

India in capacity building mode

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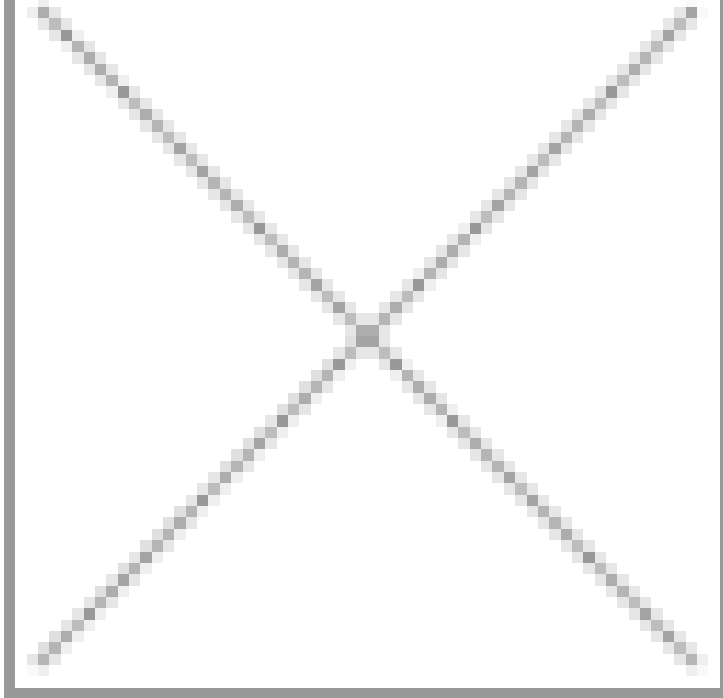
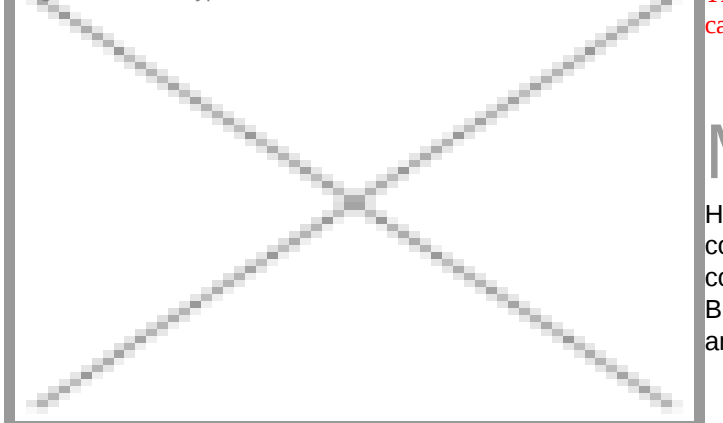


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The industry is set to take on the patent expiry with manufacturing capabilities for monoclonal antibodies, biosimilars, and recombinant

Many companies prefer to outsource their manufacturing processes to contract manufacturing organizations (CMOs) to meet their manufacturing requirements. However, an emerging trend in the industry has been companies setting up their own facilities to do so. A number of companies including Reliance Life Sciences, Virchow Biotech, Bharat Biotech and USV believe in producing biologics on-site and constantly update their manufacturing capabilities to keep

Mr K V Subramaniam, president, Reliance Life Sciences, talks about the reason behind doing so. "Reliance Life Sciences has taken upon itself to build India's largest mammalian cell culture facility, which is also approved by the European Medicines Agency (EMA). Therefore, Reliance Life Sciences has the requisite capabilities and capacities to manufacture biosimilars on a commercial scale and at competitive costs. Hence, we do not outsource any production-related requirement and ensure all product manufacturing is done in-house," he says. "The biopharmaceuticals manufacturing facility is capable of producing microbial products at 1,000 liters scale and mammalian cell culture-based products at 10,000 liters scale," he informs.

Other firms such as Transgene Biotek, believe in augmenting the services offered by the CMOs to their existing facilities to

produce biologics. Mr Chinny Rao, executive director, says, “As we are predominantly an R&D-driven company, we see our new found manufacturing expertise and skills as an effective hedge against the applied risk that we have in our large molecule innovation pipeline. And in understanding this, we’ve started to add capacity to our existing set-up and are just weeks away from the completion of a new unit, consisting entirely of fermenters and down-stream processing units that will augment our existing arrangement with our CMO partners.”

In order to be able to utilize their own manufacturing facilities, companies need to expand their existing facilities within a few years to cater to the growing demand. Dr Hemanth Nandigala, director, Virchow Biotech, says, “For every manufacturer, an improvement in manufacturing processes and systems, and up-gradation of analytical capabilities is an ongoing effort. It is no different for us. As we continue to build skill sets in systems and controls for biological manufacturing, we believe that the opportunities would open up for us as more patents expire.”

Dr Cyrus Karkaria, president, biotechnology, Lupin, echoes the fact that the impending patent cliff will have a strong impact on the manufacturing practices in our country. He emphasized the need to think ahead and take into account market scenarios.

“We have already invested in our facilities and are investing a lot more in manufacturing right now, so that we can gear up for the huge patent cliff happening in the West. We have some products that should be launched this year, so we have adequate capacity for manufacturing those drugs. We will increase our capacity accordingly when we see an increase in sales of those drugs,” he says.

Another such company that is expanding in order to meet market requirements is USV. Dr Esmail Samiwala, senior VP, USV, says, “USV is investing more than 80 crore in upgrading the drug substance manufacturing facility. This would mean a ten-fold increase (as compared to the existing capacities. Present manufacturing capacity of drug substance is more than 100gm per batch with the total capacity of drug product manufacturing facility being about 30 million injections annually,” he says.

Investing in contract biologics manufacturing	
Advantages	Disadvantages
• Access to capacity • Access to scale • Access to competencies • Access to technologies	• Risk of cost increases • Lower control over schedule • Dependency on CMOs for audit clearances when lacking experience • Variability in delivery standards • Expensive technology transfers • Additional work in technology transfer based on facility compatibility

In the pipeline

Most people perceive the Indian biologics manufacturing scenario to be mainly consisting of the biosimilars space. Others believe that Indian firms are working on only those compounds that are going off the patent cliff. However, a lot of the companies are actively working to innovate and develop methods to indigenously produce recombinant proteins, vaccines and monoclonal antibodies. Dr Krishna Ella, CMD, Bharat Biotech, presents a positive picture. “We are currently focused on novel innovative products such as REGEN-D (wound healing) and Lysostaphin (MRSA anti-infectives) among others,” he says.

Similarly, Dr Samiwala says, “This year, USV is planning to launch the first indigenously developed somatropin for injection and Teriparatide injection in the India market. USV’s drug product manufacturing facility is capable of producing a significant percentage of the total Indian and regulated market requirement.”

Similarly, Transgene Biotek is enthusiastic about the production of docosahexaenoic acid (DHA), an omega-3 fatty acid that was recently initiated in October last year and whose technology was developed indigenously.

A positive outlook

Most companies are projecting a positive outlook for the next few years through their expected growth rates.

Dr Ella says with new products in the pipeline, he is targeting a revenue growth of 25 percent in the biologics space for Bharat Biotech. Lupin is also very positive about the returns from their pipeline of seven-to-eight products, which they hope to commercialize in the next few years (including a host of biologics). Other companies such as Virchow Biotech and Transgene Biotek too are also looking at a growth rate of around 30 percent.

Constant innovation coupled with smart manufacturing practices and rigid adherence to cGMP standards seem to be the order of the day as most companies are looking to expand their portfolio as well as their manufacturing capacities.

Manasi Vaidya in Bangalore