

POSITION TITLE: VP Manufacturing & Process Development
DEPARTMENT: **Manufacturing & Process Development** **DATE:** March, 2010
REPORTS TO: **CEO**

PURPOSE: The VP of Manufacturing & Process Development will be responsible for CMC activities in support of late stage and pipeline programs including commercialization of a Phase 3 product. This position is responsible for assuring a supply chain with contract manufacturers for commercial and pipeline products, generating robust CMC packages for NDA and IND submissions, scale-up strategies, technology transfer to contract manufacturers and/or partners, coordinating process and analytical development, optimization and validation. This includes providing technical leadership, strategic direction and management controls for successful planning and execution of all technical and manufacturing activities associated with our product activities (process, analytical, and formulation development, validation, technology transfer, manufacturing, and supply chain logistics) at contract development and manufacturing organizations.

ESSENTIAL RESPONSIBILITIES:

The VP Manufacturing & Process Development will be responsible for the following:

- Responsible for management and strategic direction of the Manufacturing & Process Development Department, including both inhouse personnel and contract organizations.
- Responsible for strategic assessments of contract manufacturing organizations and establishing a supply chain in support of a commercial product.
- Responsible for delivering robust CMC packages for NDA and IND submissions.
- Responsible for the day to day operation of the Department and for establishing the overall priorities, objectives, standards and measures.
- Supervise the Directors of the Department as well as hire, train, coach, develop, monitor and appraise the manufacturing and process development team members on all facets of their jobs.
- Ensure that products are of the quality required for their intended use, incorporating cGMP and other drug regulatory requirements.
- Assurance of high quality output in analytical data and methodology.
- Responsible for the execution of all agreements containing a supply, quality and/or analytical development component.
- Coordinate processes, scale-up and technical transfer strategies for clinical and commercial manufacturing that will meet the quality standards while maintaining aggressive timelines and minimizing cost.
- Design, develop and implement strategies for optimization of the process development platform process and program including necessary automation strategies.
- Manage contract laboratories for process development, formulation development and stability studies, development of assays to characterize and/or release product, scale-up (GMP supplies for toxicology and clinical studies) and transfer of processes for GMP manufacture. This also includes any analytical biochemistry and assay transfer activities.
- Oversee preparation of necessary manufacturing, packaging, and stability study documentation and reports for regulatory filings. Will be required to interact with regulatory agencies during the drug approval process.

- Participates in assessment of potential technology acquisitions.
- Maintains current professional knowledge base of process sciences, oligonucleotide manufacturing methodologies and regulatory requirements.
- Actively analyzes procedures and develops action plans to address manufacturing or process development issues as required to fulfill corporate objectives.
- Performs other tasks and projects as assigned.

QUALIFICATIONS:

- Ph.D. in a life science or other relevant field. Proven record of achievement with at least 15 years experience in the development and commercialization of pharmaceutical products.
- Experience with the manufacture of small molecule APIs and drug product (experience with antisense or siRNA products, preferred) and working with CDER and EMEA on CMC regulatory submissions.
- Experience in the development of a novel product beginning with production, preparation and formulation chemistry, manufacturing and controls (CMC) documentation and continuing through product approval is preferred.
- Experience managing contract development and manufacturing organizations, as well as experience with the design and operation of a cGMP manufacturing facility.
- Demonstrated success in executing and implementing viable solutions to potential problems in scale-up and manufacturing, and to generate a high degree of respect from internal and external team members and work associates.
- Strong, dynamic, Pharmaceutical Development experience with a proven track record of building strong relationships and creating success.

SKILLS:

- Energetic, hands-on and results-oriented.
- Strong written communication skills regarding regulatory documents for IND submissions and product approvals.
- Must also have strong verbal communication skills regarding negotiation and presentation skills.
- Dedication to quality and reliability in all work tasks.
- Track record in identifying, developing and implementing new policies and procedures.
- Strong leader with solid motivating and mentoring skills. Track record of also working with teams in a cooperative and collaborative manner with internal and external team members.
- Ability to work cross functionally with all levels of management.
- Project management computer skills (e.g., MS Project) would be an asset to this position.
- Ability to work independently and in a team environment.
- Ability to travel as necessary, consistent with project needs.