POSITION PROFILE:

Vice President of Quality

Acer Therapeutics Inc.
(Nasdaq: ACER)
www.acertx.com

Company Overview

Acer Therapeutics is a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs. Founded in 2013, Acer completed its Initial Public Offering in 2017, has raised $93M to date, and has rapidly built a diverse portfolio of product candidates. Acer's pipeline includes four clinical-stage candidates: emetine hydrochloride for the treatment of patients with COVID-19; ACER-001 (a taste-masked, immediate release formulation of sodium phenylbutyrate) for the treatment of various inborn errors of metabolism, including urea cycle disorders (UCDs) and Maple Syrup Urine Disease (MSUD); EDSIVO™ (celiprolol) for the treatment of vascular Ehlers-Danlos syndrome (vEDS) in patients with a confirmed type III collagen (COL3A1) mutation; and osanetant for the treatment of induced Vasomotor Symptoms (iVMS). Each of Acer's product candidates is believed to present a comparatively de-risked profile, having one or more of a favorable safety profile, clinical proof-of-concept data, mechanistic differentiation and/or accelerated paths for development through specific programs and procedures established by the FDA.

The company is led by a management team experienced in the development and commercialization of rare disease therapeutics. Acer's strategy is predicated upon time and cost-efficient drug development, with the goal of delivering safe and effective therapies to patients with the utmost urgency.

Acer has a strong company culture and is committed to creating and maintaining an environment that values individual rights, hard work, fosters creativity, and promotes success. The Company is fueled by the talent and expertise of our employees, driven by the commitment to treating patients with critical unmet medical needs.

Reporting Relationship

The Vice President, Quality will report directly to the Chief Legal Officer.

Location

United States. We operate in a virtual environment, with most employees working from home. Some travel to our East Coast (Newton, MA) and West Coast (Bend, OR) offices will be required, as well as other US meeting locations from time to time.

Job Description

The VP, Quality will be an integral member of our team in advancing our programs. This role requires an individual with a collaborative and innovative approach to work with our cross-functional teams, integrate all key elements of the program, facilitate discussion on progress, risks, impediments and concerns, and ultimately drive programs forward. This individual will deploy available tools to ensure program strategies are well defined and that teams are able to successfully execute against those plans within scope, budget and in a timely fashion.

The individual will provide leadership in developing Acer's Quality Management and Compliance Systems as the company progresses into phase III product and clinical development, and commercial operations. Working in a virtual business model, the incumbent leader will be responsible for 1) Establishing quality and GMP, GLP & GCP compliance strategies; 2) Developing and maintaining systems to assure the quality of drugs, nonclinical and clinical studies through collaboration with the heads of those functions; 3) Identifying and implementing eSystems to manage product and study quality; 4) Establishing metrics, and reporting outcomes to executive management. As a small start-up company, in addition to providing strategic direction the incumbent will be expected to perform detailed tasks to produce the department's deliverables.

Responsibilities

- Own and drive the strategy, implementation & leadership of the Quality function at Acer and is accountable for the execution and administration of the GXP Quality System pertaining to GMP, GLP and GCP and relevant ICH, US and EU regulations.
- Represent Quality in internal and external meetings to ensure quality compliance requirements are met.
- Assist business functional areas in developing and implementing processes, procedures, and systems to perform critical activities in an efficient and effective manner to ensure compliance with applicable regulations and company standards.
- Develop and implement and/or revise corporate standard documents relating to GxPs such as quality manuals, policies, SOPs, work instructions, forms, reference documents, in collaboration with relevant business functions.
- Review and update quality manuals, SOPs, policies and processes regularly to ensure all quality standards are in compliance with FDA/EMA/PMDA/ICH and other applicable competent authority regulations and requirements.
- Responsible for vendor and contract manufacturer compliance including directing third party qualification and maintenance management programs, external quality system audits, quality agreement negotiation, product and process validation, method validation, regulatory submission review, approval of drug manufacturing control documents (specifications, master batch records, change controls, deviations, validation protocols, analytical test results, packaging and labelling documentation, etc.), quality investigations and batch disposition.
- Conduct and/or manage internal and external audits to ensure compliance to all relevant policies and procedures as required. This includes the issuance of audit reports and facilitation of timely closure of corrective actions.
- Investigate adverse occurrences and quality complaints
- Administer, develop, and maintain the employee GXP training program including assessments of its' effectiveness, in collaboration with business functions. Specifically: coordinate, develop, and prepare training materials (e.g., presentations) and training sessions, identify and schedule training opportunities for applicable personnel, and periodically audit site personnel training files.

- Lead the participation, preparation, execution and response to regulatory inspectors worldwide, both at the company and at clinical trial sites.
- Collaborate and interact with broad range of departments and levels of management to accomplish company objectives
- Serve as an escalation point for corporate quality issues including investigations, recalls, deviations, CAPA, Change controls, inspections, clearances, validation and training.
- Develop plans and programs to support continuous quality improvement
- Regularly report to the company's leadership team and the BOD on the state of quality
- Manage and prioritize multiple projects and demonstrate a leadership style that can marshal the organizations most important resources to the right outcome
- Continue to build and scale the Quality organization
- Drive and cultivate a culture of Quality throughout Acer
- Collaborate cross-functionally, develop strong relationships with partners both internally and externally
- Set ambitious goals within Quality and in alignment with company goals
- Develop and manage the annual budgets for all Quality functions

Qualifications

- Minimum Bachelor's degree in science, pharmaceutical sciences, or related field
- Minimum of 15 years of quality management experience in a life science regulated industry such as, distribution, manufacturing, or supply chain industry.
- 8+ years of experience in managing others in regulated industry.
- Experience in implementing quality system based on FDA and international standards.
- Working knowledge of cGMP's and regulations applicable to the FDA and comparable international regulatory agencies.
- Experience in optimizing, qualifying, validating, transferring and troubleshooting manufacturing and analytical processes.
- Experience in working in compliance with US, EU, and ICH GMP requirements, experience with writing or reviewing submission documentation, responses to regulatory inquiries and inspections.
- Preferred experience with Combination Device submissions and ISO Medical Device requirements (e.g. pre-filled syringes).
- Preferred experience with GCP requirements and maintenance of required documentation and data.
- Experience with regulatory compliance inspections. Proficiency with interpreting and implementing GXPs, FDA, EMA, PMDA, ISO and ICH Regulations and guideline
- Deep knowledge of all facets of Quality Assurance (GCP, GMP, GLP), Quality Control, and Quality Systems, with a strong emphasis on GCP
- Successful prior experience managing the preparation, execution and response to inspections by regulatory authorities, in particular at the sponsor
- A strategic thinker who can break down barriers, drive and make great decisions, and make an impact with a Quality organization
- Demonstrated ability to exercise judgment with the best interests of patients at the forefront

- Nimble and resilient to a fast-evolving small molecule drug development environment
- Ability to effectively communicate with inspiration, lead and influence individuals from multiple functional departments at all levels of the organization
- Strong organizational and time management skills to balance working on multiple projects and initiatives in parallel
- Excellent people leader with strong mentorship skills. Track record of strong personal performance combined with demonstrated ability to build and lead highly engaged teams in a high growth environment.
- Excellent written communication and oral presentation skills
- Ability to Travel (15 %)

Personal Characteristics

- Must work well in a semi-virtual environment (home office / regional offices)
- An ability to quickly contribute in a meaningful way as a strategic partner to cross functional teams
- Must be able to successfully, and respectfully, manage external partners
- Possesses the highest standards of personal and professional integrity and will insist on ethical business behavior in all of the Company's business affairs. Able to face adversity without compromising integrity
- A smart, innovative, forward thinker, yet pragmatic and operationally savvy, with a strong commitment to patients, science and a drive to "do the right thing" (and not just the very safest, most risk averse thing)
- Strategic acumen and superb leadership skills combined with a focus on helping the business devise creative solutions to reach its goals
- A solutions-oriented team-player, with a "hands-on" energetic approach and style coupled with a strong work ethic
- A passion for the treatment of rare and life-threatening diseases
- Proven experience operating with a sense of urgency while remaining flexible, open-minded, and adaptable when working in a rapidly changing environment
- Exceptional communication skills both oral and written
- Personally committed to the Acer Ethos and Core Principles

Compensation

Acer seeks an individual of exceptional ability and will offer a competitive compensation package commensurate with candidate's individual skills and experience.

The Acer Ethos

We founded Acer on the fundamental mission that we will invest in developing innovative therapies and making them broadly accessible for people impacted by serious rare diseases with significant unmet medical need. In an era when the pharmaceutical industry is making huge strides in advancing therapeutic options for rare conditions, that may not sound atypical. But we believe we

have a better way and it will deliver significant value to patients and their caregivers, healthcare systems and society.

Be led by patients, their caregivers and clinicians.

We don't just put patients first, we are fueled by their resilience to adversity. That's why patients and their caregivers lead us in how to think about shaping our drug development programs so that our products will deliver optimal outcomes and earn the commitment of treating clinicians.

We recognize that drugs can offer tremendous benefit to patients and clinicians alike, but often leave both with an incomplete promise. That's why we engage with patient and clinician communities in our targeted pipeline areas and listen to their needs in order to reflect their inputs early and throughout our drug program development.

Indeed, such collaboration enables us to solve challenges and design solutions together.

Our Core Principles

1. Obligation to prioritize the Patient & their Family
2. Be Compassionate
3. Respect other's perspectives
4. Responsibility to do what's right – always!
5. Total Transparency
6. Celebrate Diversity
7. Humility
8. Be Courageous
9. Accountability
10. Be Unconventional

We will be accountable to this Ethos and Core Principles. We encourage open and transparent communication that can help us to drive our mission forward. We may seem impatient, but it is only because we want to get there faster. We are in this, together.

Acer Therapeutics is an Equal Opportunity Employer