



February 2009

WVC Newsletter

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## Veterinary Practitioners Integral to Animal Health Drug Approval Trials and Postmarketing Studies

As a veterinary Contract Research Organization (CRO), AlcheraBio LLC offers animal health companies the services required for completing and assembling submissions to the FDA Center for Veterinary Medicine, including providing regulatory advice and conducting pivotal clinical trials under Good Clinical Practice (GCP) guidelines.

AlcheraBio also supports and conducts 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.

Clinical studies are conducted under specific protocols that govern the eligibility criteria for enrolling animals, provide detailed descriptions of study activities, and include other study related information and procedures. Investigators who qualify to participate in a given study are trained thoroughly. In the case of studies conducted under GCP guidelines, study monitors are assigned to perform site visits to ensure that the study protocol is being followed.

No matter how large or small a given study is, finding the right cooperating clinicians to serve as study investigators is vital to maintaining high quality and ensuring that enrollment, timing objectives, and other study parameters are met. Veterinarians who take part in clinical studies generally find them to be an exciting added dimension to clinical practice.

*If you are a practitioner interested in learning more about the opportunities, responsibilities, and benefits of taking part in clinical studies, please contact Michele Nichols (mnichols@alcherabio.com) or Georgiana Syby (gsyby@alcherabio.com) or call AlcheraBio, at 732 205-0192.*

## Formulations and Analytical Development Services, CTM Manufacturing and Toll Manufacturing

In October 2008, AlcheraBio LLC became a subsidiary of Argenta, a global animal health company headquartered in New Zealand. The world's first Contract Development and Manufacturing Organization (CDMO)\* dedicated to animal health, Argenta was formed in 2006.

The company offers formulation and analytical development services including all activities required for the drug product component for the FDA CVM/EMEA Chemistry, Manufacturing and Controls technical section.

In addition, Argenta manufactures clinical trial material and commercial animal health products to cGMP. Argenta now exports to more than 40 countries including the US and European nations but does not market its own products, preferring to operate as a research provider and manufacturer.

*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, Argenta head of business development and AlcheraBio president at: 011 64 9 250 3192 (office) [jane.eagleson@argenta.co.nz](mailto:jane.eagleson@argenta.co.nz).*

*\*What Is a CDMO? CDMOs are companies that provide comprehensive, "one-stop shopping" from drug development through commercial-scale manufacturing.*



### News from AlcheraBio

Growth is continuing at AlcheraBio. Earlier this month, AlcheraBio hired Johnny A. Jacobsen, DVM, MSc, as chief operating officer. To learn more about Dr. Jacobsen, please see the back page.

## AlcheraBio Welcomes Chief Operating Officer



Dr. Johnny A. Jacobsen received his DVM from the University of Saskatchewan and his MSc degree in applied parasitology from the University of Calgary. After establishing a mixed animal practice in Alberta, Canada, Dr. Jacobsen joined the technical services organization of Merck AgVet, now Merial, in positions of increasing responsibility. He oversaw more than 45 field trials and established critical relationships with key leaders in the veterinary community.

Later, as an executive in Merck AgVet's and Merial's global marketing and strategic planning organizations, Dr. Jacobsen authored a number of Statements of Interest and Market Opportunity Reports that resulted in new product development projects. He led global cross-functional development and marketing teams in support of the launches of two major cattle products and managed extensive product portfolios, interfacing with manufacturing, clinical development, regulatory affairs, and worldwide subsidiaries.

Most recently, Dr. Jacobsen has been at Merck & Co., Inc. where he was a global brand leader in several therapeutic areas in the Global Human Health organization.

*To get in touch with Dr. Jacobsen about AlcheraBio and its services, email [jajacobsen@alcherabio.com](mailto:jajacobsen@alcherabio.com) or call 732 205-0192.*

## Meet Dr. Cynthia Clendenin, AlcheraBio Senior Clinical Research Coordinator



Dr. Cynthia Clendenin received her BA in Biology from the University of Chicago and her VMD degree from the University of Pennsylvania School of Veterinary Medicine, where she also completed the Veterinary Business Management Program. After graduation, she had a small animal medical and surgical internship at Garden State Veterinary Specialists in New Jersey.

Prior to attending veterinary school, Dr. Clendenin established and managed a core facility at University of Pennsylvania, Abramson Family Cancer Research Institute. The facility provided transgenic and gene-targeted mice and related support services to molecular biologists. Earlier in her career, Dr. Clendenin worked at the University of Chicago Department of Medicine, Department of Organismal Biology and Anatomy, and Howard Hughes Medical Institute.

She also spent a summer participating in the NIH/Merck Summer Research Program, where she investigated the causative genes of lupoid dermatosis in the German shorthaired pointer.

As a senior clinical research coordinator at AlcheraBio, Dr. Clendenin manages CGP clinical trials, conducts site training and site visits, and deals with suspected adverse events.

*Dr. Clendenin is attending the WVC. To set a time to meet with her at WVC, please call her on her mobile number, 732 429-7184.*

### Other AlcheraBio Services

AlcheraBio has expertise assessing market opportunities in animal health and helping to maximize market potential. Other AlcheraBio services include business development, technology assessment, marketing communications, market research, technology transfer support, and technical due diligence. *Call 732 205-0192 for information.*