



## **Updates on Preclinical Development in China**

### **The Rise of China's Contract Research Sector: Evaluating Quality and Cost Benefits**

August 19, 2008

Prepared by Ernie Bush, Ph.D. and Eric Meyers, M.B.A., Cambridge Healthtech Associates (CHA)

Three years ago there were few if any western firms doing preclinical testing in China, but today there are already dozens, and within the next few years this will be commonplace --- much as chemistry outsourcing is today.

Drug developers of all sizes are re-examining their assumptions about their true core competencies, i.e. what should be done internally and what can be better accomplished through specific outsourcing relationships (see the recent Lilly-Covance deal). When companies begin to consider partnering with Chinese preclinical CROs as part of their overall development strategy, quality and cost tend to be the key variables of greatest focus.

In particular the quality, or GLP compliance issue has been hotly debated. As recently as three years ago, most experts were extremely skeptical of Chinese preclinical contract research facilities, especially those purporting to be GLP compliant. Anecdotes about sub-par labs, poor processes, and supply or equipment deficiencies abounded. Many labs with poor GLP implementations still exist, but the big change is that now the sector boasts a number of top-flight labs (CHA validated this through a thorough, systematic multi-year review of top labs in China).

Some are relatively new entrants, others are labs that have systematically invested and worked hard to learn how to meet the industry's quality and scientific standards. Anyone who has spent much time at these facilities, as we have, will attest that these labs are now as good as those in the west.

Importantly, their services are available at a much lower cost than at western CROs. Time and again we have found about a 50% cost differential for equivalent preclinical safety programs. Our in-depth analysis indicates that a material cost difference should be maintained for years to come.

At a time when all pharmaceutical and biotech companies, whether small or large, are increasingly pushing the envelope on what can be outsourced, this development means that they must also consider outsourcing a broad range of studies to China. The early adopters are now weighted towards small companies and with the path becoming more well traveled, more drug developers are setting up arrangements to leverage China for accelerated, lower cost preclinical safety programs.

Large pharmaceutical companies are going through a very different decision-making logic regarding outsourcing preclinical studies to China and there are some very clear splits today. At one end of the spectrum, a few are highly reluctant to outsource in general, and are firmly against doing so to China in particular. In contrast, some are now actively building China into their long-term plans.



## **Updates on Preclinical Development in China**

### **The Rise of China's Contract Research Sector: Evaluating Quality and Cost Benefits**

August 19, 2008

Prepared by Ernie Bush, Ph.D. and Eric Meyers, M.B.A., Cambridge Healthtech Associates (CHA)

In all cases, moving safety testing to China requires some changes in your paradigm for outsourcing and in some cases adjustments to business processes. In large companies, it also tends to be integrated into the larger, overall China strategy. Still, the emergence of facilities operating at global standards, staffed with western experienced managers, and offering meaningful cost savings has made these efforts worthwhile. Consequently, testing in China will be a reality for many western biopharmas for the foreseeable future.

We look forward to updating you via CHA's future "Updates on Preclinical Development in China" including topics on:

- current and future capacity
- types of testing to consider placing in China
- the degree and sustainability of cost savings
- animal welfare issues,
- regulatory acceptance
- the most frequent questions from our clients

---

### **About CHA**

CHA is the leading organizer and facilitator of biopharmaceutical collaboration and of the foremost experts on preclinical R&D in China. We reduce the costs of R&D by bringing together different companies to work cooperatively assess vendors in emerging global markets like China. Learn more at [www.chacorporate.com](http://www.chacorporate.com).

### **About the Authors**



**Ernie Bush, Ph.D., Vice President & Scientific Director, Cambridge Healthtech Associates (CHA)**

Dr. Ernie Bush serves as Scientific Director on CHA's multi-client, collaborative projects, serving as a liaison and facilitator. Ernie has spent over 23 years working in the field of biomedical R&D, including from working from 1992 to 2005 at F. Hoffmann-La Roche, Inc., the last 5 years of that time he led their Non-Clinical Drug Safety Department. Ernie received a B.A. and M.S. from University of Oregon and a doctorate in medicinal chemistry from University of Washington.



**Eric Meyers, Vice President, Global Initiatives, Cambridge Healthtech Associates (CHA)**

Eric Meyers is a leading expert, consultant, speaker and author in the area of the emerging regions, authoring two best selling industry reports on China and India, and serves as Project Director on all of CHA's collaborative projects focusing on these regions of the world. Eric has held management roles 3rd Millennium, Inc., HealthShare Technology, and Hewlett-Packard, and received both an MBA and a B.A. from Harvard University.

For more information on Cambridge Healthtech Associates' China Services, please contact:  
Eric Meyers, VP, Global Initiatives, 781-320-4007, [emeyers@chacorporate.com](mailto:emeyers@chacorporate.com)