Within the past several years, a number of government labs as well as private and joint venture CRO’s have or will soon offer preclinical GLP study services to Western clients. This report, built on discussions and facility visits to the most advanced labs, provides a detailed view of the current and evolving preclinical study capabilities in China, their structures and services, as well as an analysis of the comparative costs between US and China-based CRO’s.

- Strategies being used by small, medium, and large pharmas in China
- FDA’s willingness to accept preclinical data from Chinese labs
- Advantages of conducting non-human primate studies in China
- The importance of due diligence and project monitoring
- Options for managing China programs without an in-country presence

Cost savings are real but due diligence is necessary

Eric Meyers, MBA

July 2009

Continued on next page
Outsourcing Preclinical Studies to China: Benefits and Challenges reviews the state of preclinical study services in China to identify the current level and near-term trends for compliance with Western GLP standards. Competition to supply CRO services is beginning to cause consolidation and attrition within China. A small number of key preclinical service providers, identified and profiled in this report, have emerged as strong CRO providers. Background material for this report was obtained through discussions with executives and facility visits in China. A detailed cost comparison between China and US-based CRO’s shows that study savings of between 35–50% are achievable and that these savings are likely to continue through 2012.

The cost savings associated with using CRO preclinical services in China are discussed in this report in the context of organizational and operational differences between CRO’s based in the West and in China. A number of factors are presented that study sponsors must consider before committing to a Chinese CRO. Small- and medium-sized companies can make their preclinical studies budget go further by using China-based CRO’s through appropriate due diligence and upfront project planning. FDA and EU regulators have accepted preclinical data generated by China-based CRO’s as described in the report, and the FDA has begun to build a resident inspector network in China.

This report describes the impact that language skills and the shortages of key disciplines have on how best to structure preclinical studies in China. Also evaluated are the broad issues such as IP protection and CRO ownership as well as laboratory animal rights regulations. CRO’s in China have access to large non-human primate breeding facilities and offer a clear advantage to those companies planning non-human primate studies. The report discusses the several Western laboratory mice, rat, and beagle dog vendors and well as feed providers operating in China.

Outsourcing Preclinical Studies to China: Benefits and Challenges presents an analysis of the current and near-term state of preclinical services available in China. The report begins with a short introduction to the evolution of preclinical services as well as a description of the three laboratory ownership categories. Chapter 2 presents the differences in organizational and operational structures, business practices, as well as personnel shortages and infrastructure issues. Chapter 3 provides a cost case study comparing preclinical study cost between the US and China. Chapter 4 provides a discussion of possible caveats and due diligence factors to be considered when considering placing a preclinical study in China. Chapter 5 provides profiles covering operations, facilities and services of the eleven most advanced CRO’s in China.

About the Author: Eric A. Meyers, MBA, is a consultant to the drug development and medical device industries. His 20 years in the healthcare industry includes senior management positions with Fortune 50 companies and successful startups. Mr. Meyers is a recognized expert in drug development sectors in China and India, leading projects to assist both small and large pharmaceutical companies with their Asia drug development strategies. Mr. Meyers received both an MBA and a B.A. from Harvard University.

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CHINA PRECLINICAL MANAGEMENT SERVICES
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