

Senior Bioprocess Associate

Company Overview

NextCure is a clinical-stage biopharmaceutical company located in Beltsville, MD, focused on the discovery and development of first-in-class immunomedicines for the treatment of cancer and other diseases We are committed to professional development in the context of learning, managing, and developing our employees. We create a unique environment for our employees, providing exposure to various facets of our operations cultivating career growth and development.

Role Summary

We are seeking highly motivated engineers and scientists to lead clinical manufacturing of large molecule biopharmaceuticals. The Senior Bioprocess Associate will be expected to lead junior associates in operations in the clinical manufacturing plant in writing and execution of SOP's, batch records, deviations, and CAPA's. The Senior Bioprocess Associate will also be responsible for leading scaling-up developed process steps to pilot and/or manufacturing scale to gain a full understanding of how bench-scale development culminates into viable clinical or commercial processes. The successful candidate will work in high-performing teams, collaborate across technical functions, utilize sound scientific principles, and ultimately play a critical role in bringing innovative therapies to patients.

Responsibilities:

- Lead execution of pilot and clinical manufacturing of drug targets.
- Write SOP's, batch records
- Manage deviations and CAPA's
- Operate automated and semi-automated small, pilot and clinical-scale bioreactors and protein purification systems.
- Perform process scale-up to pilot or clinical manufacturing scale equipment using engineering principles.
- Support cell culture and/or protein purification studies at bench and pilot scale to develop bioprocessing steps for monoclonal antibodies and other complex biologics.
- Analyze and evaluate data and make sound conclusions based on scientific principles or statistical methodologies.
- Perform in-process analytical testing using Nova, cell counters, Solo VPE and other technologies
- Perform simple product quantity and quality analyses using technologies such as HPLC
- Working in teams, plan and schedule studies, develop timelines and create raw material usage plans.



Required education and experience

- Bachelor's degree in the life sciences, chemical or biochemical engineering or related field. Master's degree preferred
- 3 years of hands-on experience with execution of bioreactors or standard chromatography and filtration techniques applied in the bioprocessing industry.
- 2 years' experience in deviation and CAPA management
- Experience with standard manufacturing technologies and instrumentation
- Experience with mammalian cell culture systems and purification of antibodies or biologics.
- Experience with operation and maintenance of in-process analytics such as Nova, cell counters, pH/conductivity meters presentations and conference posters and abstracts.

Qualifications

- Knowledge and experience demonstrated by scientific accomplishments with high productivity cell lines, cell culture systems or highly innovative protein purification strategies.
- Ability to write SOP's, batch records, and management of deviations, and CAPA's.
- Experience of media and/or feed optimization to significantly increase cell culture productivity.

NextCure is an Equal Opportunity Employer and offers a competitive salary, cross functional exposure and potential career growth in a scientifically engaged team work environment.

Qualified candidates should email their resume to info@nextcure.com.