



POSITION DESCRIPTION

Position Title: Clinical Data Manager and Database Administrator
Supervisor: Vice President Clinical & Regulatory Affairs
Original Issue Date: May 2010

PURPOSE OF POSITION:

To oversee all database administration and management activities in support of medical device clinical trials.

PRINCIPAL ACCOUNTABILITIES/MEASURES:

- Develop, validate and administer a database for clinical trials.
- Develop and implement data management plans and processes to ensure timely project completion, high quality data integrity, and compliance with standard operating procedures (SOPs).
- Execute and oversee all data management activities under Good Clinical Practice (GCP) requirements including: Case Report Form (CRF) design; CRF completion guidelines; database design; data entry; data review; data query generation and resolution; data quality validation; database lock; and database security, back-up and archive.
- Serve as a liaison with Clinical Research Associates and clinical site staff in managing data collection and resolving data queries.
- Interact with external vendors (e.g., statisticians) to ensure requirements for data transfer are met.
- Identify and solve complex issues that affect the quality of clinical data and timeliness of clinical data management.
- All other tasks that may be assigned from time to time by corporate management.

QUALIFICATIONS & EXPERTISE:

- Knowledge of clinical research under U.S. Food and Drug Administration (FDA) regulations, good clinical practice (GCP) requirements.
- Prior experience in developing and administering databases (e.g., SQL Server, Oracle, MS Access, DataFax, etc.).
- Prior experience in data management for clinical trials in ophthalmology preferred.
- Strong attention to detail
- Excellent organizational, interpersonal, communication and computer skills.

EXPERIENCE REQUIREMENTS: Minimum three years hands-on experience in clinical database administration and data management.

EDUCATION REQUIREMENTS: Bachelor Degree minimum.