



Director, CMC

Black Diamond Therapeutics is a next-wave cancer precision medicine company. Black Diamond pioneered the development of selective medicines for patients with genetically defined cancers driven by oncogenes activated by allosteric mutations. Using its mutation, allostery and pharmacology (MAP) computational and discovery platform, Black Diamond is uncovering new ways to functionally assess the mutational landscape of individual oncogenes – to discover and validate new targets and develop novel approaches to creating highly selective therapeutics.

Black Diamond is currently seeking a Director, CMC. Reporting to the VP Preclinical Development, the incumbent will oversee Black Diamond's CMC activities from candidate nomination through clinical development, accomplished in an outsourced model. We are looking for a consummate team player seeking a collaborative environment in which to grow their career in drug development. This person will be responsible for process chemistry, formulation and drug product, and analytical development.

Key Duties & Responsibilities:

- In partnership with functional/project leaders, develop CMC plan and timelines for Black Diamond's early development programs
- Establishment and oversight of activities, including process optimization, formulation development, API and drug product manufacturing at external laboratories and manufacturing facilities
- Be the functional area representative for Drug Substance and Drug Product on project teams
- Manage CMOs and other vendors, including participation in vendor audits as a CMC expert. Oversee all aspects of CMC outsourcing including vendor selection, planning and reviewing technical content, leading technical and data-based decision making, negotiating plans, and holding CMOs accountable for delivery
- Develop integrated risk mitigation strategies for critical path issues/program risks to ensure timely delivery of program milestones
- Author and review CMC sections of regulatory documents, study reports and other development related documents
- Contribute to building and maintaining Quality infrastructure in support of external CMC operations

Requirements:

Ph.D. in Organic Chemistry, Chemical Engineering, Pharmaceutical Sciences or related discipline, with 7-10 years of relevant small molecule CMC experience in the pharmaceutical/biotech industry. Small molecule oncology experience preferred

Technical depth and a broad understanding of chemical process, analytical and formulation development.

Expertise overseeing the design of new syntheses and process improvements to achieve bulk and quality goals, to ensure that API processes and manufacture of Drug Substance can be successfully accomplished.



Experience with solid oral dosage form development with expertise in the interplay between formulation modality, bioavailability and PK. Experience with diverse oral dosage form technologies a plus.

Proficient in the management of Contract Manufacturing Organizations, leading GMP manufacturing activities, and managing drug supply for clinical studies

Operational experience and familiarity with the drug development process, including external regulatory requirements and cGMP. CMC project leadership experience is a plus.

Well versed in authoring and reviewing CMC sections of regulatory dossiers, and interactions with global regulatory agencies.

Excellent communication and organizational skills; comfortable navigating complexity and ambiguity in a fast-paced environment interacting with consultants, external vendors and internal cross-functional, global project teams. A track record of achieving results in a virtual/outsourced model.

To Apply:

Please forward applications via email only to careers@bdtherapeutics.com including a cover letter and resume. In the e-mail subject line, please indicate the position title Director CMC.

Black Diamond Therapeutics is an equal opportunity employer and welcomes and encourages all applications. Diversity and inclusion are important core values and will encourage our creativity and growth as a company.