

Formulation Scientist, Analytical 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.

Role Summary

We are seeking a highly-motivated formulation scientist with a deep interest in contributing to the delivery of biopharmaceutical therapies to the patients to work with our Analytical Development team. The team is involved in a wide range of development activities including, formulation & analytical method development/characterization, pre-clinical and clinical study support and regulatory filings. The candidate will be expected to make significant contributions to ongoing formulation, analytical development and characterization activities to meet critical timelines and milestones for the company

Responsibilities

- Development liquid and lyophilized formulations for protein therapeutics.
- Design and perform compatibility studies
- Provide leadership in formulation development and analytical characterization of NextCure's protein therapeutics utilizing biochemical and biophysical characterization methods.
- Define and assess critical quality attribute (CQA) of products in development.
- Development and perform analytical assays to determine product quality (e.g., SDS-PAGE, Bioanalyzer/cIEF, HPLC methods such as SEC, IEX, CEX, RP-HPLC, ELISA, Octet, Mass spectrometry).
- Provide leadership and subject-matter expertise in project teams and across departments
- Author relevant CMC sections for regulatory filings. Participate in addressing technical questions from regulatory agencies.
- Participate in internal scientific discussions, author technical reports, present scientific data at meetings and maintain tight timelines.

Required education and experience

- BS/MS/PhD in Chemistry and/or Biochemistry or related field. MS/PhD in Biochemistry or related field preferred

- Minimum of 2 years of industry experience in analytical development and characterization of protein-based therapeutics required; 5 years preferred
- Experience in liquid and lyophilized formulation development of large molecules.
- Knowledge in protein chemistry concepts involved in CQA assessments, product characterization, formulation development.
- Hands-on experience using equipment such as HPLCs, Bioanalyzer/cIEF, Biacore/Octet
- Experience in authoring technical reports
- Experience working in a GMP environment
- Experience working with LIMS

Qualifications

- Strong motivation and commitment to developing personal skill set while contributing to the goals of the organization by continually improving and building their capabilities, efficiency, effectiveness, and practical implementation of state-of-the-art technologies
- Detail oriented
- Strong verbal and written 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.