



June 2009

AAVPT

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A bronze sponsor of the 16th  
Biennial AAVPT Symposium

*AlcheraBio LLC is pleased to be a Bronze Sponsor of the 16th Biennial AAVPT Symposium. AAVPT symposia have traditionally provided an opportunity for academicians, industry, students, and the regulatory community to exchange information and ideas in a comfortable atmosphere; offered an enticing blend of pharmacology education, regulatory updates, and reports on critical areas of veterinary medicine; and honored people who have made significant contributions in the field. We are delighted to support its activities.*

AlcheraBio LLC was established in 2001 by Linda Rhodes, VMD, PhD and Katherine Moldave, MBA to support the animal health industry. The company was acquired in 2008 by Argenta (see page 2). As a veterinary Contract Research Organization, we offer our clients services required for regulatory approval of animal drugs and vaccines. We provide regulatory advice and have in-house staff to conduct clinical trials under Good Clinical Practice (GCP) guidelines, including data management (see page 2) and QA (see below). We can support target animal safety studies, and provide guidance for other technical sections required by the FDA Center for Veterinary Medicine. AlcheraBio also provides guidance on approvals by other regulatory agencies (USDA, EPA), and we are now able to conduct studies in Europe in collaboration with Dr. Marie-Paul LeFay, a well-known expert in veterinary contract research. In addition, we conduct and support post-marketing studies. To learn more about us and other services that we offer please see page 2.

## Spotlight on Quality Assurance



AlcheraBio's Quality Assurance (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 (GLP and GCP), and served as a study director for GLP worker exposure studies. He has established QA systems and developed and administered SOPs.

AlcheraBio offers QA services to support GLP and GCP:

Good Clinical Practices	Good Laboratory Practices
<ul style="list-style-type: none"> <li>■ Development of QA programs for clinical studies</li> <li>■ Training of clinic staff and QA Auditors in VICH GL9 GCPs</li> <li>■ Training of clinic staff in handling FDA inspections</li> <li>■ On-site audits of procedures, records, and data</li> <li>■ Audits of databases and draft and final reports</li> </ul>	<ul style="list-style-type: none"> <li>■ Development of QA programs for new facilities</li> <li>■ Training of staff and QA Auditors in GLPs and handling FDA inspections</li> <li>■ Facility inspections</li> <li>■ On-site in-life audits</li> <li>■ Audits of raw data, databases, draft, and final reports</li> </ul>

To learn more about AlcheraBio's QA services, please contact Dr. Linda Rhodes or Mr. Nicholas Meo at 732 205-0192.

### Who's Attending AAVPT from AlcheraBio?

AlcheraBio senior managers Dr. Jane Eagleson, Ms. Katherine Moldave, and Dr. Johnny Jacobsen are attending. Senior Clinical Research Coordinator Dr. Cynthia Clendenin and Clinical Research Coordinator Georgiana Syby will also be at the meeting. Ms. Syby and Clinical Research Coordinator Ms. Rebecca Reynolds are participating in the post-symposium workshop. To learn more about these and other members of AlcheraBio's staff, as well as our broad range of services, visit our website at [www.alcherabio.com](http://www.alcherabio.com) or just speak to us at AAVPT.



Jane Eagleson, DVM, Argenta head of business development and AlcheraBio president



Katherine Moldave, MBA, AlcheraBio cofounder and vice president - market support



Johnny A. Jacobsen, DVM, MSc, AlcheraBio chief operating officer



Cynthia Clendenin, VMD, AlcheraBio senior clinical research coordinator



Rebecca Reynolds, AlcheraBio clinical research coordinator



Georgiana Syby, MS, AlcheraBio clinical research coordinator

### Spotlight on Data Management

Many of our clients turn to AlcheraBio for data management to support their pivotal and post-marketing studies. We've developed a data management system customized to meet the needs of the animal health community. The system is a double data entry system with an audit trail, secure off-site backup, and other critical features. It features an easy system for generating queries and cleaning the data. Alexander Greenberg, MS, our full-time in-house IT manager and SAS programmer, can prepare listings and tables, program edit checks, create derived data sets, generate efficacy and safety summary reports, produce graphs, and design layouts for Final Study Report tables.



Mr. Greenberg received his MS from the College of Steel and Alloys in Moscow, Russia. He has extensive expertise in SAS programming as well as other systems. Mr. Greenberg has experience in numerous aspects of software development as well as programming- and data-related clinical trial development and support. He has a thorough understanding of the processes involved in planning and conducting clinical studies and the reporting functions related to clinical trials, as well as experience generating analysis data sets, tables, listings, and study reports including efficacy and safety. Mr. Greenberg has worked with Wyeth and Schering-Plough.


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

### More about AlcheraBio

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.

AlcheraBio also helps clients assess opportunities in animal health and maximize market potential. Services include business development, technology assessment, marketing communications, market research, technology transfer support, and technical due diligence.

### An Introduction to Argenta, our Parent Company: Animal Health Formulations and Manufacturing

 AlcheraBio LLC is a subsidiary of Argenta, which is headquartered in New Zealand and is the world's first Contract Development and Manufacturing Organization (CDMO) dedicated to animal health. Argenta offers formulation and analytical development services, and manufactures clinical trial material and commercial animal health products to cGMP. Argenta exports our clients' products to more than 60 countries, including the US and European nations. For more information, see [www.argenta.co.nz](http://www.argenta.co.nz) or contact Dr. Jane Eagleson, Argenta business development manager and AlcheraBio president, at: 011 64 9 250 3192 (office) or [jane.eagleson@argenta.co.nz](mailto:jane.eagleson@argenta.co.nz).