



Job #: 02-254

Job Title: Manager, Quality Assurance (QA) Systems

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 Quality Systems Manager who will be responsible for developing, maintaining and executing Quality Management Systems (QMS) and processes to ensure GxP compliance. We are looking for a hands-on manager that can partner with internal departments to develop and support QMS process improvement implementations that meet business and regulatory requirements.

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

Key Responsibilities:

- Supports the Document Management Systems and assists in the system implementation, administration, migration and training of modules of Veeva Vault (QualityDocs, RIMS, QMS, eTMF, contracts management, platforms, etc.).

- Leads the implementation and administration of Quality Management Systems using the Veeva Vault modules for CAPA, Change Control, Deviations/Investigations and Vendor Management.
- Quality representative for the implementation of platform for the public disclosure module in Veeva Vault.
- Establish and implement effective QMS measurement, analysis, trending and reporting standards and processes.
- Assists with User Acceptance Testing, as well as oversee and participate, as needed, in validation.
- Establish and maintains the lifecycle of controlled documents, including but not limited to: records management including version control, periodic review, document distribution, archival, retrieval, retention and destruction.
- Act as the QA lead in identifying requirements, supporting validation testing verification and administration of all modules of Veeva Vault.
- Manage the training program, documentation of SOP read and understood training in QualityDocs.
- Manage the SafetySkills training program and provide quality metrics on compliance.
- Assist with the development and implementation of SOPs, training materials, system job aids, work instructions and help guide(s).
- Primary QA contact for Veeva Vault, SafetySkills and Starting Point (templates).
- Establish partnership and collaborate with Veeva IT administrator at Deciphera
- Primary point of contact with Veeva Administrators and Managed Services

Required Qualifications:

- Bachelor’s degree in Computer Science or related field.
- 5+ years IT experience in the life sciences industry
- Experience in Quality Assurance, process improvement or related function.
- Thorough knowledge of Quality Management Systems, and Quality Documentation Systems
- Strong software proficiency with Microsoft Suite, all modules of Veeva Vault, Starting Point, SafetySkills and other desktop applications
- Excellent communication, and collaboration skills

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.