

Job Description:

Director, **Biometrics**

The Director, Biometrics is responsible for building and leading the Biometrics department/line of business, which is comprised of Clinical Data Management, Clinical Data Programing, Statistical Programming, and Biostatistics. The Director develops, implements, and maintains Biometrics procedures and processes to ensure qualified and trained personnel perform timely and accurate Biometrics activities in accordance with company policies and procedures, Good Clinical Practice, and all applicable regulations. This role supports Business Development with new proposals and drives new business. This role is accountable for financial performance of the line of business, as measured by revenue, profitability and growth.

Responsibilities

- Leads Clinical Data Management, Data Programming, Statistical Programming, and Biostatistics services
- Contributes to project activities in a supervisory capacity and contributes directly to work/services that result in billable time that is in proportion to service line demands, as set by periodic budget and objective setting.
- Adheres to and develops Company policies/procedures, according to best practices for clinical trial conduct, Sponsor requirements, and relevant Standard Operating Procedures (SOPs), GCPs, ICH and ISO guidelines
- Ensures qualified Biometrics resourcing on all clinical projects through use of forecasting and resourcing to profit expectations, which includes recruiting and management of US and foreign contributors.
- Trains new staff, fosters inclusion and a cohesive working environment, and develops staff through coaching/mentorship. qualified Biometrics resourcing on clinical projects
- Serves as a point of escalation above the assigned Biometrics team member for the Sponsor of clinical trials. Responsible for the oversight of project activities and deliverables by Biometrics.
- Advises Biometrics team on actions to improve/impact project financial performance (utilization, margin, revenue)
- Implements Key Performance Indicators (KPI) to oversee proficiency and excellence of Biometrics delivery to Sponsors and within HCC to assess project health and suitability of Biometrics performance
- Contributes to Business development initiatives, including proposal development (strategy development, content generation, costing, review), prospective client outreach, and participates in Bid Defense meetings
- Responsible for the development of short-term and long-term business strategic goals to meet Company and department objectives
- Attends relevant off-site meetings for training or to represent Company, as needed
- Participate in Sponsor or vendor audits as assigned
- Actively seeks to increase operations efficiencies by reducing redundancies and drive technological enhancements
- Participates in the documentation and implementation of Company corrective and preventative actions (CAPA) plans upon request
- Other duties as assigned



Qualifications

- Bachelor's Degree from a four-year college or university in Data Science, Business Administration, Medical, Nursing, Life Sciences, or related field
- Minimum of ten (10) years in the CRO and/or pharmaceutical, biotech, or MedTech industry supporting or leading clinical projects required
- Minimum of seven (7) years experience in Biometrics required
- Minimum of five (5) years experience as line manager required
- Expert knowledge of Good Clinical Practice and FDA regulations/guidelines for clinical research, ICH and ISO 14155
- Experience in Electronic Data Capture Systems and electronic Trial Master Files required
- Experience selecting and managing vendors preferred
- Experience establishing and managing budgets
- Must be able to work independently with minimal supervision
- Strong interpersonal skills and ability to work as an effective team member and with cross-functional groups
- Must be willing to travel (domestic and internationally) and work evenings and weekends as needed
- Must be highly customer service oriented, effective at executive-level communication and have creative initiative with a positive, solution-oriented attitude
- Understands and shares the Company values of developing and maintaining good relationships internally and externally
- Excellent verbal and written communication skills
- The ability to travel 10% of the time

Position Reports to: Vice President, Clinical Operations

Position Supervises: Clinical Data Management, Clinical Data Programming, Statistical Programming, and Biostatistics teams

The Chief Executive Officer has the discretion to hire personnel with a combination of experience and education that may vary from the above listed qualifications.

This is to acknowledge that I have read and understand the above job description. This copy supersedes any others previously distributed. I have familiarized myself with the material in the job description and will conduct myself according to its contents. I further understand that Hart Clinical Consultants may change, rescind, or add to any procedure described in this job description at its sole discretion with or without prior notice.

Employee Name (Printed)

Date

Employee Signature