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“Vaccine & biological therapies are expected to increase investment in R&D to create demand in CDMO industry”

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Bengaluru-based Kemwell Biopharma, a biologics contract development and manufacturing service provider, is working aggressively on augmenting its existing infrastructure. In addition, the CDMO is exploring strategic partnerships with biopharma players in the ecosystem to fit out its additional capacity which can be executed within 12-15 months.

In conversation with BioSpectrum, Karan Bagaria, Managing Director, Kemwell Biopharma, Bengaluru reveals the future plans of the company.

Edited excerpts-

What were the key highlights at Kemwell during the FY20-21?

Kemwell had achieved several feats during this phase. To begin with, we acquired two new clients from USA for end-to-end novel biologics projects, which include both development and clinical manufacturing. Besides, we continued supporting commercial drug product manufacturing for two of our clients despite the lockdowns to ensure uninterrupted supplies to patients and successfully manufactured over 20 batches of a commercially approved drug substance at 2000 L scale.

At the same time, we also took a few expansion initiatives. We added AMBR250, a high throughput process development

equipment to its existing facility. We also initiated bioreactor capacity expansion by ordering 200 L and 1000 L single-use bioreactors (SUBs). Last but not the least, we built India's first cGMP Cell Therapy manufacturing site as a CDMO during the same period.

Future plans of Kemwell Biopharma, for 2021 & beyond?

At Kemwell, we look forward to securing more clients for both development and commercial manufacturing. We also aim to qualify the cGMP cell therapy manufacturing suite and initiate commercial production by Q3 of 2021. Besides this, we are looking at upgrading our analytical labs by adding advanced analytical equipment to support biologics characterization. We are also planning to install a pre-filled syringe line (PFS) and get our overall facility audited by US FDA by 2022. Kemwell is looking to grow and add additional manufacturing capacity of 12,000L and other new technologies as an Indian CDMO in the next 3 – 5 years.

How much revenue was generated during the FY20-21 & how much growth is expected this year?

We would not like to comment on the revenue figures as a private limited company. We expect growth in the range of 20-25 per cent.

Has the CDMO industry undergone any changes due to the pandemic and has Kemwell Biopharma adopted any strategy to meet the changing requirements?

We have been following an agile approach to tackle the ongoing pandemic. We have prioritized all COVID-19-related projects and would be offering hybrid technology to support various projects from small to large-scale manufacturing. We look forward to boosting and assisting Indian biopharma companies for the production of COVID-19 antibody therapies while also planning to expand our facilities to meet the demand of therapeutics antibodies manufacturing.

What are the future trends & challenges of the CDMO industry in India?

We believe production link incentives will support the pharma industry to become self-reliant. Also, vaccine and biological therapies are expected to increase investment in R&D to create demand in the CDMO industry.

Speaking of challenges, the CDMO industry is facing restrictions on external R&D and manufacturing projects due to COVID-19; the idea now is to primarily utilize resources on internal tasks until things normalize. The supply chain is also affected as the focus has shifted to the manufacturing of COVID-19 vaccines, causing a delay in the import of materials. At this time, capacity expansion has also become cost-intensive and time-consuming, disrupting the overall operations of the CDMO sector.

How is Kemwell currently contributing to the covid-19 vaccine space?

We have already obtained manufacturing licenses for one of the COVID-19 antibody therapies and are not restraining our capacity in order to meet the growing demand. Besides, we are also exploring manufacturing needs from pharma companies to support vaccines and therapeutics production.

Dr Manbeena Chawla

(manbeena.chawla@mmactiv.com)