

SENIOR MANAGER/ASSOCIATE DIRECTOR, CMC API PROCESS CHEMISTRY

Crinetics Pharmaceuticals is seeking a highly motivated professional to lead activities for API process chemistry. The successful candidate will be responsible for directing the API process development and manufacturing activities at Crinetics' CMOs, including development, scale-up, validation and process improvements. This individual will be an integral part of the company's effort to discovery and develop small molecule therapeutics for rare endocrine disorders and endocrine-related cancers. This is a unique opportunity to work with a proven and well-funded drug discovery and development team in a small company environment in the heart of San Diego's biotechnology community.

Responsibilities

- Plan, direct and oversee CMC API activities related to API physico-chemical characterization including solid state characterization, identification of salt form and stable polymorphic form
- Plan, direct and oversee phase appropriate CMC API activities related to process development/optimization, scale-up and validation
- Set clear outcomes/deliverables for projects and own them, staying accountable to the company management team
- Provide budget, manage financials and forecast API expenditures (including expenditures with CMOs and consultants)
- Forecast CMC API related expenses (including expenditures with CMOs and consultants)
- Prepare and review regulatory filings (including INDs, IMPDs, NDAs, briefing packages and other regulatory dossier) to enable an efficient drug development program
- Attend and participate in meetings with the FDA or other regulatory bodies
- Develop relationships with external CMOs, RM suppliers, consultants, etc. and actively manage/oversee these external parties. Evaluate and recommend external parties for API characterization and development to senior management
- Review and approve external party's technical documents (e.g., cGMP documentation with CMOs)
- Stay current on industry trend, practices and regulatory guidances
- Manage priorities and timelines while also creating value by devising new possibilities and practicing the best/most practical technologies using QbD and PAT where appropriate
- Set high standards on deliverables while managing risks such that maximum benefit is achieved on projects/programs
- Create new systems/policies and oversee these for compliance
- Provide guidance/tutoring for administrative personnel and project teams as necessary
- Provide direction/oversee EHS aspects and mitigate/manage risks
- Understand cross-functional needs to meet internal customers' requirements/timelines including chemistry, toxicology, analytical (including stability) and drug product development and accordingly provide appropriate support to management and guide them as necessary

- Provide presentations and updates as necessary to senior management
- Other tasks as assigned

Minimum Qualifications

- M.S. or Ph.D. in chemistry with at least 5 years of related technical (process chemistry, problem solving, scale-up) and management experience
- Prior experience selecting and working with domestic and international CMOs and consultants is desired
- A thorough understanding of synthetic and process chemistry and solid form science is desired
- Excellent writing skills as they relate to preparation of RFPs, protocols and reports. Preparation of regulatory documents is a must
- Excellent interpersonal skills with strong oral/written communication and presentation skills
- Excellent negotiation skills and a tactful approach that leads to high value on services obtained and outcomes achieved
- Excellent problem-solving skills
- A strong understanding of cGMP requirements and ICH and regulatory guidances
- Good judge of risks and a keen ability to analyze options and manage outcomes
- Familiarity of Quality and Regulatory Affairs as applicable to CMOs compliance and regulatory filings
- Well versed with the latest trend in API technologies and the outsourcing industry

Travel: Requires 25-30% domestic and international travel

About Crinetics

Crinetics Pharmaceuticals Inc. (www.crinetics.com) is a rare endocrine and endocrine-related cancer therapeutics company. Crinetics' benefit package includes health insurance, stock options, a 401K and paid time off, and the company provides a dog-friendly work environment. To apply, please email CV with an optional cover letter to hr@crinetics.com.