Job Description		
Title **Director, Clinical Operations**		
Department Research and Development	***Reports to: VP, Medical Operations***	
	Supervises: No	
Effective Date: ***June 8, 2016***	*Page: 1 of 4*	***FLSA*** Exempt

Position Overview

The Director of Clinical Operations will have key responsibilities to build the clinical operations team and direct and manage all aspects of the clinical operations program in coordination with other leadership within the company. This includes strategic and operational leadership relative to the direction, planning, execution, and interpretation of clinical programs and the data collection activities. Director will establish (with internal Pierian leadership and colleagues, CRO, and approved vendors) scientific methods for design and implementation of clinical protocols, data collection systems and final reports. Director will have collaboration responsibilities with cross-functional team members in the areas of specimen kits, supplies, training, labeling, and package design. This position has overall responsibility for defining and adhering to protocols and project timelines following good clinical practice principles and operational excellence. Mentors and develops Clinical Operations staff. Directs internal staffing and performance management, including hiring, training, coaching and performance reviews. This individual has direct management responsibility for the financial success of study management; supervises and directs the staff resourcing, project implementation, and monitoring of clinical trials.

Essential Job Functions

Responsible for:

- Oversight, coordination, and management of all clinical trials, and resourcing of the studies
- Development and maintenance of short- and long-term Clinical Operations plans
- Provide expertise and guidance to the Clinical Operations group (and beyond) regarding operational best practices, company SOPs, ICH GCP, Country and Local requirements, and industry standards
- Provide oversight and leadership to the cross-functional study team(s)
- Participation in scientific discussions on study design; review all clinical protocols for assigned clinical indications prior to finalization
- Ensure projects progress to timelines, budget and quality standards (ICH GCP/ Country and Local requirements/ Company SOPs)
- Ensuring SOP and regulatory compliance of staff
- Manage study activities, including investigator recruitment and selection, study start-up, enrollment, data collection, sample management at the site level, shipping kit and vial projections, and reports
- Manage study sites and train clinical site staff to ensure specimen collection, protocol, and regulatory compliance
- Responsible for CRO selection, development of RFPs, budget negotiations, and CRO management
- Responsible for clinical site budget and contract negotiation; ensures that trials are conducted within assigned budgets, and oversee CTM responsibilities for approvals of clinical trial invoices and accruals, and trial budget management
- Planning, monitoring, and managing budgets for all clinical operations.
- Manage team members responsible for sites and CRO and vendor oversight
- Participate and provide guidance for monitoring plans, coordinating study reports, sections for Investigator's Device Brochures, and regulatory documents (e.g., IDE, PMA, CE Marking)
- Collaborate with Data and Systems management personnel to ensure collection of required clinical data

- Interact with investigators and thought leaders for protocol development, presentations, and publications
- Coordinate and participate in investigator meetings as needed
- Build and maintain contact and relationships with Key Opinion Leaders, Investigators, and clinical sites
- Participate in monitoring visits, including Site Qualification and Site Initiation, as needed.
- Participate in the on-boarding, training and mentorship of new hires
- Planning resources and tasks to meet corporate goals for timely initiation and completion of clinical studies
- Develop and review SOPs and guidelines for compliance with global regulatory requirements, including establishing appropriate processes and procedures to conduct global clinical trials
- Coordinate clinical site audit activities including pre-inspection and specimen shipping training at clinical sites
- Establish systems for tracking of various activities during clinical trials, e.g., tracking of clinical reviews, data query resolution, etc.
- Collaborate with data management, informatics, platform leads, and quality to ensure coordination and integration of specimen and clinical data points
- Develop Clinical Trial Master Files according to applicable domestic and/or international regulations and internal SOPs
- Provide regular updates (dashboards) to Clinical Management and others (as appropriate) on progress of studies
- Participate in other research related activities, as assigned

Education/Experience Requirements

- BS degree, preferably in the life sciences (MS degree preferred)
- Minimum 8 years prior relevant experience in the pharmaceutical/biotech/medical device industry or relevant clinical research organization; prefer experience building operations groups and associated infrastructure
- Demonstrated experience in project management/clinical operations and leadership (e.g. managing cross functional study teams, managing outside collaborators and CROs)
- Knowledge and experience with managing contracts (vendor and site) and clinical operations budgets
- Strong/Expert proficiency in regulatory submissions/filings (Experience with PMA and IDE preferred)
- Oncology experience preferred
- Combination of drug/device experience a plus

Knowledge, Skills, and Abilities (KSAs)

- Excellent working knowledge of FDA & ICH/GCP regulations and guidelines; knowledge of GMP and GLP is preferred
- Complex problem solving skills and an orientation toward details
- Ability to adjust to multiple demands, shifting priorities, and unexpected events while maintaining a positive work attitude

- Excellent interpersonal skills, strong written and verbal communication/presentation skills necessary to meet the needs of various audiences and cross-functional teams.
- Demonstrated proficiency in required software (MS Word, Excel, Outlook, Project, Power Point, Electronic Data Capture Systems) and computer skills
- Travel, up to 25% of the time may be required

NOTE: This job description is not intended to be all-inclusive. Employee may perform other related duties as negotiated to meet the ongoing needs of the organization. Pierian is an Equal Opportunity Employer with a strong commitment to the achievement of excellence and diversity.

PHYSICAL REQUIREMENTS CHECK-OFF FORM

Check off only the physical abilities that can be directly related to the essential functions of the job. (***Caution:*** Make sure you are not setting stricter requirements than for similar workers already employed.)

Job Title:				
Physical Activity Required	**Amount of time**			
	None	**Less than 1/3 (Occasionally)**	**1/3 to 2/3 (Frequently)**	**More than 2/3 (Regularly)**
Standing			x	
Walking			x	
Sitting			x	
Fingering or manual dexterity				x
Repetitive finger motion				x
Lifting or exerting force				
Up to 10 pounds			x	
Up to 25 pounds		x		
Up to 50 pounds		x		
Up to 100 pounds		x		
Over 100 pounds		x		
Reaching or stretching			x	
Climbing or balancing			x	
Crouching or stooping			x	
Speaking				x
Hearing				x
Seeing (with correction)				x

Completed by: *Yvette Payne* Date: 8 June 2016