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Demand for cell isolation techniques to increase manifold

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The Asia-Pacific (APAC) is the fastest growing region in the global cell separation market, due to rapid development of healthcare infrastructure and increasing medical tourism.

As per market report published by Transparency Market Research (TMR) in 2012, stem cells research and cancer research comprised approximately 52 percent of the overall cell separation technologies market.

Global rise in research activities in the field of stem cells and cancer, due to rapidly increasing prevalence worldwide, and predictable benefits of stem cells in medical industry have flourished the demand for cell separation technologies.

"North America is expected to retain its dominance from 2012 to 2019. Rapid adoption of advanced technologies and well-defined regulatory framework are major factors which will drive the North American cell separation technologies market," emphasized Ms Snehal Deshmukh, a senior research analyst at TMR.

APAC is a lucrative market for cell separation technologies. However, emerging economies in this region will play a key role in the development of cell separation technologies market.

This is due to growing focus of the respective government on the improvement of biotechnology industry, availability of increased funds towards research activities, offering public-private partnerships to international players to enter into the domestic market, which are seen as attractive factors for global researchers to this region, say analysts in the industry.

What's in and what's hot

Recently, the trend is shifting towards the use of microfluidics in cell isolation.

"Advancement in microfluidic technology has provided robust solutions for isolation of cells which are present in low quantity

in the body. Microfluidic chips are easy to use, and provide reliable and efficient isolation of cells even from a small volume of sample," stated MarketsandMarkets (M&M), a market research firm.

Citing the potential of microfluidic technology in cell isolation, various research studies are being performed for evaluating the performance of microfluidic chips in isolating other types of cells.

In this regard, in August 2013, Qiushui Chen and his team published a study in Scientific Reporter regarding the efficient usage of microfluidic technology for isolating stem cells.

M&M noted that the increasing application of microfluidic technology in cell isolation will help in overcoming the present challenges in this market, which in turn will present significant opportunities for the market growth.

Several companies operating in the cell separation technology market are shifting focus from research laboratories to clinical research and translation laboratories, to offer their products such as reagents, instruments and other tools used in cell separation process.

In addition, companies are focusing on partnerships, collaborations, new product launches, and acquisitions to attain a leadership position in the market, M&M said.

Global rise in the morbidity and mortality rate of chronic diseases such as cancer, diabetes and arthritis has become areas of concern for healthcare professionals, and thus the demand for cellular therapy to treat such diseases is rapidly increasing.

Another research analyst, Ms Shraddha Pashankar from TMR opined that rising demand for cellular therapy will fuel the growth of research activities worldwide, and thereby escalating cell separation technologies market globally.

"Furthermore, stem cell research, immunology, neuroscience research and cancer research are major application areas of cell separation technologies," she added.

Challenges for new entrants

Currently, the isolation of highly purified cells in high quantity from low volume sample is a major challenge faced by researchers and clinicians.

For instance, recovering T regulatory cells in high volume from limited volume sample is a cumbersome process due to the lack of specific cell surface markers on these cells.

Furthermore, these cells are found in low frequency in peripheral blood which makes the process more burdensome.

Analysts at Persistence Market Research (PMR) remarked that complexities related to reagents development will pose another major challenge.

Moreover, reluctance amongst researchers in emerging economies to use advanced cell isolation techniques is another burden faced by the cell isolation market, highlighted analysts at M&M.

The use of advanced cell isolation techniques is largely dependent on the cost of the instrument and technical know-how.

Due to budget constraints and dearth of technical know-how, users in emerging countries are relatively reluctant to adopt new techniques such as automated magnetic cell separators and flow cytometers.

The survival of small players and new entrants in the cell isolation market is another challenge. Huge investments are required to enter into this market.

"This particular market demands continuous improvement of existing products and technologies as well as the launch of novel products. Thus, to remain competitive, companies have to invest heavily in R&D which is very difficult for small players and new entrants," observed M&M.

Booming Asian markets

Relatively untapped Asian market is a major opportunity for cell separation technology market.

"Emerging economies are expected to become a focal point for the growth in the cell isolation market. Taking into consideration the growth opportunities in the Asian market, major companies are expanding their presence in this region," commented M&M.

For instance, in August 2013, Beckman Coulter Life Sciences acquired the flow cytometry business assets of ReaMetrix India.

Moreover, biopharmaceutical and pharmaceutical companies are increasingly focusing on drug discovery outsourcing.

M&M attributes this to the ever-increasing demand for better drugs, drying drug pipelines, and rising R&D costs.

"The Asian markets, especially China and India, have a large number of CROs that offer drug discovery services for pharmaceutical and biotechnology companies. As a result, the demand for cell isolation techniques is expected to increase in the Asian region and will present an array of opportunity for the cell isolation market to flourish," it reasoned.

Also, public-private organizations are increasingly providing numerous grants and funds to researchers and research institutes for their stem cell-related projects.

For instance, BD Biosciences annually provides reagents worth US $1,00,000 to 10 scientists, who pursue innovative ideas in stem cell research.

"Taking into consideration rapidly increasing research and development activities worldwide, application area of cell separation technologies is expanding with every innovation entering into the market," held Ms Snehal.

On the other hand, PMR stressed that the need for solutions with higher purity yield, lesser turn-around time, and simplicity at cheaper rates will offer wide range of opportunities in this area.

Revolutionizing new technologies

The cell separation technologies work on technologies such as gradient centrifugation and surface marker separation. Surface marker separation is further segmented as magnetic activated cell sorting (MACS) and fluorescence activated cell sorting (FACS).

MACS is the major technology segment, and FACS is expected to grow potentially, due to increased adoption of the technology in cell purity sensitive research area.

The growing demand of this technology is due to its ability to separate even small molecules from a given sample.

"Furthermore, FACS can be used on a large-scale for isolating desired cells from a large-cell suspension. It is widely used for separating white blood cells from other cells. The wide usage of this technique in the biopharmaceutical and biotech industries is a major reason for the growth of the market," commented M&M.

MACS possess various advantages like using it for isolating cells from a small mixture easily and efficiently without disrupting the cells. Such advantages, along with the increasing adoption rate of MACS are major reasons for high growth.

According to another market report published by TMR in 2012, MACS technology market comprised approximately 35 percent of the overall cell separation technologies market.

"In spite of availability of many technologies, only gradient centrifugation, MACS and FACS technologies are commercially used for cell sorting. Other technologies such as lab on chip, microfluidic, field-flow-fractionation (FFF) and affinity-based cell sorting are in developmental stage for improvement of purity of the yield and reduce turnaround time," explained Ms Shraddha.

Cost pressures

Most analysts believe that the high cost of cell isolation instruments is a major hurdle.

"Various cell isolation instruments such as flow cytometers and magnetic cell separators are equipped with advanced features and functionalities and thus are priced at a premium," explained M&M.

The price of a flow cytometer varies from US $35,000 to $100,000. For instance, the price of a CyFlow Cube 6 (Partec) is approximately US $35,000.

Stratedigm's SE500 flow cytometer is priced at approximately US $68,000 (source: The Scientist Magazine, May 2011).

Biopharmaceutical companies require many such instruments and hence the overall cost of production of biopharmaceuticals increases significantly due to these expensive systems.

Another hurdle faced by the cell separation market is the limited funds for embryonic stem cell isolation.

M&M remarked, "Limited funding for embryonic stem cells is undermining the market potential of stem cell therapies and research."

Countries such as Australia, Belgium, Singapore, Spain, South Korea, Sweden, and the UK have adopted tightly regulated but permissive approaches towards research involving the use of human embryos to generate embryonic stem (ES) cell lines.

On the other hand, other countries such as the US and Germany have restricted the funding for stem cell research involving ES cell lines.

For instance, in 2007, the California Institute for Regenerative Medicine (CIRM) funded 100 embryonic stem cell research projects. However, this number decreased to 6 in 2012.

"Such restrictions on embryonic stem cells funding are likely to restrict research on stem cells, which in turn is expected to restrain the growth of the cell isolation market," pointed M&M.

Regulatory woes vs product development

The regulations for cell separation are mostly complicated due to legal technicalities.

"The safety, performance, and consistent quality of cell separation are necessary facets that need stringent evaluation for international public health," said PMR.

The regulations differ from country to country. For instance, in Singapore, the isolation and use of human embryonic stem cells, for therapeutic or research purpose, is only allowed when they are not more than 2 weeks old.

In China, stem cell research is not practiced at clinical level due to strict regulations of trials over safety and ethical concern.

In India, isolation of embryonic stem cells for clinical research purpose is banned.

In Japan, the guidelines for 'Derivation and Utilization of Human Embryonic Stem Cells, 2001', permits the embryonic stem cells to be isolated only from spare IVF embryos, and are younger than 14 days donated with informed consent without any financial compensation beyond necessary cost.

"Such regulatory affairs may act as hurdles for companies requiring stem cell isolation for developing their products," pointed M&M's analyst.

Competing with Goliaths

The cell isolation market is marked by high competition. There are various big firms with strong financial strength, as well as several smaller organizations with similar product offerings.

This market is dominated by Thermo Fisher Scientific (TFS) (US), Becton Dickinson (BD) (US), Beckman Coulter (US) and Miltenyi Biotec (Germany) which together constituted more than 85 percent of the market share in 2013.

TFS leads the cell isolation products market. In February 2013, it acquired Life Technologies.

Life Technologies was the leading supplier of magnetic beads (Dynabeads), an expensive and high-growth opportunity cell isolation product.

This acquisition helped the company to become a leader in the cell isolation market by adding various cell isolation products in its portfolio.

The acquisition also added magnetic beads, centrifuges, flow cytometers, various cell isolation reagents, enzymes, and media to TFS's product portfolio.

BD is the second-largest player in the cell isolation market followed by Beckman Coulter, and Miltenyi Biotec respectively.

Key Players:

ï‚§ Beckman Coulter
ï‚§ Becton Dickinson (BD)
ï‚§ Biosafe
ï‚§ GE Healthcare
ï‚§ Merck Millipore
ï‚§ Miltenyi Biotec
ï‚§ pluriSelect
ï‚§ STEMCELL Technologies
ï‚§ Terumo BCT
ï‚§ Thermo Fisher Scientific (Life Technologies)