

Senior Scientist for Quality Studies of Biologics

Location: Nanjing

Report To: Senior Director of PD & MFG Dept. and/or Director of QC Dept.

Job Description:

GenScript ProBio is seeking a senior scientist who has the professional skills in studies of biologics for developing biologics testing platform (physicochemical & biological). This position needs the ability to understand methods of investigating structure, purity, and function of biologics, preferably with experience in IND application in aspects of preclinical studies. This position also will work closely with the CMC process development department and regulatory department.

Responsibility:

1. Responsible for improving the capacity of the platform of biologics studies and establishing the core competency of this platform. Responsible for the development, optimization and qualification of analytical methods for biologics (including antibodies, recombinant proteins and other recombinant biological products). The analysis methods include but are not limited to the following: protein concentration, purity, related substances, impurities (HCDNA, HCP, etc.), safety (bioburden, endotoxin, sterility, etc.), structural analysis (disulfide bond analysis, peptide mapping, etc.), post-translational modification (glycosylation, deamidation, oxidation, etc.). The analytical procedures include but are not limited to: LC-MS, CE, HPLC, UHPLC, electrophoresis, ELISA, WB, qPCR, etc.
2. Responsible for conducting systematic preclinical studies on biologics in accordance with the requirements of NMPA, FDA, etc.
3. Responsible for ensuring the compliance of the platform In accordance with the requirements of NMPA, FDA, etc, including but not limited to: transparency, traceability, and data authenticity; electronic record management; audit trails; instrument calibration and validation, etc.

Job Code CBA-NJ-06



4. Responsible for managing and implementing CMC projects, especially the part of quality studies.
5. Responsible for communicating VIP clients.

Qualification:

1. PhD in biopharmaceuticals, (bio)analytical chemistry or related fields, or Master degree with years of experiences in the field of biologics quality studies.
2. Good organization skill, strong communication skill, strong learning ability and team management ability.
3. Strong background in instrument analysis, proficient in mass spectrometry and liquid chromatography, etc.
4. Ability to communicate in both Chinese and English.

Please send inquiry with Job Code identity to:
tammy.chen@genscript.com