CMC Regulatory Specialist Job Description

MENTRIK Biotech, LLC is a fast growing oncology-based drug development company located in Dallas, Texas. We are recruiting for a CMC regulatory specialist with experience in antibody manufacturing. The CMC specialist will collaborate with the research team, including biostatisticians and international antibody manufacturers, and others for drug development and manufacturing in the pharmaceutical and biotech industry.

Responsibilities include:

- Writing regulatory documents and serving as in-house regulatory expert to internal and external parties
- Overseeing the development and formulation processes at our manufacturing site and providing relevant guidance and advice to expedite the manufacturing process while ensuring conditions for meeting regulatory requirements are maintained
- Be responsible for maintaining up to date knowledge of regulatory affairs
- Serve as a liaison between our company and regulatory bodies
- Responsible for overseeing biosimilarity assays with the intent of obtaining clinical-grade material
- Responsible for obtaining FDA and EMA approval of new batches of antibody in order to initiate Phase III clinical trials

Qualifications:

- M.S. or PhD in chemistry, biology, pharmacology, or closely related field
- Minimum of 5 years of regulatory affairs industry experience specific to antibody manufacturing
- Significant CMC and line management experience with demonstrable knowledge of the manufacturing and regulation of biotechnology products for human use
- Successful experience in negotiations with regulatory bodies and experience writing CMC documents that comply with regulatory requirements
- Ability to maintain high standards of professionalism, quality, and prioritization

About MENTRIK Biotech:
MENTRIK is committed to the development and optimization of antibody-based therapeutics, targeting unmet therapeutic needs. MENTRIK's lead drug has completed Phase I and II clinical development. The company is now developing a Phase III clinical trial to investigate the efficacy of the drug for the treatment of non-Hodgkin's lymphoma. Additional trials in autoimmune diseases are also in development, and MENTRIK is pursuing additional in-licensing opportunities.

MENTRIK is a dynamic and diverse team composed of individuals with drug development experience and energetic professionals. This is an exciting opportunity to join a start-up company led by highly successful entrepreneurs and contribute to a rapidly developing biotech industry.

Please email a résumé to Adrienne O'Reilly, aoreilly@mentrik.com, for review.