



## January 2009 NAVC Newsletter www.alcherabio.com

### An Overview of AlcheraBio Clinical Study Support Services

*AlcheraBio LLC was established in 2001 to support the animal health industry. As a veterinary Contract Research Organization, we offer our clients services required for completing and assembling submissions to the FDA Center for Veterinary Medicine, including providing regulatory advice and conducting clinical trials under Good Clinical Practice (GCP) guidelines. AlcheraBio also interacts with other regulatory agencies and supports and conducts post-marketing studies.*

Our clinical study support services include:

- Working with Sponsors to design a development plan and negotiating this plan with the FDA Center for Veterinary Medicine (CVM)
- Designing protocols and case report forms
- Developing study-specific SOPs
- Identifying, recruiting, and training clinical sites
- Providing a variety of study-related functions including monitoring, project management, report writing, and quality assurance (QA) services
- Providing comprehensive data management using a double data entry system with audit trail

Since our clients range from top multinational animal health companies to emerging biotechnology and life sciences companies, their needs vary. We configure our services on a client-by-client basis to meet those needs. For example, we can provide a single monitor to support an ongoing trial, an entire team to run your development program from start to finish, or any appropriate array of services.

Once a given client's requirements have been defined, we work with the client to design a cost-effective approach to achieving the goals of the project. Our emphasis is on high quality, on-time support. Unlike some CROs, we maintain a permanent, experienced, full-time staff, which allows us to deliver the consistency that is critical to providing what our clients need when they need it.

Linda Rhodes, VMD, PhD (see profile on back page) is the AlcheraBio Vice President for Clinical Development with overall responsibility for all activities related to conducting GCP trials. Contact Dr. Rhodes at [Lrhodes@alcherabio.com](mailto:Lrhodes@alcherabio.com) or call 732 205-0192 (office) or 732 895-5420 (mobile) for additional clinical trial information, to discuss an upcoming study, or to find out about our other services.

#### News from AlcheraBio

In October of 2008, AlcheraBio was acquired by Argenta ([www.argenta.co.nz](http://www.argenta.co.nz)), a company specializing in formulation development and toll manufacturing for the global animal health industry. Together, Argenta and AlcheraBio are pleased to offer an expanded range of services to the animal health industry. Please see the back page.

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## The Argenta-AlcheraBio Combination: More Client Services

The world's first Contract Development and Manufacturing Organization (CDMO) dedicated to animal health, Argenta was formed in 2006 through the acquisition of Nufarm Health and Sciences, which manufactured animal health pharmaceuticals, and Chemlabs, an animal health research and development company. Argenta now exports to more than 40 countries but does not market its own products, preferring to operate as a research provider and manufacturer.

Thanks to our recent acquisition by Argenta, AlcheraBio can now assist companies with formulations, method development and validation, stability, and all activities required for the FDA CVM Chemistry, Manufacturing and Controls technical section. We have regulatory experience in assembling and submitting the CMC technical section, and can provide manufacturing of clinical trial materials and final toll manufacturing of animal health drugs.

For additional information about Argenta's services, visit Argenta's website at [www.argenta.co.nz](http://www.argenta.co.nz) or contact Dr. Jane Eagleson at 011 64 9 250 3192 (office), [jane.eagleson@argenta.co.nz](mailto:jane.eagleson@argenta.co.nz).

## Profile of Dr. Linda Rhodes, Vice President – Clinical Development



Dr. Rhodes received her VMD degree from the University of Pennsylvania School of Veterinary Medicine. After her veterinary clinical experience, she completed her PhD in physiology at Cornell University with funding from the NIH and then held a post-doctoral position in molecular biology at the State University of New York at Albany.

She has worked for major pharmaceutical companies, including Merck and Merial, published in peer-reviewed journals, and presented research at international meetings. She is a member of the adjunct faculty of Rutgers University graduate program in animal science where she developed and teaches a seminar on veterinary drug development. She has contributed to AnimalPharm and spoken at international animal health meetings. She is on the board of directors of the US animal health company ImmuCell Corporation, and has served on the board of the Alliance for Contraception in Cats and Dogs, a nonprofit organization.

Dr. Rhodes' extensive experience in human and animal drug discovery and development, physiology, molecular biology, and clinical veterinary medicine make her uniquely qualified to identify and maximize drug development opportunities for all species.

### A Glance at Post-marketing Studies and Other Services

AlcheraBio has expertise assisting clients to assess market opportunities in animal health and maximize market potential. We conduct post-marketing studies, which are undertaken after a veterinary product is approved for commercial use to enable an animal health company to introduce an approved product to the veterinary community, expand the use of a product among a given veterinary segment, or compare one approved product with another for the same indication. AlcheraBio services include business development, technology assessment, marketing communications, market research, technology transfer support, and technical due diligence. Call 732 205-0192 for information.