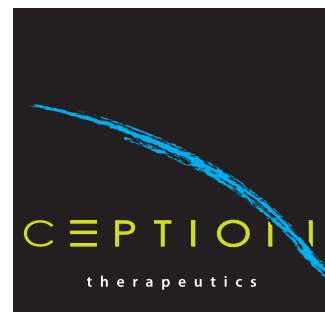


Ception Therapeutics, Inc.

Ception Therapeutics, Inc. is an emerging biopharmaceutical company focused on the discovery and development of novel products to address areas of unmet medical need. The Company's pipeline includes a late-stage biologic agent in clinical development for multiple inflammatory conditions, a small molecule anti-TNF program and other discovery programs. Ception Therapeutics pursues new drug targets in these and other disease areas through a proprietary thermodynamics-based rational drug design platform. For further information, visit [HYPERLINK "http://www.ceptiontx.com" www.ceptiontx.com](http://www.ceptiontx.com).

**Position:**

Principal Scientist/Senior Scientist/Sr. Manager/Manager, CMC Technical Operations Support

We are seeking an experienced biotechnology professional for the Principal Scientist/Senior Scientist/Sr. Manager/Manager, CMC Technical Operations Support position. The position is responsible for supporting manufacturing and analytical testing activities related to mammalian-cell culture-based bulk protein drug substance at third-party contract sites. Major duties and primary responsibilities include: supporting production, scale-up, process validation, and analytical testing of bulk protein drugs for commercialization, serve as person-in-the-plant during production, reviewing manufacturing records, process validation, analytical testing and validation documentation and CMC regulatory sections for technical accuracy, and supporting investigations and deviations at contract sites. Ability to support fill-finish drug product production related activities is a big plus. It does not have a supervisory role. It requires up to 30% travel. The position reports to Head of Chemistry, Manufacturing and Controls and is located in Malvern, PA

Responsibilities:

- Reviews production batch records, and process validation documentation for bulk protein production from contract organizations for technical accuracy and regulatory compliance.
- Shares a role as person-in-the-plant during production at contract sites. Travels up to 30% to observe production of bulk protein drug substance for clinical and/or commercial use at contract manufacturing organization sites.
- Ability to support fill-finish protein drug product activities is a plus.
- Reviews documentation for release, stability, and characterization assays, analytical test methods qualifications, validation protocols and reports, and specifications for bulk protein from contract organizations. This includes assay for clinical product raw materials, production intermediate, bulk drug samples, environmental samples, process validation and cleaning validation samples, investigation samples.
- Supports investigations of laboratory test results of release and stability testing for non-conformance to specifications, cGMP and regulations.
- Supports deviations and failure investigations related to bulk protein manufacturing records/specifications, and process validation activities.
- Supports in pre-approval inspections and GMP inspections.
- Drafts, reviews/authors validation protocols/reports, SOPs, bulk protein production records and other associated documents.
- Authors and reviews technical reports, standard operating procedures and applicable sections of regulatory submissions.
- Deploys strategic thinking for coordinating multiple tasks and positively responding to changing priorities.

Accountable for accuracy, validity, and timeliness of document reviews. Reviews data for unusual trends and notifies supervisor of potential problems. Participates in investigations to resolve and correct discrepancies. Analyze and interprets project/study investigation results and findings. Learns to determine the next steps under guidance from supervisor and in compliance with regulations; carries out technical and administrative tasks as assigned. Strong flexibility in daily duties and changes in assignments, and extensive team work are essential. Makes a positive contribution demonstrated by making suggestions for improvement, learning new skills, procedures, and processes.

Ph.D. or MS in Biotechnology/Biochemical Engineering, Biology/Chemistry, Pharmaceutical Sciences/Industrial Pharmacy or equivalent degree and a minimum of 5-8 years post-PhD and 8-12 years post-MS working experience in Process Sciences/Process Technology or Technical Operations/Support in the Biotechnology Industry. Having demonstrated required work experience in support of manufacturing, scale-up, technology transfers and process validation of mammalian-cell culture-based bulk protein production and analytical testing at contract sites is a must. Prior working experience in a virtual biotech company is highly desirable. Familiarity with aseptic manufacturing for bulk proteins, cGMPs, ICH, FDA and EMEA regulations is required. Proficiency in technology transfers of fill-finish protein products is a big plus. Experience in technical writing/reviews, and meeting presentation preparations is required. Excellent written and verbal communication skills, multitasking skills and a highly motivated, detail-oriented team player are highly desired.