

Position Specification

Company: Argenta Limited
Division: AlcheraBio LLC
Title: Director, Research & Development
Reports to: Head of Clinical Research & Development
Location: Metuchen, NJ or Kansas City, KS

The Argenta Group

Argenta Limited is a highly regarded, privately owned company that was formed in New Zealand and specializes in formulations R&D and manufacturing specifically for the global animal health industry. The company owns a state of the art manufacturing plant in Auckland, New Zealand, which also houses its formulation R&D laboratory. The NZ organization currently employs approximately 150 staff including 25 R&D scientists.

In October 2008, Argenta acquired AlcheraBio LLC, a US-based CRO providing animal health clinical trial management, regulatory consulting and portfolio analyses.

The Argenta Group provides the full range of contract services from pre-clinical development through to commercial product manufacture and beyond.

The Division

AlcheraBio LLC is a leading veterinary contract research organization (CRO) and animal health consultancy with extensive experience in drafting clinical protocols, negotiating protocol concurrence with US-FDA and conducting pivotal clinical studies to Good Clinical Practice standards (GCP) and has a small team dedicated to designing and conducting market support studies and producing marketing communications. Experienced staff also undertake portfolio reviews, identifying products with animal health applications and writing development plans for product registration in the US and other developed markets.

Animal health clients include major multi-national companies, non-US based companies interested in working in the US and small and medium sized enterprises, including virtual and start up companies.

AlcheraBio is based in Metuchen, NJ and has a staff of 17 full time employees. In June 2011, AlcheraBio opened a regional office in Kansas City and is actively recruiting for additional staff that will be based at the regional site.

The Role

The Director, Research & Development will have responsibility for strategy, support and

execution of development plans and clinical studies and for regulatory liaison on behalf of sponsors ensuring excellence in service delivery.

As a key member of the senior team, the Director, Research & Development will be able to work autonomously, providing expert advice and direction to study teams and to sponsors.

Key Responsibilities

The Director, Research and Development will:

- liaise directly with sponsors/clients, providing expert advice on animal health product development
- use knowledge of global regulations (FDA-CVM, EMEA, regional agencies) to provide guidance to clients and AlcheraBio staff on requirements for product development and approval in multiple markets
- liaise directly with regulatory agencies on protocols, development plans and other dossier components
- liaise with key opinion leaders on behalf of clients
- write protocols and study reports, including those for pivotal studies
- provide input into cost estimation and proposals for GCP and GLP studies
- train staff in clinical and non-clinical study processes and documentation including GCP/GLP and regulatory requirements
- provide oversight of staff conducting GCP studies including clinical research coordinators, quality assurance/quality control personnel and data entry personnel to assure the highest quality outcome
- build trust and maintain credibility, at times under significant pressure, with competing priorities and multiple client relationships
- have the ability to establish and manage relationships with management, staff and clients
- support team and individual development
- provide project execution that encourages repeat business from existing clients
- serve as an ambassador for AlcheraBio helping to generate new business and new business leads

Minimum Qualifications

- An advanced degree (DVM, VMD or PhD) is highly desirable.
- Strong interpersonal skills
- Excellent verbal and written communication skills
- Ability to work in a collaborative culture
- Ability and desire to mentor colleagues
- Demonstrated ability to multi-task
- Computer literacy with the standard Microsoft Office products and project management tools

Experience

- Minimum of ten years experience in animal health product development

- Known within the animal health industry for high work standards, ethics, personal integrity and a focus on high quality outcomes
- Experience working directly with regulatory agencies including face-to-face meetings and contributing to regulatory dossiers
- Experience in drafting full development plans, clinical protocols and study reports
- Hands-on experience conducting clinical studies
- Proven ability to gain trust, lead, collaborate, negotiate, and influence
- Experience in management of personnel in a matrix environment

Applications

Send cover letter and *curriculum vitae* to jeagleson@alcherabio.com