POSITION PROFILE:

Sr. Manager/Associate Director, Manufacturing

Acer Therapeutics Inc.
(Nasdaq: ACER)
One Gateway Center
Suite 351
Newton, MA 02458
www.acertx.com

July 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 are 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 Sr. Manager/Associate Director, Manufacturing will report directly to the Senior Director, Manufacturing.

Job description

Acer is seeking a Sr Manager/Associate Director, Manufacturing to develop and manage manufacturing, packaging and supply chain operations for clinical and commercial drug products at contract manufacturing (CMO) facilities.

Responsibilities

- Manage and interface (including person in plant oversite (PIP)) with CMOs to ensure finished dosage form and related primary packaging operations are completed in compliance with cGMP requirements.
- Establish and drive appropriate timelines and deadlines for both internal and external manufacturing tasks.
- Drive development and/or technical review of manufacturing documents (batch records, formulation/process data, protocols, reports).
- Provide manufacturing expertise to CMOs during manufacturing campaigns including assistance with troubleshooting.
- Identify manufacturing problems and initiate/coordinate manufacturing investigations with Quality Assurance
- Review technical information for different manufacturing operations and assess change controls and deviations. Review routine reports, Non-Conformance and Corrective Action and preventive Action (CAPA).
- Drive product development and process optimization
- Compile CMC related information and draft CMC sections of regulatory submissions

Current Product Specific Responsibilities

- Support manufacturing activities, including PIP and process validation ,for NDA submission and potential launch for ACER-001 for treatment of Urea Cycle Disorders
- Support manufacturing and development activities for related to drug product manufacturing across multiple programs
- Support additional pipeline activities as new projects arise.

Success Factors

- Ability to work collaboratively and effectively with others
- Ability to work under pressure, determine priorities, adapt to change, and meet deadlines
- Strong analytical and communication skills
- Self-directed, well organized and detail oriented

Job Requirements

- A minimum of 5-7 years of pharma/biotech industry experience in drug development including experience in clinical drug development, commercialization, and regulatory knowledge. Minimum of 2-4 years' experience managing CMOs with 2-4 years' experience managing process validation is preferred.
- BS or equivalent combination of education and experience in Chemistry, Biology, Biochemistry, Pharmaceutical Science, Pharmaceutical or Chemical Engineering or related field
- Strong scientific knowledge and understanding of product development with relevance to drug product manufacturing, and packaging.
- Knowledge of GMP regulations, ICH guidelines; as well as CMC content of regulatory submissions.
- Displays sense of urgency to resolve problems that arise during drug development and manufacturing. Able to develop solutions to complex problems and influence resolution both internally and externally.
- Good verbal and written communication with solid organizational, time management, and project management skills.
- Familiarity with pharmaceutical supply chain management
- Flexible schedule to accommodate regular telecons with CMOs and travel up to 30%
- Experience in rare disease products desirable
- Finally, the candidate will need to embrace our ethos and 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 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 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.