



## **Scientist / Sr Scientist Cell Line Development**

### **Company Overview**

NextCure is a growing clinical-stage biopharmaceutical company located in Beltsville focused on discovering and developing first-in-class immunomedicines for the treatment of cancer and other diseases. NextCure is committed to professional development in the context of learning, managing, and developing its employees. We create a unique environment for our employees, providing exposure to various facets of our operations cultivating career growth and development. We are excited about the ongoing work at NextCure and invite you to come join us in the culture and build your career in an environment that nurtures professional growth and development.

### **Department Overview**

#### *Development*

We develop products from gene cloning to final drug product focusing on production efficiency and ease of technology transfer and process operations. This “All Stream” approach integrates all aspects of development with the highest level of quality and is designed to improve outcomes by eliminating the traditional “silos” between cell line development, cell culture process development, downstream process development, formulation, analytical chemistry, and product characterization.

#### *GMP Manufacturing*

NextCure’s dedicated, state-of-the-art GMP manufacturing facility supports our biologics pipeline and candidates advancing into clinical development. The cleanroom space features state-of-the-art construction materials and utilizes single-use production systems. The clinical production space is designed to operate as a multi-product facility to support NextCure’s robust pipeline of first-in-class immunotherapy-based product candidates.

### **Position Summary**

The Scientist/Senior Scientist in Cell Line and Cell Culture Process Development is expected to be a technical expert in cell sciences and provide hands-on technical leadership in designing, planning, execution, analysis and reporting of cell line development and cell culture process development studies to advance NextCure’s innovative biologics pipeline products. The Scientist, either independently or in a team, would be responsible for utilizing advanced cell line development technologies, improving our current cell line development platform and developing highly productive manufacturing cell lines from DNA construct to cell banks for NextCure’s products. He/She will utilize high-throughput clone screening and process development tools to evaluate cellular productivity, performance and production processes. The Scientist/Senior Scientist would be expected to make recommendations based on study results, scientific principles and industry best practices on clone selection and process design.

## **Responsibilities**

- Plan and execute experiments using established practices and technologies to construct product specific clones from industry-standard mammalian host cell lines, evaluate clone performance, product quality, productivity and recommend primary clone.
- Improve existing clone development and screening practices. Evaluate and implement new technologies to significantly shorten construct to final clone timeline and probability of finding the most preferred clone.
- Provide leadership for cell bank manufacturing and safety and genetic characterization studies working with a contract service providers and Quality Assurance.
- Plan and conduct appropriate process development studies using high-throughput (e.g., AMBR-15 and AMBR-250) and bench-scale bioreactor systems to enable rapid advancement of development programs to first-in-human clinical studies
- Extensively utilize internal and external resources to perform media screening, process condition optimization and product quality evaluation.
- Utilize scientific principles to scale-up from bench to pilot scale bioreactor.
- Participate in internal clinical manufacturing as needed.
- Utilize QbD principles and statistical methodologies to design and analyze development studies.
- Author technical reports, participate in scientific presentations and seminars, present data and recommendations to senior management
- Provide team leadership when appropriate, participate in Project Teams for NextCure's programs, and coach/mentor scientific staff

## **Required education and experience**

- Degree in Cell Biology, Molecular Biology, Biochemical/Chemical Engineering, Biochemistry, or other related field. PhD with 3+ or Master's degree with 5+ or Bachelor's degree with 8+ years industry experience
- A strong understanding of the pharmaceutical/drug development process
- Knowledge and application of CGMP principles and working in an FDA-regulated environment
- Outstanding interpersonal, and leadership skills

## **Qualifications**

- Independent problem solving and systematic data-driven experimental design and execution
- Good understanding of biochemical engineering mammalian cell biology and cellular pathways
- In-depth hands-on experience of generating stable cell lines
- Experience of designing and executing clone screening and process development studies using laboratory-scale cell culture systems and preferably high-throughput process development tools
- Thorough understanding of mammalian cell culture-derived product characteristics and product quality
- Innovative and analytical thinker
- Ability to work under pressure and analyze processes within scheduled timeframes
- Ability to work with cross-functional teams to support CMC development activities
- Excellent organization skill
- Strong written and verbal communication skills

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](mailto:info@nextcure.com).