Global drug makers have increasingly looked to Asia as an ideal test bed for new drugs. With large populations and improving patent protection legislation, multinational pharmaceutical giants and central laboratory providers have been quick to set up bases across the region.

In April, MDS Pharma became the third international central laboratory provider to set up a testing facility in Singapore, joining the ranks of Covance and Quintiles Transnational which set up facilities in 2000 and 2001. With its $1 million facility (US$0.6 million), MDS Pharma became the third of the world’s four largest central laboratory providers to establish a presence in Singapore.

These global investments have engineered a new industry of clinical trials across Asia. Since 1999, Korea has experienced a four-fold increase in the approval of clinical trials from just 31 in 1999 to 145 in 2003.

Similarly, China’s US$10 billion market is continuing to expand at 20% per annum, attracting an increasing number of investment projects from global pharmaceutical companies. Approved clinical trial projects have also increased at a comparable rate to Korea’s, from 982 in 2001 to 4307 in 2003.
The Lure of the Far East

Asia offers an extremely attractive proposition for global pharmaceutical companies. With an excellent talent base, a large patient pool and significantly lower staff costs than in the US or Europe, many global pharmaceutical companies and central laboratories have outsourced clinical trials to Asia.

Recognizing the value of the industry, governments in the region have also been quick to draw up attractive schemes to draw investments and claim a slice of the burgeoning pharmaceutical R&D pie.

Challenges of Managing Clinical Trials in Asia

However, the growth of clinical trials in Asia has not been without challenges. Despite the potential cost savings for pharmaceutical companies, Asia’s poor transportation infrastructure and government regulatory framework mean that logistics continues to remain a challenge, particularly when it comes to the movement of diagnostic specimens.

Unlike the transportation of other products, the movement of diagnostic specimens such as blood samples in clinical trials is extremely delicate. Diagnostic samples are both time and temperature sensitive. In order to maintain the accuracy of the test specimens, they need to be kept at a temperature below minus 20 degrees Celsius, and tested within 72 hours.

Furthermore, unlike North America and Europe, Asia lacks a homogenous and well-connected road transportation network. As a result, 90% of diagnostic specimens are transported by air, rather than by road. In countries such as Malaysia and the Philippines, study facilities may be located in any one of the numerous islands in the region, posing challenges for domestic transportation.

When diagnostic samples need to be exported out of the country, pharmaceutical companies may also face difficulties because of Asia’s complex government regulatory framework. While diagnostic specimens in North America and much of Europe can be moved relatively freely, their movement within Asia is subject to varying export permits and requirements.

For example, China remains one of the most regulated markets and poses one of the biggest challenges. According to the “Laws and Regulations on the Supervision of Drug Clinical Research in China,” clinical research projects are subject to the approval of State Food and Drug Administration (SFDA).

In addition, the export of diagnostic specimens in China also requires permits from the Human Genomic Research Institute and at times the Ministry of Health. The application process can take as long as 10 to 12 months, making it virtually impossible to export diagnostic specimens from China.

Some countries in Asia, however, are showing promising signs of improved regulatory change. In March 2004, Japan eased regulations on the data requirements for new drug registrations. As a result, clinical data from countries in the region such as Korea and Taiwan can now be accepted. This enables international testing laboratories — many based in biomedical hubs such as Singapore — to be involved in the Japanese clinical studies.

Despite improvements in some markets, Shengjie Ni, General Manager, Life
Sciences, TNT Asia, believes positive change will still take time, “Of course there is lobbying for change, but any progress is only possible at individual country level. In countries like China, I suspect, any positive change will come only in mid to long term,” he says.

Cost Considerations and Lack of Awareness

Taken together, these considerations translate into more complex and costly clinical trials logistics management in Asia; costs which TNT believes many pharmaceutical companies ignore at their peril.

“It’s crucial to raise awareness amongst pharmaceutical companies of the importance of logistics,” says Ni. “When pharmaceutical companies ask, ‘What is the cost of bringing medicines to the market?’, logistics needs to be part of these considerations because it can determine the success of the trials.”

The need for greater awareness of logistics considerations should not be limited to management personnel in pharmaceutical companies. According to TNT, there is a real need for awareness of the regulations and requirements in packaging diagnostic specimens even among doctors and laboratory technicians at research sites.

“The transportation of specimens is subject to regulation by the International Air Transport Association (IATA), which is stringent in its requirements for packaging, declaration and paperwork,” says Ni. “Many Asian medical doctors are becoming involved for the first time in clinical trials and are not usually trained or certified by the IATA. Despite this, they are signing dangerous goods declarations when shipping infectious specimens.”

This practice has serious legal implications if detected by local customs and transportation authorities. Without adequate knowledge, many investigators may confuse packaging materials, for example, using packaging for infectious samples for non-infectious specimens. This not only increases shipping costs, but can also affect the validity of customs declarations.

Recognizing this need, organizations like the IATA have begun offering training programs on dangerous goods management to raise awareness of logistics at investigator sites. IATA does this via a network of certified trainers throughout Asia. However, at this stage, such certification programs only cover the subject of dangerous goods in a very broad sense.

There is a vital role for logistics companies to provide more specific training programs and several, such as TNT, offer IATA certification programs which focus on dealing with diagnostic specimens.

“TNT has gone one step further by providing education programs for medical doctors on behalf of a number of contract research organizations,” said Ni. “To do this, research sites need to set up an internal infrastructure which can support such programs; they also need people who are trained in the clinical sector who can facilitate clinical trial programs.”
Specialist Services and the Entry of International Logistics Players

The complexities of managing clinical trial logistics in Asia have spawned the entry of both niche courier companies and global, full service logistics providers into the pharmaceutical logistics industry in Asia.

Niche courier companies specializing in clinical trial logistics provide a next-flight-out arrangement by shipping specimens individually without consolidating with other express parcels. Whilst some achieve good, on-time performance, cost can still be prohibitive, with some intra-Asia shipments costing as much as US$800-$1000 per 10 kg package.

The full service logistics companies such as TNT on the other hand, offer distinct cost advantages by consolidating shipments, particularly non-infectious specimens which can travel at normal temperatures.

Recognizing the growth opportunity in this industry, TNT has invested in developing specialist expertise, packaging and solutions. In 2004, TNT set up its Life Sciences Excellence Center (LSEC) in Singapore to provide expertise in handling specialized and time-critical goods primarily for clinical research. TNT’s LSEC serves as a regional coordination and knowledge management center, functioning as a resource hub on the biomedical sector for the region.

With its dedicated life sciences expertise and offering, TNT can offer the services of niche, specialist logistics providers at a fraction of the cost. According to TNT, some 60% of diagnostic specimens currently on the move within Asia are managed by such companies.

Companies such as TNT have also spearheaded the development of specialist packaging materials specially designed for the transportation of non-infectious specimens requiring temperature-controlled packaging. Certified by International Air Transport Association (IATA), TNT’s Medpak Thermo is a robust polyurethane packaging. By packing the specimens with cooling agents, Medpak Thermo can maintain below minus 20 degrees Celsius for up to 72 hours.

According to Ni, as a result of lessons learned from their experience of decentralized logistics management, research organizations are increasingly choosing a more centralized process by limiting their use of logistics partners to a highly qualified two or three.

Consolidation brings about obvious benefits. Companies can command better pricing, they can achieve further cost savings by outsourcing non-core activities, such as storage and distribution of diagnostic kits to their logistics partners, and they can also achieve a better quality service by the centralization of shipment booking and tracking via the dedicated service center of the chosen partner.

“These are exciting times for the budding life sciences industry in Asia. The industry has grown tremendously, and all eyes are on the region for the potential it offers in clinical trials,” said Ni, “The sooner pharmaceutical companies recognize the benefits of outsourcing logistics and focusing on their core competencies, the more efficient the whole process will be and yield even greater returns on investment.”
About the author

Mr Shengjie Ni joined TNT Asia in November 2002 with more than seven years of experience in the pharmaceutical industry. As the general manager for life sciences, Mr Ni spearheads business development initiatives in the pharmaceutical and life sciences industries in Asia. Under his charge is a regional team of business development managers and operation managers located across key markets in the region such as Singapore, China, India and Korea.

In addition, Mr Ni is responsible for managing the Clinical Express Center of Excellence (CECE) in Singapore. The CECE is TNT’s first regional coordination center and knowledge management center for the life sciences industry in Asia.

Prior to his current appointment, Mr Ni was the Regional Business Development Manager with Bayer AG, a leading German pharmaceutical company, and was extensively involved in sales and marketing in Germany, Singapore and Malaysia.

He is an MBA graduate from the Asian Institute of Management (the Philippines) and a member of the Singapore Management Institute. Mr Ni enjoys Chinese literature, photography and travelling. He is also an avid tennis player.