POSITION PROFILE:

Director Regulatory Affairs

www.acertx.com

September 2021

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.

Location – United States

As a part of the Acer team, you will have the opportunity to work where you're most productive. We have offices in Newton, Massachusetts and Bend, Oregon. Some travel, post COVID-19 pandemic, to our East Coast (Newton, MA) and West Coast (Bend, OR) offices may be required, as well as other US meeting locations.

However, most of us work out of a home office, co-working space, in a rainforest, at the beach, on a train, in a plane, you name it, we're there. We're a talented, unconventional and collaborative team that knows no boundaries who are always looking to work smarter and support one another. In addition to ultimate work flexibility, we also provide world-class benefits to support the ongoing health and wellness of our employees and their families.

Reporting Relationship

The Director will report directly to the Head of Regulatory Affairs.

Job Description

The Director is part of the Regulatory Affairs team and will be an integral member of our team in advancing our programs. He/she will primarily function as a Regulatory leader and is responsible for ensuring the execution of regulatory strategy in line with the registration strategy of a project in collaboration with the Head of Regulatory Affairs.

He/she is expected to provide regulatory support for multiple Regulatory Affairs programs that may span proof of concept (PoC), development, registration, approval, launch, and post-approval projects within Acer's portfolio. This role requires an individual with a collaborative and innovative approach to work with our cross-functional teams, and the ability to 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. This position is also responsible for providing internal expertise on FDA regulations governing promotion and advertising of assigned products.

Responsibilities

- Manages and ensures execution of regulatory strategies.
- Leads preparation, coordination, authoring and monitoring of submissions (e.g., IND/NDA submissions, annual reports, investigator brochures, IND amendments, briefing book for FDA meetings, adverse event reporting) and responses to FDA information requests and interacts with Regulatory Operations to submit electronically.
- Reviews nonclinical, clinical and CMC documentation (e.g., nonclinical study reports, clinical protocols/study reports, investigator brochures, CMC information/data) and contributes to content as needed.
- Ensures quality and content of submissions to FDA (or other Health Authorities).
- Monitor external environment for changes to applicable regulations and standards, assesses and communicates regulatory requirements ensuring activities are in compliance with applicable regulations and guidelines.
- Advises team members of major regulatory issues and provides possible solutions and may lead the mitigation strategy.
- Represents regulatory affairs on project related meetings and provides regulatory updates and input as appropriate.
- Leads and coordinates project team members in developing strategy for applicable documents/activities.
- Leads the documentation of regulatory interactions including decisions and outcomes.
- May lead FDA meetings and liaise with FDA and company governance boards for assigned projects.
- Assist with the development of regulatory risk assessment profiles through the research, review and interpretation of related product approvals, current regulatory guidance documents and recent public Advisory Committee proceedings to support the successful submission activities and achievement of target product labeling.
- Ensure compliance with regulatory requirements and adherence to regulatory internal policies and processes.

- Participates in the promotional review committee along with Marketing, Legal, Medical/Clinical team members in the development of advertising and promotional materials.
- Conducts regulatory review of promotional and non-promotional materials in accordance with business goals and objectives, FDA/Health Authority regulations, ICH guidelines, PhRMA guidelines, company policies and established precedents and recommends revisions/actions that balance risks and opportunities.
- In collaboration with the Regulatory Operations, ensures all submissions to the Office of Prescription Drug Promotion (OPDP) are complete and presented to facilitate agency review.
- Collaborates effectively with Regulatory Operations.
- Maintains professional working relationships with colleagues, fostering collaboration, and idea sharing.
- Contributes to budgets, forecasts, and inquiries for Regulatory Affairs.

Qualifications

- Bachelor's degree (preferably in a scientific discipline); higher degrees preferred.
- Minimum 10 years prior pharmaceutical industry experience; minimum 8 years' focused experience in Regulatory Affairs.
- Requires a detail-oriented self-starter with excellent organizational, planning, and follow-up skills, as well as communication, teamwork, and interpersonal skills.
- Demonstrated ability to adapt to changing priorities and work effectively in a fast-paced organization to achieve results, meet tight competing deadlines, juggle multiple priorities.
- Demonstrated ability to facilitate appropriate team decisions.
- Experience contributing to electronic regulatory submissions and working with regulatory templates.
- Solid understanding of medical terminology, and FDA and ICH regulations/guidance specific to clinical research and general product development in the pharmaceutical industry.
- Experience reviewing nonclinical, clinical and CMC documentation (e.g., nonclinical study reports, clinical protocols/study reports, Investigator Brochures, CMC information/data) and contribute to content as needed.
- Understands issues, problems and opportunities by comparing data from different sources to draw conclusions and then choose a course of action or develop the appropriate solution.
- Capable of effectively negotiating with others while maintaining composure.
- Experience interacting with the FDA.
- Experience in successfully leading teams.
- Develop and prepare successful regulatory strategies and the ability to contribute to the development and writing of regulatory strategy documents in coordination with clinical plans and marketing objectives.
- Proven success/major involvement in submissions and approvals.
- Ability to learn new therapeutic areas when necessary.
- Prior history with post-marketing/brand optimization strategies and commercial awareness.
- Expertise on regulations governing promotion and advertising of assigned products.

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 is committed to continuously work to create a diverse and inclusive workplace and is proud to be an equal opportunity employer. Our goal is to promote a culture where diversity of thought, backgrounds, gender, gender identity, race, national origin, sexual orientation, religion, genetics, disability age or veteran status, is given equal consideration for employment.