Interview with EPS International Co Ltd

President and CEO

Dr Tatsuhiko Ichiki

EPS is a Japan-based clinical research organization. Tell us about the background of EPS International.

Contract research organizations (CROs) were first set up in the US in the 1980 to support the big pharmaceutical companies who were working on many interesting new drug compounds. However, CRO business in Japan was behind about 10 years from US and Europe.

In 1990, Japanese authority first introduced Japanese Good Clinical Practice (GCP) Guidelines. Many Japanese pharmaceutical companies started to reorganize their organizations in order to adapt to the GCP requirements. As such, these pharmaceutical companies started to consider using CROs in drug development process in Japan.

In 1997, Japanese authority inaugurated revised Japanese GCP which was based on the agreement of ICH-GCP. Many Japanese pharmaceutical companies considered to adjust their organizations in order to establish new organizations in accordance to the revised GCP and other authorities’ requirements. After the enforcement of new Japanese GCP, many pharmaceutical companies started to use the services of CROs to conduct clinical drug trials in order to follow the new GCP’s requirements.
In line with the growth of clinical outsourcing needs within the pharmaceutical industry, EPS started its operations in 1991 to primarily focus on providing data management, bio-statistical analysis and patient enrolment management. In 1995, EPS expanded its business by offering monitoring services and subsequently expanding its scope of services from preclinical, clinical development (phase I – IV) to product registration in order to best support the industry. At the same time, EPS also established its overseas operations to support clinical drug development activities for its clients. Since 1995, EPS has gradually become one of the top three CROs in Japan offering the full range of contract research services. In addition, EPS also strengthened its capability by expanding into Site Management Organization (SMO), Contact Sales Organization (CSO), e-clinical trial support and IT system development services. Till today, EPS is still progressively evolving into new business ventures to meet the industry’s need in research, development and commercialization in the Asia region.

Several factors limited the growth of the Japanese pharmaceutical industry in the beginning. The main reason is that the circumstances of medical treatments and hospitals where patient enrollment was very small. The second reason is that strict government regulations required pharmaceutical companies to conduct all clinical trials (range from phase I to III/IV) in Japan, thus required a huge pool of resources. Combined with the increasing competition, the drug development in Japan proved to be very costly and slow.

In 1998, Japanese authority issued new acknowledgment on bridging studies by using the data of foreign countries in order to file into Japan New Drug Application (NDA) based on ICH-E5 guideline. The International Conference on Harmonization Good Clinical Practice (ICH GCP) Guideline was already introduced in 1996.

What are EPS’ vision and goals in Japan and Asia?

EPS’s vision is to expand its presence in Asia in five to ten years to create a “pharmaceutical EU” in Asia, i.e. a borderless Asian pharmaceutical company. Using the same set of data, we hope to file for licenses in different countries in Asia, such as Taiwan, South Korea, China, Singapore, and Japan. This would cut costs immensely and increase the speed to market.

EPS aims to be a gateway for Japanese companies to reach other countries worldwide, as well as for foreign companies to access the Japanese market. Our plan to increase market share is twofold: aggressively conduct clinical studies in the Asian region for Japanese trials, while simultaneously increasing market growth in Japan. To this end, we are not only pursuing growth outside of Japan, but also supporting trials in Japan for global companies.

Who are some of your clients?

Our clients are mainly Japanese pharmaceutical companies and venture companies in Asia. Specifically, we target countries that have high consumer purchasing power and top-tier, high-quality data,
such as China, South Korea, and now Singapore. After all, it is not the number of countries in which you get the data, but rather the quality of the data itself, that determines the usefulness of the trials conducted. We also work with large MNCs in supporting global trials in Japan for global submissions.

**What is EPS’ competitive edge over other CROs? How does EPS compare to other CROs such as Covance and Quintiles?**
The big CROs such as Quintiles and Covance are big global companies, but they may not know the Asian market very well, such as China and Japan. In contrast, our strategic focus is on Asia. EPS’ competitive edge is that we are very familiar with and have a wide presence in each of the important Asian markets, such as China, Japan, and South Korea. As a Japanese parent company, we understand the Japanese market very well; we are also the experts in the national cultures, hospital cultures, outpatient cultures, regulations, doctors’ opinions, and treatment styles of the other Asian countries.

By sharing complementary power/knowledge between EPS and client, we follow the philosophy that medical science is a kind of culture in itself: the basic science is the same, but medical treatment and clinical trials are different in different countries.

**What are some of the problems or constraints encountered by Japanese pharmaceutical companies conducting clinical trials in Asia?**
Many industry players are looking at markets in China and South Korea, which have a large population and market size. However, due to the language barrier, many business opportunities are missed. Japanese companies cannot understand other countries’ regulations, and communication is a big problem. Also, each country’s culture and disease prevalence is different, so gathering/collecting data between different Asian countries is difficult. In addition, we have to consider how to protect patients in each country from toxicity, thus requiring more careful checking of toxicity data.

**Why has EPS decided to set up an office in Singapore?**
Singapore is a strategic place to set up an office for international businesses. The pharmaceutical market here is big enough to incorporate different players. Many MNCs are located in Singapore, and we can utilize the lab services of other global CROs to assist our own clients. Convenience is also a factor, as English is the common language and many international flights connect in and out of Singapore daily. In addition, Singapore has recruited many foreign talents and, because of its good cosmopolitan mix of different races and cultures, it is an ideal location for clinical trials to take place. Perhaps most importantly, Singapore serves as the clinical research hub for Southeast Asia, with links to Malaysia, Vietnam, and Indonesia, and others; we can also expand our reach to these areas while still being based in Singapore, where it is safer to conduct business operations given its political and economic stability. In short, EPS Singapore is well positioned as a representative for global CROs to conduct studies in Japan and in Asia region.