

## Cleanroom consumables market to exceed \$8 billion in 2015

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The global cleanroom market consists of a plethora of consumables and hard ware products carrying phenomenal precision and quality.

The biotech and pharmaceutical sectors require cleanrooms and controlled environments which need to control the concentration of airborne particles, micro-organisms, temperature, humidity, and pressure.

The cleanroom trends began in the area of medicine and research where experts saw a close relationship between hygiene and manufacturing quality products.

As Indian pharmaceutical and biotechnology industry faces stringent manufacturing and export regulations from Indian and foreign regulatory bodies, companies now are seeking to match up with superior quality in their manufacturing processes,

and the demand for cleanrooms is now catching up far more than ever before.

Says Mr P Pradeep, CEO, Whitenair Technologies, "Cleanroom technology has great demand in the biotech sector and is growing day-by-day. The sector is involved in multiple activities such as safety laboratories, production units, bio-exclusion, and animal supply facility to name a few. Cleanrooms and controlled environment play a crucial role in the bio technology industry."

In 2014, McIlvaine predicted that there will be 131 million sq.ft of cleanroom space in use across the world. This is an increase of five percent in 2013.

It also states that in 2013, the pharmaceutical industry employed 2.3 million people in the cleanroom industry, which can jump to 2.4 million by 2015.

In terms of cleanroom consumables, Asia is projected to be the largest hub by 2015 witnessing growth in consumables and hard ware products.

A press release published by McIlvaine in 2012 predicted that the cleanroom consumables market would reach \$7 billion in 2013 and may exceed \$8 billion in 2015.

The pharmaceutical and biotechnology sector is expected to be the third largest consumers of clean room products. On the other hand, the cleanroom hardware sales are estimated to be \$4.9 billion this year.

Asia is considered both, the largest and fastest growing region for clean room hardware and consumables. The pharmaceutical industry continues to show steady growth mostly taking place outside the US and Europe.

However, pharmaceutical and hospital markets are much larger in the US and Europe than in Asia. The semiconductor industry paved the way of mini environment concept, which is now widely adopted by the pharmaceutical industry, led by contract manufacturers.

Global pharmaceutical contract manufacturing market clocked revenue of \$13.43 billion in 2012, according to analyst firm Frost and Sullivan, and the market is expected to reach \$18.49 billion in 2017.

According to market analysis firm, Vision gain, the global market for pharma contract manufacturing is estimated to have expanded by five percent in 2013.

According to the analysis firm, pharmaceutical companies' urgency to focus on their core competencies of research and development and expiring blockbuster drug patents is driving the need to outsource pharmaceutical manufacturing.

Pharmaceutical and biotechnological emphasis on complex disease areas, trends in disease control, growth in emerging markets, and reformulation of existing products have widened the scope of the contract manufacturing market.

Contract manufacturing is expanding in the areas of solid dose, liquid and semisolid dose and injectable dose formulations, according to a report by Frost and Sullivan.

"Investments and capacity expansions in the inject able dose formulation segment are in the near future, as it is likely the most significant source of income for the global pharmaceutical contract manufacturing industry," said Ms Aiswariya Chidambaram, healthcare research analyst, Frost & Sullivan.

"Cytotoxics manufacturing, in particular, offers immense growth potential, given the demand from the cancer research and therapy segments."

According to industry reports, the US and Europe are major markets for outsourcing finished dose formulations and sterile preparations and Asian CMOs are preferred destinations for active pharmaceutical ingredients, intermediates and generics.

Countries like India, China and Taiwan have been providing cost benefits to global pharmaceutical industry and would continue to be preferred destinations for solid dose formulations.

Contract manufacturing allows pharmaceutical companies to transfer noncore activities to external partners, leverage their

own resources and focus on strategies for future growth.

Even pharmaceutical companies are not shying away from creating their own contract manufacturing wing that embarks on the opportunities of outsourcing services.

Pfizer, for instance, has revealed its plan to win contracting work for its hormone plant in Sweden and may Global even include molecule drugs for its own competitors.

The pharmaceutical industry is considered as the number one major cleanroom hardware purchaser. On the other hand, the semiconductor industry is considered to be the largest user of cleanrooms worldwide.

Under consumables, gloves are the most purchased cleanroom consumable in the world, followed by wipes and disposable garments.

Other widely purchased consumables include disinfectants and cleaning solutions, mops, and special pens. Cleanroom hardware includes ceilings, floors, modular rooms, HVAC, mini environments, and instrumentation.

According to experts, the healthcare industry offers greater potential for consumption. Cleanrooms in bio pharmaceutical manufacturing plays crucial role in the manufacturing processes at the same time keeping in mind low-cost and environmental friendliness.

When designing cleanrooms, it is crucial to stick to stringent requirements of regulatory body such as FDA, WHO, cGMP, and URS (User Requirement Specification).

Asian countries provide a significant cost advantage for pharmaceutical manufacturing accounting for almost 50 percent cost reduction as compared to that in Europe or USA.

India, in particular, is an attractive destination as it has a strong pool of qualified and skilled manpower with the knowledge to operate manufacturing facilities.

In India, there are more than 100 FDA approved pharmaceutical facilities, the largest number of sites outside the US.

China and Taiwan are also gearing up to build more regulatory approved manufacturing sites that win confidence of the companies to outsource production services.

"Implementation of new technologies such as Variable Frequency Drive (VFD) to control the plug fan of an AHU, adopting IVRF air conditioning system to reduce operational cost along with cleanroom monitoring systems, which includes particle counting, controlling temperature and humidity for different zones are highly recommended," adds Mr Pradeep.

In January 2013, GEF South Asia Clean Energy Fund invested \$8.4 Million in Integrated Clean Room Technologies (IClean), a provider of turnkey cleanrooms and associated equipment to biotechnology, pharmaceuticals and microelectronics sectors.

As cleanrooms consume large amounts of power, the need for incorporating and introducing cleanroom smart technology is also the need of the hour to cut exorbitant costs.

However, Mr Pradeep feels that the cost of instilling cleanrooms do not have any impeding effect on clean room industry.

"Most of the customers realize the advantage of having quality products and are sticking to the compliance of regulatory bodies like cGMP,WHO, and US FDA. Hence, implementation of cleanrooms has become an integral part of the quality process," he expressed.

According to Mr Robert W McIlvaine, president, McIlvaine Company, the cleanroom industry is now accelerating forward because of intense activities taking place in China in the area of cleanroom technologies.

"Over the next decade, China will become the largest consumer of cleanroom products as well as one of the largest suppliers," he said in a report.

Commercial survivability of a company is largely decided by the quality of products it produces. A cleanroom ensures

production of products with high quality, adding to the overall success of any company.

By Raj Gunashekar with inputs from Amrita Tejasvi