely remediation
- As appropriate, escalate issues of critical non-compliance and/or lack of urgency in remediation to senior management via the Quality Board
- Perform program specific root cause analysis of compliance issues and provide the appropriate metrics for tracking and trending for the overall QA reporting requirements to functional and senior management
- Assist with inspection readiness, and regulatory inspections as needed

Required Qualifications:

- At least 5 years of direct GCP pharmaceutical/biotechnology experience
- Solid understanding and application of GCP, GLP and ICH requirements, especially ICH E6R2
- A well organized, self-motivated and independent work style with the ability to initiate and follow through on assignments

- Excellent interpersonal skills with knowledge of basic negotiation, influencing and conflict management to assure effective interactions within and across departments
- The ability to simultaneously handle multiple project issues while dealing with time demands, incomplete information, or unexpected events
- Ideal candidate will have broad experience in product development, clinical operations, regulatory compliance and GCP auditing
- A strong team player is required with the ability to effectively communicate sound Quality advice cross-functionally based on experience, regulations & business needs
- Experience with using risk-based principles & decision making to ensure compliance at all stages of development
- Proven track-record of leadership & building relationships with both internal & external customers
- Strong negotiation skills, flexibility & ability to provide a solution-based approach to emerging challenges

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.