# Shing-Mou Lee – Founder and President, EMO Biomedicine, Taiwan

***One of EMO's missions is to help the government promote the cell therapy field in the right way***

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*Shing-Mou Lee, founder and president of EMO Biomedicine, the leading CDMO provider of cell-based products in Taiwan, discusses the major regulatory and maturation trends in the region and shares his future strategy for expanding the company's position in the sector.*

**Can you please introduce yourself and EMO Biomedicine?**

EMO was established in 2004 at a time when cell therapy was still a very new field that had very little precedent, not only in Taiwan but around the world. In order to become a world-leading company in the field of cellular therapy, our first step was to develop the necessary platform technologies related to manufacturing and analysis for therapeutic cell-based products, including safety and functionality assays.

Since our establishment, we have provided comprehensive cell-based bioassays and contract research services to both local and global clients, namely pharmaceutical and biotech companies. EMO established a quality management system specific for cell-based product characterization which is compliant with international standards. In 2007, we received accreditation as a testing laboratory from the Taiwan Accreditation Foundation (TAF) and for which our testing scope includes cell-based products, cell culture supernatant, and whole blood. Later on, in 2011, EMO started to provide contract manufacturing services of said products to cell therapy companies and hospitals.

**What is the complete service offering that EMO leverages as a specialized cell therapy CDMO?**

Safety, identity, and potency are the values at the core of all our manufacturing, testing, and research service solutions. EMO's CMO services include human peripheral blood mononuclear cell (PBMC) and mesenchymal stomal cell (MSC) isolation, dendritic cell (DC) generation, T cell expansion, and customized human cell process and cell product manufacturing.

Most of our testing services including safety and purity testing, identity testing, and biological and potency assays are accredited by TAF. TAF is a member of the International Laboratory Accreditation Cooperation – Mutual Recognition Agreement (ILAC-MRA), accredited by TAF and is also bilaterally recognized by 60 economies and 73 accreditation foundations. In most cases, people only know the biomarker of a cell but do not fully understand its functionality which is believed is one of the biggest issues for cell-based companies.

In June 2013, EMO was qualified as a CRO for pharmaceuticals by the Industrial Development Bureau, Ministry of Economic Affairs and we expect to provide the best service to all clients for accelerating the development of cellular therapy and biologic products. These services include basic research and comparability studies for new drug and biosimilar discovery, bioassays, optimization, and validation for pre-clinical development, and performing validated bioassays for clinical trials.

**What is EMO's positioning within the cell-based products space and what are the company's production capabilities?**

EMO is a very specialized company, highly focused on R&D. In fact, we do not have a sales department, yet our unique offering allows to be well-positioned with sufficient demand in the market both locally and internationally. Outside of cell therapy, we have major clients in the biopharma market such as OBI and Mycenax. EMO is very focused on human cell research; we do not work with animal models. Therefore, each time we have a new research project we are able to simultaneously gain more experience working with complex cells.

EMO has three cleanroom production lines for the manufacturing of cell-based products. Capacity is not our major concern as expansion is always possible. EMO's highest priority is on our software and the expertise of our personnel.

**In Asia, the regulation for cell therapies is still very fragmented. Countries like Taiwan, Singapore, and Japan are more advanced than Indonesia, China, or Malaysia, etc. What possibilities exist to develop a pan-Asian regulatory landscape – similar to that of the EU – for cell therapies?**

Speaking on Taiwan and Japan, Taiwan's regulations for regenerative products are undergoing major changes and will soon be similar to those in Japan. Under the government's new regulation, if our product for osteoarthritis is approved by the Taiwan FDA, we will be able to treat patients without having to wait until phase III trials. Although Taiwan is exploring new regulations for cell therapies, the environment is still much more stringent than Japan. In Japan's regulatory environment, cell therapies were free to be used as long as the doctor would agree to treat the patient. In Taiwan, the chemistry, manufacturing, and controls (CMC) must be submitted to the TFDA which will also inspect manufacturing facilities for GTP/GMP compliance, just like biologics. This results in safer and more regulated products, but also more expensive therapies. Although the cost is much higher than in Japan, the functionality and safety of cell products can be better assured in Taiwan which is very important for treating patients.

The key question in maturing cell therapy is how we can identify the critical attributes that determine the functionality of cells. Most clinical trials going on in the world do not take this extra step in trying to analyze and understand their product. Instead, therapies are pushed through the clinical trial phases to quickly see whether they work or not.

One of EMO's missions is to help the government promote the cell therapy field in the right way. Therefore, it is very important to be aware of international trends and developments in the field, not just be focused on Taiwan only.

**Looking outside of Taiwan, what is your internationalization strategy to become a globally active company in the field of cellular therapy?**

Unlike traditional pharma, cell therapies operate under a very decentralized model due to the sensitivity manufacturing demands of such products. The best strategy we can have is to build a successful module here in Taiwan and later duplicate it in a new market. Thanks to AI technology, this can be done much easier. We are currently considering establishing a new headquarters in Japan. We are also discussing with partners in South Asian countries like Singapore, Vietnam and

Thailand. The location is not an issue as long as the regulatory environment can be harmonized among countries.

Aside from the collaborations we have in Japan, we are also often in discussion with other industry players in markets like the US. I was working in cell therapy over 20 years ago, when the field extremely small, so I know many stakeholders from around the world. Up to now, EMO has not had any VC partners or external development cooperators. However, as more people become aware of the field and regulations being to mature, perhaps it is time to extend EMO's reach and grow as a company in this way.

**What strategic objectives do you have in mind to grow EMO Biomedicine in the next three to five years?**

EMO is quite small, and we cannot compete with other big companies in the US, China, or the EU. Nevertheless, we have built a strong technology platform within the company and we have begun to see positive results from our clinical trials. Therefore, I am looking to enter into collaboration with other players in the space, particularly CAR treatments to link antibodies with human cell-based products in Taiwan.

**What is your motivation for working in such a challenging field of medicine?**

My main motivation is to help patients. I believe cell therapies can be the solution to many of today's unmet medical needs. The most important aspect is to truly understand how cell-therapies work and develop these products more effectively to touch the lives of patients.

Currently, there are over 1,000 clinical trials in the field of MSC therapies, but up to now, there have been no approvals for these products in the US, only one in Europe and one in Japan. The cell therapy field is still very new, and its potential functionality and future development path is still unclear. Within the past ten years, I have seen many companies fail in this area. With EMO I hope to unlock the secret of cell-based therapies!

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