Position: Associate Director (Contracts), Clinical Operations

The Associate Director of Clinical Operations, Europe will report into the Head of Clinical Operations, Europe and will be responsible for all aspects of clinical trial operational delivery for a series of clinical trials, plan and manage contracts for all trials in Europe, line manage clinical operations staff and provide functional back-up to the Head of Clinical Operations, Europe. The Associate Director provides leadership and serves as a technical and scientific resource in the conduct of Phase II to Phase IV trials.

ESSENTIAL DUTIES:

- **Directs and manages the overall execution and delivery (programme management) of a suite of clinical trials to meet metrics, quality, time and budget specifications, undertaking trial activities where required. These activities include, but are not limited to:**

  *Managing and assisting the team to ensure activities such as the development of protocols, case report forms, investigator's brochures, consent forms, study manuals and specifications are completed in accordance with timelines

  *Assuring timelines are developed for each clinical trial, communicated and managed in accordance with corporate timelines and goals

  *Assuring the clinical studies are adequately monitored, data are collected in timely fashion and cleaned for all trials

  *Assuring site selection activities are completed, appropriate information is collected and reviewed to enable timeline and efficient investigator selection

  *Assuring all functions internal and external are set up and managed to enable efficient start-up of sites

  *Effectively interfaces with other functional departments (e.g. Data Management, Biostatistics, Safety, Program Leadership, Regulatory and CMC) to facilitate completion of cross-functional study tasks and enhance communication

  *Assuring accurate estimates for clinical trial material needs are provided to CMC to plan for and adequately provision IP for each study

  *Assisting with overall study budget development for new studies (e.g. CRO, Investigator fees, pass through fees) and providing information conjunction with the Finance Department

  *Ensuring the budgets for external services are tracked by clinical operations to provide status regarding contract to budget actual

  *Assist with budget forecasting and accruals as requested

  *Responsible for the development, preparation, maintenance and adherence of team members to clinical operations SOPs

  *Responsible for ensuring training records are in place for clinical operations departments

*Provide regular updates and report on key milestones and study progress

- **Manage Clinical Operations contracts liaising with Legal, Finance, CRAs and sites to negotiate budgets and contracts across all EU trials (~0.3 FTE)**
- **Close oversight and involvement of ongoing GCP inspection readiness activities**
- **Non-trial activities e.g. SOP writing/review, process improvement**
- **Line manage, develop and mentor a number of Clinical Operations staff**
- **Provide functional back-up and acts as a point of delegation to the Head of Clinical Operations, Europe**

QUALIFICATIONS/REQUIREMENTS:

•BS / BA (Life Sciences preferred) or RN degree

•Minimum of 12 years' experience in the biotechnology, pharmaceutical or CRO environment

•Strong leadership and team management skills and experience

•Extensive budget and contract negotiation experience

•Extensive Vendor and Clinical Operations Management experience

•Management of Phase I-III clinical trials, including multi-center, and multi-country registration trials

•Experience with compliance issues, corrective action procedures and strong understanding of European and FDA Regulations, GCP and/or SOPs in a clinical operations context

•Understanding and familiarity of the drug development process

SPECIAL SKILLS / KNOWLEDGE:

•Results and goals oriented

• Experience with recruiting, hiring and managing clinical operations personnel

•Ability to effectively prioritize

•Excellent written and oral communication skills

•Accuracy and attention to detail

•Excellent cross-functional team participation skills

•Outstanding problem solving skills