Apellis

Position: Project Manager – Regulatory/CMC

Location: Waltham, MA

Description:

As a Project Manager at Apellis, the successful candidate will provide strategic leadership and operational expertise in support of various Regulatory and CMC projects having a direct impact on our complex clinical development programs. This role is responsible for liaising with Regulatory and CMC colleagues on selected programs to coordinate and develop Regulatory and CMC strategies, submissions and compliance activities to facilitate successful outcomes.

Job Responsibilities:

- Coordinate Regulatory and CMC teams to effectively manage activities and timelines
- Leverage input from key stakeholders to create integrated development plans that identify key Regulatory and CMC goals, milestones, timeline, risks, assumptions, alternative scenarios, and budgets
- Foster strong relationships with team members and functional line managers, and serve as key point person for regulatory and CMC on project-related communication, issue identification, and management
- Develop and maintain knowledge of US, EU and ROW regulations
- Perform literature searches and assembling documentation to support project teams
- Additional duties and responsibilities as required

Experience and Background:

- Degree in a scientific discipline, or equivalent
- Minimum of 8 years of total pharmaceutical industry experience, including at least 2 years in a project management role
- Significant experience within the pharmaceutical industry, and strong understanding of all aspects of drug development, Regulatory and CMC specifically
- Knowledge of GMP, GCP, GLP, and ICH guidelines
- Significant experience across drug development stages from research candidate evaluation to late-stage development; phase III experience preferred
- Strong leadership skills, including demonstrated ability to lead a cross-functional team, and influence at all levels of an organization.
- Experience in the application of program management principles and practices
- Excellent oral and written communication skills, including presentation and facilitation
- Ability to work independently and with flexibility to handle work flow in a fast-paced environment
- Some travel will be required, up to 25%

Apellis

Apellis is…

A clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

Visit **http://apellis.com/about.html** to learn more.

EEO Statement:

Apellis is an equal opportunity employer and complies with all applicable federal, state and local fair employment practices laws. Apellis strictly prohibits and does not tolerate discrimination against employees, applicants or any other covered persons because of race, color, religion, creed, national origin or ancestry, ethnicity, sex (including pregnancy), gender (including gender nonconformity and status as a transgender or transsexual individual), age, physical or mental disability, citizenship, past, current or prospective service in the uniformed services, genetic information, marital status, AIDS/HIV status, smoker/nonsmoker, and occupational pneumocononiosis or any other characteristic protected under applicable federal, state or local law.