**CMC Regulatory Affairs Project Manager**

Position Type: Full-time

Location: Rockville, MD

Immediate Supervisor: Senior Director of Regulatory Affairs

**Position Description:** As a project manager of regulatory affairs (RA) CMC in Rockville, MD, you will play an important role in developing innovative drugs that provide patients with treatment options that work better and cost less.

Reporting to the CMC Lead of US regulatory affairs, the project manager of regulatory affairs CMC is a regulatory professional with strong project management capabilities responsible for coordinating the end-to-end planning, coordination, and execution of the CMC portion of regulatory deliverables, such as INDs, BLAs, and meeting packages, etc. This person is also an integral part of the regulatory affairs team in establishing and implementing procedures and processes for regulatory affairs within the company. This person is expected to work with various cross-functional teams (CMC, clinical, nonclinical, and commercial) and external vendors to ensure the delivery of objectives.

**Essential Responsibilities:**

* Coordinate the planning, preparation (including authoring where relevant), and delivery of CMC related modules in IND and BLA submissions throughout the product’s life cycle from pre-IND to BLA approval, under the guidance of regulatory affairs CMC project lead
* Lead and coordinate all internal and external RA related meeting planning
* Coordinate the identification of regulatory risks and corresponding mitigation plans with cross-functional teams.
* Execute and maintain CMC submission delivery plans, submission content plans, and proactively provide status updates to all relevant parties.
* Serve as the point of contact between RA CMC project management and internal/external stakeholders for the specified projects
* Participate in the development and establishment of appropriate procedural and process flows within the RA group

**Qualifications:**

* Strong project management skills
* 0 to 3 years/3+ years of experience of regulatory affairs or equivalent in drug development including product approval/launch
* Extensive working experience within the biopharmaceutical industry or at a health authority
* Thorough understanding of drug (biologics) CMC development process
* Self-motivated and goal oriented
* Ability to work with multi-disciplinary project teams without authorities

**Education:**

* Bachelor's Degree, Master's Degree or higher in science and related field
* A RAC certification is “nice to have” but not required

**Language Skills:**

* Superior written and spoken communication skills in English
* Ability to communicate complex issues

**Please send your Resume/CV to** **jobs@topalliancebio.com, Attn: Emily Xu, HR**