Vice President, Quality

Reports to: SVP, Regulatory Affairs and Quality Assurance

Classification: Exempt

Summary: Serve as a senior leader to provide organization-wide strategic direction and guidance for quality standards while leading the management and continued development of the Company's Quality Management System to ensure that Quality is central to the way CymaBay does business.

This role will lead maturation of the Company's quality systems to meet clinical Phase 3 development standards and ensure readiness for the companies first commercial product.

Essential Functions and Job Responsibilities:

- Establish a vision and provide long range planning of Quality System-related activities across the organization on a global scale
- Ensure compliance with domestic and international current good practice quality guidelines and regulations including Good Manufacturing, Clinical, Laboratory, Distribution and Pharmacovigilance Practices (collectively, "GXPs")
- Hire, develop and retain Quality personnel (including contract staff) and ensure a high-performing Quality organization
- Direct all Quality Operations activities for the global disposition of products
- Interact/influence technical operations teams and leadership to promote continuous improvement programs and establish a culture committed to quality excellence
- Establishes and maintains policies, plans, procedures to ensure GXP compliance with regulations governing drug development and eventual commercialization of Company's first marketed product
- Implements and manages the document control system
- Refine and maintain the Corporate Compliance program, and assure adequate resource allocation for the management of GXP audits
- Accountable for the management of document control and training systems
- Ensure quality oversight of external vendors contract manufacturing and quality
- Oversee preparations and manage preapproval and routine regulatory agency inspections
- Identifies potential areas of compliance vulnerability and risk; develops and implements corrective action plans for resolution to ensure conformity with regulatory commitments and regulations
- Provides metrics on a periodic basis to keep senior management apprised of the operation and progress of GXP compliance efforts
- Oversee development and management of budgets for various Quality departments to ensure expenditures are within budget
- Complete other responsibilities as assigned

Minimum Qualifications:

- BS degree in a scientific field (advanced degree preferred)
- Minimum of 15 years of experience in a pharmaceutical and/or healthcare organization, to include demonstrated leadership positions

- 10 or more years of experience in positions with increasing responsibilities including product quality, senior leadership and strategic planning
- Must be a proactive and engaging leader who will set the tone for the technical organization and be able to energize, motivate and develop a top-notch team
- Strong understanding and experience with quality principles, and be a change agent
- Strong business acumen and excellent written and verbal communication skills
- Demonstrate knowledge of quality systems (i.e., deviations, CAPA, change control, etc.) and their implementation
- Thorough understanding of GXP regulations and industry practices
- Knowledgeable in developing and overseeing GXP compliance systems
- Ability to effectively lead and participate on multi-disciplinary teams
- Ability to adapt to changing priorities in a “start-up” environment
- Experience with regulatory agency interactions
- Strong attention to detail and excellent organization skills
- Proficient in Microsoft Word, Excel, and Outlook or comparable software
- Ability to travel 25% domestically and internationally as required