JOB DESCRIPTION

POSITION TITLE: **Manager of Clinical Resources**

Reports to: Head of Quality, AlcheraBio LLC

Duties: Coordinates the allocation of clinical and administrative resources to meet the company's ongoing and future business needs. Coordinates the improvement of AlcheraBio processes and procedures to ensure the work product is of the highest quality. Quality control of data including clarifying errors or omissions using a defined query procedure. Provide administrative assistance for clinical studies. Assists AlcheraBio senior management as required.

Supervises: Supervises Administrative Staff (Clinical Administrator, Associate Clinical Administrator and Study Assistants)

Qualifications: Requires a Bachelor's degree, preferably in a scientific discipline, or equivalent experience. Good communication skills required to interact with study team. Accuracy and attention to detail is required. Position requires significant computer skills including the ability to use Microsoft Word, Excel, and Adobe Acrobat.

Experience: Minimum of 3 years' experience in office administration, veterinary/veterinary technician experience, or scientific discipline. Experience with personnel management within a project team structure.

Specific Responsibilities

- Collaborate with the Head of Quality on AlcheraBio business needs which include, but are not limited to the following items:
  - Coordinate improvement of AlcheraBio processes and procedures:
    Timesheets, project resourcing, data management flow, study materials and goals/objectives.
  - Oversight and participation in Quality Assurance inspections by regulatory agencies and clients.
  - Identify current and future project resource requirements and assist management with hiring process to ensure projects are appropriately resourced.
- Manage and support direct reports, provide feedback and mentor their development to fulfill the requirements of their job and their role within AlcheraBio.
- Collaborate with the Head of Clinical Services and Project Managers on AlcheraBio business needs which include but are not limited to the following items:
  - Allocation of resources (administrative) to maintain efficiency and best meet client and project needs.
  - Assess administrative needs and maintain appropriate staffing to meet project targets and timelines.
  - Evaluate candidates and assist in hiring and training of employees.

Data Entry and Quality Control

- Follows established standard operating procedures and/or study specific data management plan for data transcription and QC reviews of electronic data capture systems.
- Review project needs with Project Manager and coordinate tracking and study support resources.
- Perform second data entry while utilizing science/veterinary background to ensure high quality of dataset.
- Oversee and perform QC by reviewing entries for accuracy and completeness versus hard copy case report form or copies.

Investigational Veterinary Product/Control Product (IVP/CP) Handling

- Oversee all aspects of IVP/CP inventory for specific project(s).
- Communicate directly with study Monitors and clinical site personnel regarding IVP/CP handling.
- Coordinate and maintain IVP/CP accountability.
- Write study specific IVP/CP labeling and handling procedures.
- Complete regulatory and appropriate documentation for IVP/CP shipments; includes IVP/CP that may have special handling considerations (refrigeration, etc.).
- Organize international IVP/CP shipments with Sponsor and couriers; ensuring regulatory and country specifications are met.
- Ship IVP/CP to clinical sites.
- Perform final IVP/CP accountability and coordinate final disposition of IVP/CP (to Sponsor or designated company).

Study Support Tasks

- Oversight and training for all Study Assistants, Clinical Research Assistants, and Clinical Research Associates.
- Assist Monitors, Project Managers, and Senior Management with designated tasks (protocol/form development, SOPs, tables/listings for Final Study Report, etc.).
- Maintenance of Central Files including organization and filing of documents on a regular basis.
- Scanning, bookmarking, and QC of documents to prepare for submission of study specific data.
- Work with Project Managers to determine study start up needs.
- Facilitate and create/QC of study materials, *e.g.,* study notebooks, computer tablets, Owner folders, etc.
- Assists Monitors in preparation for site visits; may also accompany a Monitor during an on-site visit for administrative support.
- Shipment of study materials, study documentation, electronic data, etc. to Sponsor at study completion.
- Provides miscellaneous administrative support, *e.g.* answering telephones, scanning documents, filing, FedEx shipments, photocopying, etc.

SIGNATURE:

_____	_____
Manager of Clinical Resources*	**Date**
_____	_____
Bryan H. Beaird **Head of Quality, AlcheraBio LLC**	**Date**

*** I have read and understood this job description.**