



## **Perspectives on Pre-Clinical Outsourcing in China**

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**Mark Twain has been credited with the oft-quoted observation that “A lie can travel halfway around the world while the truth is putting on its shoes.” In the Internet age, lies travel much faster, and they lose little, if any of their punch in translation.**

In 2006, the president of a U.S.-based pharmaceutical company that had developed a preclinical testing facility in China, commented to the media that global pharmaceutical companies (“pharmas”) were moving to China because it is cheaper and faster to do animal work there, and in addition, there are no regulations. That quotation was referenced several times at a recent Animal Welfare Forum in Shanghai (March 30, 2008). Were the comments based on fact? Fiction? Accurate in 2006, but not now? It doesn’t really matter. The story continues to circulate, and it supports the public’s preferred perception of the pharmaceutical industry and its use of animals to develop and test new products.

In a 2006 Boston Globe story entitled “ Outsourcing animal testing: US firm setting up drug-trial facilities in China, where scientists are plentiful but activists aren’t,” damaging statements were made by PETA’s Asia-Pacific director, “We are very aware and very concerned about this recent and disturbing trend of companies to contract with laboratories in countries in which animal welfare oversight is poor and public awareness is low. There is no doubt this is intended to circumvent American animal welfare laws, as minimal and unenforced as those may be.”<sup>1</sup>

Both of these examples highlight several lessons: Don’t believe everything you read. Don’t believe everything you hear, even at a professional meeting. Don’t underestimate the reach and the growing acceptance of the animal rights movement around the world. Most importantly, don’t buy into the buzz that companies and institutions outsourcing animal-based research don’t adhere to the highest international standards of animal welfare by every Contract Research Organization (CRO) with which they choose to do business, no matter where they are based.

The price of cutting corners to cut costs is always too high and can ultimately hurt the entire industry. Consequently, decisions about the outsourcing of animal work must take more than economics into account; there are scientific and ethical considerations as well.

Within the industry, much attention is being paid to the issues of outsourcing in vivo research. Recent articles that offer excellent guidance for assessing CROs, include Dr. Stacy Pritt's "Working with Contract Research Organizations"<sup>2</sup> and "How to Conduct an Audit of an Outsourcing Provider"<sup>3</sup> by Andy McCallum.

There are still many questions concerning animal work in other countries; however, that require firsthand experience of the market or detailed knowledge gained by those familiar with the area. When considering preclinical CROs in China, start by reviewing the lessons mentioned above.

### **China's BioPharma Valley**

China may be old, but it is changing rapidly and fast becoming a world leader in drug discovery and development, along with out-sourcing capabilities. All eyes and energy are directed towards the future, where China sees itself filling a significant niche in the field of preclinical research. The Central Government and city governments are making huge investments in biopharmaceutical research, both public and private. High tech parks in Beijing and Shanghai are vying for the title of China's "BioPharma Valley." Every global pharma has some sort of presence in China, and companies are sending teams to visit facilities all over the country to assess their capabilities and to establish organizational relationships for collaborations for the long-term. Several Western preclinical CROs are forming joint ventures with established local operations, most of which did not exist a decade ago.

There is a race to ramp up capacity and capability (a process that takes at least two to three years, even in modern China), and native-born, Western-trained scientists are leading the charge. These so-called "sea turtles," thousands of highly educated Chinese nationals with Ph.D.s, MDs, and MBAs, are returning home, bringing back years of experience with global pharmas and biotechs. Imbued with entrepreneurial spirit and a taste for capitalism, they are a priceless natural resource and highly valued partners who know how to operate in the "new China."

### **Active Presence**

At the same time, the animal rights movement is establishing a foothold in Asia. The Chinese Animal Protection Network (CAPN), currently comprised of 40 separate groups, is an umbrella that includes the Chinese Companion Animals Protection Network, ChangChun Animal Protection Network, and Animal Rights in China (ARC). Developed over the Internet in 2004, CAPN claims to have two local branches and 10,000 individual supporters.

As of April 2008, PETA's Asia-Pacific director was advertising for a Campaign Coordinator in China "to coordinate and manage a media plan and an agenda of celebrity events, protests, and other campaign issues that can be done in China in order to bring attention to animal rights issues throughout China with a youth focus." There is no obvious link between PETA and ARC, which was started in July 2006; however, ARC's website had graphic photographs publicizing World Lab Animal Day and links to sites with horrific images that don't require translation of the text (in Mandarin) to mean that animal research is a prime target of the fledgling group.

### **Gaining Accreditation**

During the 1990s, the American Association for Accreditation of Laboratory Animal Care (AAALAC, International), a private, nonprofit organization that accredits laboratory

animal facilities according to standards set forth by the Guide for the Care and Use of Laboratory Animals founded by veterinarians and researchers in 1965, was already active in other countries outside of the United States and recognized for its commitment to enhancing life sciences and quality animal care around the world. In 1996, AAALAC changed its name to AAALAC International to describe its expanded scope. The group has accredited more than 700 organizations worldwide. To date, eight institutions in P.R. China have been awarded accreditation, and many more, public and private, are at various stages in the rigorous process.<sup>4</sup>

In preparation for the First Shanghai Animal Welfare Forum on International Standards and AAALAC's Accreditation Process for Preclinical Programs in China held at the end of March 2008, several laboratory animal experts who have visited animal facilities in China were asked to share their observations. Contrary to popular belief, they found differences but not glaring deficiencies:

*"A big surprise...all the animal facilities that I saw were incredible with superb engineering controls. However, I still have difficulty believing that they are all that good! There are concerns about ongoing oversight."*

*"The four IACUC/Ethics committees that I saw exceeded my expectations. The outcome at the cage level was as good as or better than many programs in the U.S. or EU. There are concerns about the actual authority of the IACUC and of the attending veterinarian."*

*"Veterinarians get an undergraduate BS, and have no concept of laboratory animal medicine but they want to learn!"*

Given the relative newness of the preclinical CROs in China, it is not surprising that visitors are finding state-of-the-art laboratories and well-designed animal facilities. Their learning curve has been shortened considerably due to the high level of awareness carried back by enterprising "sea turtles," and the training opportunities and resources eagerly sought by home-grown talent staffing labs and supporting scientists.

Companies that want to outsource preclinical work in China have a vested interest in playing an active role in the development of programs and facilities that meet or surpass the highest international standards of animal welfare. Industry recognizes that obstacles exist, that the science of animal welfare continues to evolve, and that now is the opportune time to collaborate in the creation of centers of excellence to rival the best animal welfare programs anywhere in the world.

## References

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