



**Position:** Associate Director, Pharmaceutical Development

**Location:** La Jolla, California-San Diego 92037

**Position type:** Full-time

**Job Code:** 2010005

**Reports to:** Vice President, Pre Clinical Development

**Required Education:** PhD

**Area(s) of expertise desired:** CMC drug development, pre-formulation/formulation/manufacture of small molecule APIs and drug products

**Position Summary:**

Intellikine, Inc. is seeking an experienced pharmaceutical/physical scientist with demonstrated abilities to lead CMC drug development program and actively manage contract research/manufacturing organizations. This position will support drug development activities spanning API scale-up and manufacture, preformulation, formulation development and manufacture, and release testing for small molecule APIs and drug products. Participation in project teams and other internal/external collaborations, and preparation and review of regulatory/CMC documents are also important aspects of this position.

**Primary responsibilities will include:**

Oversee CMC drug development projects

Select and actively manage CROs in the areas of: API synthesis development, formulation development, analytical development, stability and clinical packaging and labeling

Author CMC sections for Regulatory filings

**Required Qualifications and Experience:**

A PhD degree (or equivalent experience) in chemistry, engineering, pharmaceuticals, or a related discipline with 8-12 years experience in the research and development side of the pharmaceutical industry.

Experience in pharmaceutical pre-formulation and formulation studies, process development and scale-up is required.

Direct involvement in preclinical/clinical drug development projects including CMC regulatory filings;

Experience with international drug development projects

Significant experience with outsourcing of drug development activities.

**Required Skills and Abilities:**

Demonstrated ability to effectively serve in cross-functional project teams as a member and/or leader is highly desirable

Must have strong written and oral communication skills and proven ability to be an effective contributor working independently or on teams.

A thorough understanding of CMC regulatory guidelines as related to pharmaceutical development of API, dosage forms, and process validation is needed.

Can prioritize multiple tasks and goals and ensure that activities are timely, on-target and within-budget

Good judgment and decision-making skills

Can prioritize multiple tasks and goals and ensure that activities are timely, on-target and within-budget

Flexibility to work in a dynamic, fast paced environment

Must have ability to travel – 20%

Intellikine offers an attractive salary and benefits package, including stock options. To apply for this position, please send us your resume at [careers@intellikine.com](mailto:careers@intellikine.com) and indicate the job code for which you are applying.