



## September 2009 Contract Pharma Contracting & Outsourcing Conference

[www.alcherabio.com](http://www.alcherabio.com)

*Let's say your company has a potential animal health product or may be considering possible animal health applications of a human health product, and you're attending Contract Pharma's 2009 Contracting & Outsourcing Conference. Or, you have an early stage animal health product that needs to be developed. You'll want to know that Argenta and its subsidiary, AlcheraBio, offer the perfect combination to see your product through development, manufacturing, clinical studies, and commercialization.*

AlcheraBio ([www.alcherabio.com](http://www.alcherabio.com)) was established in 2001 to provide services and consulting for the animal health industry and is a full-service animal health Contract Research Organization (CRO). The company was acquired in 2008 by Argenta ([www.argenta.co.nz](http://www.argenta.co.nz)), a global leader in animal health manufacturing, formulations, and related services. Argenta and AlcheraBio are represented at the Contract Pharma's 2009 Contracting & Outsourcing Conference by Dr. Jane Eagleson, Argenta head of client services and AlcheraBio president. To talk with Dr. Eagleson at the Conference, call her at 347 261-0065.



### The Argenta-AlcheraBio Combination: "One-Stop" Services for Our Clients

Thanks to the acquisition of AlcheraBio by Argenta, the combined company can offer clients seamless, strategic project development and management; eliminate the need to identify and negotiate agreements with different outsourcers to work on a project as it progresses through various stages; and prevent the technology transfer bottleneck that often goes along with manufacturing scale-up.

### AlcheraBio's Pivotal Clinical Trial Services

As a full-service clinical CRO, AlcheraBio offers our clients services required for drafting development plans and protocols; interacting with regulatory agencies; conducting early stage and pivotal clinical studies, including monitoring, data management and final report writing; and assembling regulatory submissions. We have experienced, in-house SAS programming and can provide QA (quality assurance) staff for all aspects of development (GLP/GCP). Our clinical research services are available in the US and we have recently expanded our clinical trial services to include Europe.

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. Our emphasis is on high quality, cost-effective, on-time support. 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.

*For information about AlcheraBio's pivotal clinical trial services in the US or Europe, call Johnny Jacobsen, DVM, MSc – AlcheraBio chief operating officer at 732 205-0192.*

## AlcheraBio Management Team

### **Jane Eagleson, DVM:**

Argenta business development manager and AlcheraBio president.

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### **Linda Rhodes, VMD, PhD:**

AlcheraBio founder and vice president – clinical development

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### **Katherine Moldave, MBA:**

AlcheraBio co-founder and vice president – market support

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### **Johnny Jacobsen,**

#### **DVM, MSc:**

AlcheraBio chief operating officer

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## Data Management Services

Many of our clients turn to AlcheraBio for data management to support their pivotal and postmarketing studies. We've developed a data management system customized to meet the needs of the animal health community. It's a double data entry system with an audit trail, secure off-site backup, and other critical features. It features an easy system for generating and resolving queries. Our in-house SAS programmer can prepare listings and reports, perform edit checks, create derived data sets, generate efficacy and safety summary reports, produce graphs, design layouts for final report tables and perform full data analysis according to the Sponsor's strategic analysis plan.

*To learn more about AlcheraBio's data entry and data management services please contact Ms. Michele Rivera or Dr. Johnny Jacobsen at 732 205-0192.*

## Quality Assurance Services

AlcheraBio offers Quality Assurance (QA) services to support GLP and GCP. AlcheraBio's QA unit is headed by Nicholas Meo, AlcheraBio senior clinical research coordinator. Mr. Meo has more than 30 years' experience in the human and animal health industries, including R&D, clinical research, QA and regulatory affairs. He has coordinated laboratory and clinical studies, monitored clinical and non-clinical studies under GLP and GCP, and served as a study director for GLP worker exposure studies. He has also established QA systems and developed and administered SOPs.

*For information about AlcheraBio's QA services call Johnny Jacobsen, DVM, MSc – AlcheraBio chief operating officer at 732 205-0192.*

## Technology Assessment and Business Development

AlcheraBio offers clients services required for assessing opportunities from technical and business standpoints, putting together development plans and protocols, designing proof-of-concept studies, interacting with regulatory agencies, conducting pivotal clinical studies, and completing and assembling product approval submissions. We have helped biotechnology and life sciences companies determine whether there are technically and commercially viable animal health applications for their technologies or products, and have assisted clients with their partnering efforts. For more information, contact Katherine Moldave, MBA, AlcheraBio vice president – market support or Johnny Jacobsen, DVM, MSc – AlcheraBio chief operating officer at 732-205-0192.

## Post-Marketing Studies and Other Services

In addition to our clinical trial and related services, AlcheraBio provides regulatory affairs consulting. We also 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 also include marketing communications, technical writing, website development, launch support, market research, technology transfer support, and technical due diligence. For more information, contact Katherine Moldave, MBA, AlcheraBio vice president – market support or Johnny Jacobsen, DVM, MSc – AlcheraBio chief operating officer at 732-205-0192.

*To learn more about AlcheraBio and meet the members of our staff, visit [www.alcherabio.com](http://www.alcherabio.com).*