PIONYR IMMUNOTHERAPEUTICS

Position: Senior CMC Engineer, Upstream

Pionyr Immunotherapeutics Inc. is a growing South San Francisco-based immuno-oncology company focused on novel approaches to cancer immunotherapy. We are seeking an experienced, motivated and committed CMC Engineer to drive our monoclonal antibody upstream cell culture activities. This role reports to the SVP, Technical Operations and will play a key role in the scale-up, validation and tech transfer of our upstream development methods and processes. We are open to candidates with senior level industry and leadership experience.

Responsibilities include but not limited to:

- Guides CDMO upstream process development activities including cell line development, clone selection, cryopreservation, small scale model development/qualification, scale-up (1-1000L), process characterization, and validation.
- Demonstrates innovative design, development, and execution of process development projects through literature review, industry knowledge, and scientific teamwork.
- Leverages strong understanding of mammalian cell culture, scale up, and bioreactor design, to design, assess and interpret experimental data, using DOE and statistical techniques.
- Develops robust, scalable, transferable processes for upstream production of clinical material. Leads process transfer from and to CDMO and supports regulatory filings.
- Assure cGMP compliant cell line development, cell banking, manufacturing, and material supply for production of research, toxicology and clinical materials to meet project timelines.
- Establish relevant cGMP documents and technical packages to support successful implementation of process technology in clinical/commercial manufacturing operations.
- Internal to external, and external to external transfer of cell lines, methodologies, technical process/analytical packages, manufacturing processes and documentation to support drug substance/drug product manufacturing and follow-on support.
- Lead from the desk (designing studies, analyzing data, reviewing and authoring reports, documents, and regulatory filings), with prior experience from the bench (hands-on laboratory work), provides support at CDMO.
- Provide leadership and influence as a primary contact with various CDMO.
- Authors and reviews study reports, process characterization reports, transfer documents, and regulatory documents. Authors manuscripts and presents results at appropriate scientific meetings.
- Maintains a current awareness and contributes to current scientific literature; actively applies new concepts and technologies as appropriate.
- Leads and supports research initiatives such as new technology development and continuous improvement projects.
- Observes and complies with Company's and CDMO's Safety policies and procedures.

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Requirements:

- PhD (Chemical engineering, Bioengineering, Biology, Biochemistry, Immunology, Virology, or related field) with 2+ year experience, MS with 5+ year experience, or BS with 10+ year experience in process development of biologics or cellular therapies with background in protein engineering preferred.
- Knowledge and working experience of upstream (cell culture) process development in mammalian cells, including (flask, ambr, DASBOX, DASGIP, single use bioreactors, and scale up (1-1000 L), media development/optimization, process scale-up, bioreactor design, harvest, and Good Manufacturing Practices (GMP).
- Experience with process characterization and technology transfer is essential. Expertise in DOE and statistical analysis of data is highly desirable, as is experience in process troubleshooting, deviation management, and root cause analysis.
- Successful demonstrated ability to work independently and support others in designing and executing experiments, processes, analyzing and interpreting data, and troubleshooting.
- Ability to work in a team-based environment cooperatively and supportive of multiple viewpoints and approaches.
- Ability to assess and triage risk, negotiate and influence, and lead CDMO as primary liaison without direct authority to drive for best development path forward and successful commercialization.
- Ability to multi-task and support more than one project simultaneously.
- Understanding and knowledge of US/EU regulatory requirements for biologic products (CFR, Eudralex, and ICH guidelines), and experience in authoring CMC sections of IND filings.
- Strong organizational skills, analytical and problem-solving skills
- Strong communication skills, both written and oral, with demonstrated ability to present ideas and information and data effectively via one on one discussions, team meetings, and teleconferences.
- Technical SME across multiple aspects of industrial mAb platform preferred, including product and process development, upstream cell culture, downstream purification, technology transfer, formulation, validation, manufacturing, and quality.
- Internal/external analytical assay development/qualification experience, including in-process and drug substance/drug product release, is a plus.
- Ability to travel domestically and internationally 15%.