

■ Bio Business ■



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- Conduct of research in stem cells consistent with ICMR and DBT guidelines.
- Allogenic clinical trials are conducted based on approvals of Drug Controller General of India.
- Efficacy of stem cell therapies are based on clinical data generated through trials conducted as per ICH-GCP guidelines, which are accepted by the international community.
- Processing of stem cells for clinical trials and commercial therapies are carried out in a cGMP environment, approved by FDA.”

—K V Subramaniam, President & CEO, Reliance Life Sciences, Mumbai, India

Coming to the rest of Asia, India has no clear policy regulating stem cell research but the country has its fair share of research going on—though blazing success stories from India are yet to come by. Also, the Indian regulations are by far more relaxed and quite supportive than some other countries in the region. “However, there is a need for regulation of individual investigator (doctor) initiated cell based therapies, as these tend to be conducted in variance with international standards of clinical trials and cell processing and the imponderables on safety and efficacy are not scientifically addressed,” says K V Subramaniam, President and CEO, Reliance Life Sciences, a Mumbai-India based stem cell research and biopharmaceuticals company.

Subramaniam says if India has to grow as a top stem cell research hub, regulators would have to ensure that the:

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In India several scientific departments and institutions of the government, such as Department of Biotechnology, Department of Science and Technology, Indian Council of Medical Research and Council for Scientific and Industrial Research are promoting stem cell research. The priority areas of research have been identified through discussions at various forums on basic and applied sciences. Among the various programs being supported in embryonic and adult stem cells research are: establishment of hESC lines, use of limbal stem cells for repair of ocular

surface disorders, isolation; purification and characterization of hematopoietic, mesenchymal cells among others.

Reliance Life Sciences is developing a wide range of novel research-led, autologous and allogenic cell therapies and tissue-engineered products to get into regenerative medicines business. Under the “regenerative medicine initiative”, the company has divided several groups who work in areas such as embryonic stem cells, ocular stem cells, haematopoietic stem cells and skin and tissue engineering. Cell-based therapies from Reliance Life Sciences aim to meet unmet patient needs in the areas of cardiac disorders, neural degeneration, spinal cord injury, metabolic disorders, ophthalmic diseases, hematological diseases, oncological diseases, burns and wound management, diabetic and venous ulcers, skin pigmentation disorders, orthopaedic and cartilage disorders.

One of the newest companies in stem cell research in India is Stempeutics Research, a Bangalore-based company focused on research, therapeutics and therapy in the field of regenerative medicine.

B N Manohar, President of Stempeutics told BioSpectrum that since its inception two years ago, Stempeutics has focused on two major types of stem cells—Adult Stem Cells and Mesenchymal Stem Cells while also focusing on human embryonic stem cells. It has developed cell characterization for purity and identity by flow cytometry, functional assay for multipotency, process validation for manufacturing, large scale cGMP complaint up-scaling of mesenchymal stem cells and quality control testing and quality assurance.

Stempeutics has established cell and tissue manipulation facilities at Bangalore, Manipal (India) and Kuala Lumpur in Malaysia. “India has massive potential for stem cell research as there is a very good environment and we have things going for us,” says Dr Manohar.

Stempeutics’ research is into embryonic stem cells, stem cell niches, self-renewal and signaling pathways, cancer stem cells, mesenchymal stem cell biology, differentiation and transcriptional determination, diabetes, cardiovascular, neuro-regenerative potential of adult stem cells, ocular

stem cells, and dental stem cells.

The island nation of Taiwan has a pro-stem cell policy that has made the country a place of choice for stem cell research.

Dr Oscar Lee, who is with Department of Orthopaedics and Traumatology, Taipei Veterans General Hospital, Taipei and Institute of Biopharmaceutical Sciences, National Yang-Ming University, Taipei has been a foremost stem cell researcher in Taiwan.

He says just like other Asia Pacific countries such as Singapore, Hong Kong, and even Mainland China, the Taiwan government is putting a lot of emphasis on the development of the stem cell industry.

“The government is pouring in considerable resources in setting up and helping stem cell industries,” says Dr Lee.

There are about 100-200 stem cell startups in Taiwan and this number is quite huge considering the country has a population of just 23 million. Both domestic and international VCs are quite active in Taiwan offering to fund anyone that comes up with an interesting project. Dr Lee predicts that in 20-30 years Taiwan will be one of the most active countries in stem cell research and the country to watch out for.

Taiwan has a lot going for it in the stem cell business. The country is also benefiting from its researchers returning to work in the country after retiring as professors and professionals in top Western universities and top stem cell research labs across the world.

Taiwan researchers, informs Dr Lee, are working on usage of stem cells to treat liver and cardiac diseases, gastroenterology, regrowing of limbs and even human embryonic stem cells.

The major research theme of Dr Lee’s lab is plasticity and application of mesenchymal stem cells. Being an orthopedic surgeon as well as a stem cell scientist, Dr Lee says he is particularly interested in developing new application of mesenchymal stem cells to treat orthopedic problems.

His lab at National Yang-Ming University in Taiwan has successfully isolated mesenchymal stem cells from human term umbilical cord blood.

In addition, he says his research team has demonstrated the differentiation

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