**Associate Director/Director, CMC Regulatory Affairs (Biologics)**

**Company Overview**

Genescience is a focused healthcare company and a leader in endocrine and growth disorders. We are expanding our research unit in therapy areas of endocrine disorders and chronic metabolic diseases with the mission to discover novel treatments for patients inflicted with those disorders.

**Position Overview**

This position is reporting to Head of Global Regulatory Affairs and will be responsible for the implementation of regulatory CMC strategy in support of overall global regulatory CMC activities, from early phase clinical through marketing applications for multiple projects and teams simultaneously. This position will also provide support for the delivery of high-quality regulatory submissions, including directly preparing submission content and managing submission project deliverables and timelines.

**Key Responsibilities**

* Lead the development, implementation, and execution of regulatory CMC strategy
* Ensure all regulatory submissions and CMC projects align with defined regulatory strategy and proactively identify gaps/work with teams to develop mitigation proposals
* Work in cross-functional matrix project teams in regulatory, chemical, and pharmaceutical development and manufacturing areas
* Maintain high quality standards and raise performance through continuous improvement in the evolving regulatory environment
* Lead initiatives for project and timeline management in support of regulatory CMC objectives and projects
* Actively participate/lead regulatory CMC infrastructure and capability building, including developing best practices, training tools, and cross-program learning
* Represent regulatory CMC in co-operative multi-disciplinary meetings/forums

**Basic Qualifications**We are looking for professionals with these required skills to achieve our goals:

* Ph.D. degree in Chemistry, Biochemistry, or related pharmaceutical science required
* 6 or more years of direct CMC regulatory experience in pharmaceutical industry or regulatory agency
* Sound understanding of chemistry/biochemistry for biological products.
* General knowledge of US regulatory framework, with demonstrated understanding of US FDA regulatory requirements and guidance as applicable within technical expertise area
* Demonstrated ability to work effectively both independently and in a collaborative/team environment, with the flexibility and strength to navigate high-stress situations with multiple disciplines and personalities.
* Demonstrated strong organizational skills, including ability to prioritize work tasks across multiple projects and timelines. Direct project management experience is a plus.

**Job Location**

US Remote