POSITION PROFILE:

Associate Director/Director Quality Control

Acer Therapeutics Inc.
(Nasdaq: ACER)
One Gateway Center
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Newton, MA 02458
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Company Overview

We are a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs. Acer was founded in 2013, went public in 2017 and raised $100 million to date. Acer's pipeline includes four programs: ACER-001 (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; ACER-801 (osanetant) for the treatment of induced Vasomotor Symptoms (iVMS); and ACER-2820 (emetine), a host-directed therapy against a variety of infectious diseases, including COVID-19. 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 growing and is fueled by the talent and expertise of our employees and driven by the commitment to treating patients with significant unmet medical needs.

Reporting Relationship

The Associate Director/Director Quality Control will report to the Chief Technical Officer

Job description

Acer is seeking an Associate Director/Director Quality Control to join the Manufacturing team. This person will oversee all Quality Control activities for both drug substance and drug product including method development and routine testing with all activities currently carried out externally at contract sites.

Responsibilities

- Manage and interface with contract labs to develop and qualify appropriate analytical methods for drug substance and drug products in compliance with cGMP requirements.
- Assist with development and execution of Supply/Service Agreements and Quality Agreements as related to QC activities in coordination with Manufacturing, Legal, and Quality Assurance.
- Interface with Quality Assurance and Manufacturing teams to ensure timely testing to meet clinical and commercial demands.
- Establish and drive appropriate timelines and deadlines for both internal and external QC related tasks.
- Drive development and/or technical review of quality control documents (test methods, method qualification/validation protocols and reports, method development reports, stability protocols and reports, specifications, certificates of analysis).
- Provide QC expertise to contract sites including assistance with troubleshooting.
- Manage/review out of specification and out of trend investigations along with Quality Assurance and Manufacturing
- Compile QC related information (batch analysis data, stability data, method descriptions, OOS information) for specification proposals and trend review.
- Draft QC sections of regulatory submissions.
- Propose appropriate product test specifications in coordination with Manufacturing, Quality Assurance, and Regulatory Affairs
- Create appropriate internal QC procedures and systems in coordination with Manufacturing, Quality Assurance, and Regulatory Affairs. Recommend/initiate SOP updates and improvements related to QC activities
- Participate in conducting internal and vendor audits, as needed
- Report product Quality status to Senior Leadership
- Perform other related duties as assigned from time to time based on company needs such as technical site visits

Qualifications/Job Requirements

- A minimum of 8-10 years of pharma/biotech industry experience in drug development including experience in clinical drug development, commercialization, and general regulatory knowledge.
- BS Degree or equivalent experience in a scientific discipline
- Knowledge of GMP regulations, ICH guidelines; as well as CMC content of regulatory submissions.
- Knowledge of structure/function and appropriate analytical methods used in product characterization
- Ability to conduct investigations of OOS results and other QC related issues through critical thinking
- Strong and effective verbal and written communication skills with solid organizational, time management, and project management skills.
- Ability to identify QC issues/discrepancies and effectively resolve discrepancies within the organization
- Flexible schedule to accommodate regular telecons with contractors across multiple time zones and occasional (approx. 10-20% post COVID-19) travel

Success Factors

- Ability to be self-directed and set priorities to meet organizational goals.
- Ability to work collaboratively and effectively with others in a remote environment
- Ability to work under pressure and meet deadlines
- Strong analytical and communication skills
- Well organized and detail oriented

Location

United States. We operate in a virtual environment, with most employees working from home. Some travel, post COVID-19 pandemic, 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.

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 for people impacted by serious rare diseases with significant unmet medical need and make them broadly accessible. 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