Navitor Pharmaceuticals, Inc.is realizing the potential of modulating mTORC1, the master regulator of cellular function, to develop a pipeline of therapeutics that help patients live longer and healthier lives. Our industry leading team is unlocking the promise of recent discoveries in mTORC1 biology to address a broad range of chronic diseases. Our initial clinical application is a first-in-class drug to address unmet needs in depression. For more information, please visit www.navitorpharma.com.

About the Position

Director, Process Chemistry

We are seeking highly motivated, energetic scientist who will be responsible for the API process development of small-molecule drug candidates and for manufacturing at contract manufacturing organizations (CMOs) from research through development to commercialization, developing safe, robust, compliant, and cost-effective API manufacturing processes. As a hands-on scientist, you will work in an innovative and collaborative environment, operating at a detailed technical level while keeping CMC and program milestones in mind to deliver on program goals within a defined budget.

.As a key contributor, you will

- Oversee the design, planning, and execution of multi-step organic syntheses of small molecules for scale-up.
- Support drug substance scale-up, GLP, and GMP manufacturing activities. Plan and manage API process development and manufacturing at contract manufacturing organizations (CMOs) from research through development.
- Develop safe, robust compliant, and cost-effective API manufacturing processes.
- Collaborate with external Analytical and Formulation groups to establish and implement all analytical requirements for process development; and integrate technical API information into formulation and drug product development activities.
- Develop plans and manage implementation of process qualification, process validation, and technology transfer activities to meet regulatory agency and quality expectations. Integrate quality by design and risk management principles.
- Hold primary responsibility for the chemistry sections of regulatory filings. Participate in the writing and review of scientific reports and regulatory submission documents.
- Build professional and long-term relationships with contract development and manufacturing organizations. Document and archive data and reports from CMOs.
- Work closely with medicinal chemistry and contribute to the development of the pipeline including the selection of lead candidate molecules.

Required Qualifications and Professional Skills:

- MS with at least 10 years of experience or PhD and equivalent experience in small molecule medicinal chemistry, process chemistry and process development in the biotech/bio pharma industry.
- Technical depth and a broad understanding of chemical process and analytical development
- Proven experience working with CMOs through the various stages of drug development, participating in vendor selection, developing scopes of work, planning and reviewing technical content, leading technical and data based decision making, negotiating plans, and holding CMOs accountable for delivery.
- Proven experience managing external teams.
- Demonstrated operational and collaboration capabilities and experience interfacing with vendors and regulatory agencies. Demonstrated strong communication skill and ability to work effectively across functions and with external teams is required
- A "hands on" approach to moving projects forward and an ability to be highly adaptive in a fluid and fast-paced work environment is needed.

Contact Info: Please submit your resume to careers@navitorpharma.com with the job title in the subject line of your email.

Navitor Pharmaceuticals is an Equal Opportunity Employer. All applicants must be legally entitled to work for any employer in the United States.

Note to Employment Agencies: Please do not forward any agency resumes. The company will not be responsible for any fees related to resumes that are unsolicited.