Scientist I/II, Analytical Development
Cambridge, MA
Requisition Number: AD21-001

At Blueprint Medicines, as our name indicates, we are creating a blueprint for the future of healthcare. We are a leading company in the personalized medicine revolution by focusing on delivering new medicines that are targeted to the genetic driver of disease. We do this by leveraging our one-of-a-kind drug discovery platform to discover, develop and work to bring highly-selective kinase inhibitors to patients globally. This prolific scientific platform has enabled Blueprint Medicines to build a pipeline of novel therapies that span three distinct areas of medicine; genomically defined cancers, rare diseases and cancer immunotherapy.

[Objective of position]

Blueprint Medicines seeks an exceptional candidate for a Scientist of Analytical Development position to work within CMC and contribute to the overall CMC strategy of drug development at Blueprint. The ideal candidate is expected to contribute to the planning and execution of analytical development activities of small molecule candidates from the pre-Development Candidate stage through commercialization for both drug substances and drug products.

Responsibilities:
- Lead the design and execution of analytical method development, validation, and transfer for drug substances (DS) and drug products (DP) in development in collaboration with Quality Control.
- Develop and implement phase appropriate specifications in collaboration with key stakeholders.
- Apply critical thinking to the phase appropriate control strategies for DS and DP in collaboration with Process Chemistry, Formulation Development, and Quality.
- Manage analytical activities at Preferred Provider CMO partners.
- Work with Regulatory Affairs and Preferred Provider CMO’s to contribute to author, manage and coordinate analytical-related sections for clinical and commercial submissions.
- Author and/or review analytical development and validation reports.
- Author and/or review pertinent sections of clinical and commercial regulatory submissions.
- Coordinate internal and external structural confirmation and elucidation studies for Reference Materials, impurities, unknowns, etc.
- Establish and maintain effective working relationships with key internal and external stakeholders.

Qualifications:
- B.S degree in chemistry or related discipline with 5+ years or PhD with 2+ years of experience in small molecule analytical development in the pharmaceutical industry.
- Comprehensive understanding of analytical development, regulatory, and quality requirements, including GMPs and ICH guidelines, and extensive knowledge of state-of-the-art analytical technologies.
- Experience in managing analytical outsourcing activities at CROs and CMOs.
- Excellent communication skills, both written and verbal, keeping key stakeholders and management informed of status, issues and recommended solutions.

Capabilities:
- Ability and track record of successfully working in cross-functional teams to progress projects as a representative of CMC team and/or CMC team leadership.
- Ability to effectively prioritize and manage multiple projects and tasks in a fast pace environment.
- At home in a results-driven, highly accountable environment where you can make a clear impact.
- A team player, who listens effectively and invites response and discussion.
• A collaborator who communicates in an open, clear, complete, timely and consistent manner
• Up to 20% travel may be required

All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, or status as a protected veteran.

WHO WE ARE:

Blueprint Medicines’ mission is to dramatically improve the lives of patients with genomically defined diseases. Our singular focus is to use our deep understanding of the genetic blueprint of cancer and other diseases driven by the abnormal activation of kinases to craft highly selective medicines aimed at eradicating these diseases.

We don't think in small steps. We think in giant leaps.

We are driven by the pursuit of new ideas, new innovations, and new ways of thinking.

We know that what each and every one of us does matters and that our success depends on our ability to work together. We believe we are at our best as a company when our employees are thriving and foster a culture that provides opportunities to grow and develop professionally, while also having fun.