

CPHl Worldwide Report: CMOs will account for four of the five top bio manufacturing capacities in 2025

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230 Covid-19 supply agreements known, with demand for larger biocapacity remaining constrained as a consequence of the circa 1000 vaccines in development

Ahead of the world's largest pharma event – CPhI Worldwide taking place in Milan, Italy (9-11 November, 2021) – the third part of the CPhI Annual Report is released with key findings for biologics manufacturing, biotechs and CDMOs.

CPhI experts – Dawn Ecker, Managing Director of bioTRAK Database Services at BDO and Fiona Barry, Editor at GlobalData PharmSource – look ahead to 2025 to predict the future demand for biologicals by volume, as well as the total capacity available and, the consequential impact in the short-to-medium term of the proliferation of Covid-19 supply contracts.

These new findings are released ahead of the in-person event, which is being held at the Fiera Milano, Italy – with an online platform running from October 25th through until November 19th – and is expected to welcome the end-to-end pharma supply chain. More than 1200 exhibitors will attend including finished dosage and ingredients manufacturers, pharma packaging specialists, CDMOs, bio companies and pharma machinery providers. All registered attendees will receive an advanced copy of the entire CPhI Report.

Tara Dougal, Head of Content and Insights at CPhI Worldwide, added: *“this year’s agenda will explore many of these issues, and we have one session, produced in collaboration with BioProduction, which looks specifically at the viability and commercial challenges of manufacturing Large Biologics. A further webinar will address Building Viral Vector Capacity and Capabilities to Realise the Promise of Gene Therapies, as the latter’s manufacturing challenges been severely exacerbated by the mRNA vaccine demand, which also requires viral vector manufacturing.”*

CPhI expert, Ecker predicts that biologics manufacturing volume will grow by circa 8% per annum, reaching approximately 3,900kL [up from 2,700kL in 2020]. However, during the same period, global biological manufacturing capacity will increase to 7,500kL [up from 5,200kL], but significantly, the location

and type of companies that have capacity will show a marked change from five years prior.

In 2025, nearly half of all capacity (44%) will shift from in-house manufacturing to CMO/hybrid companies. In fact, according to Ecker's findings, 5 of the top 6 companies by capacity volume in 2025 will be CMO or hybrid. The exception being Hoffman-La Roche, which will maintain its position as the company with the largest total biologics capacity. A number of CMOs are currently investing heavily in increasing their volumetric capacity and, in 2025, Samsung Biologics, Lonza, WuXi Biologics and Fujifilm Diosynth Biotechnologies respectively will make up places two through five – with the latter two rapidly rising from outside the top ten in the 2020 rankings.

“What’s interesting is that at the same time as CMOs are raising capacity, we are also seeing a geographic shift in where capacity is located, with Europe and Asia growing much faster than North America. In 2025 Europe will be home to the largest biologics capacity in the world, overtaking North America,” commented Ecker.

According to Ecker's research, another significant shift is the scale of manufacturing needed for future products in the pipeline, with over half the recombinant products currently in late phase development (*phase ii & iii*) forecast to need only a single 2,000L or 5,000L bioreactor to meet commercial demand.

“While capacity will increase over the next five years, demand for capacity – pandemic aside – will increase at nearly equivalent rate allowing for some short-term loosening of capacity constraints, but after 2025, capacity tightening may occur. In recent years, the industry was experiencing some capacity constraints at the clinical scales due to very high clinical demand and has responded in kind with a wave of facility expansions. However, many of the current Covid-19 therapeutics and preventatives require large-scale capacity. With new bioreactor installations reflecting a pre-pandemic demand profile, we are watching to see how the industry is adapting to the challenge of meeting both the typical and additional demands for capacity. In a further layer of uncertainty, should additional Alzheimer’s drugs and PDL/PDL-1 checkpoint inhibitors be approved, demand could be much higher than predicted, with increasing pressure being placed on large-scale manufacturing networks,” Ecker added.

In a further boon for the contract manufacturing industry – widely seen as a big beneficiary of the demand from the last two years – GlobalData reports show that there have been over 230 disclosed contract manufacturing agreements for Covid-19 vaccines and therapies, with many more (undisclosed) likely to exist. The larger biologics CMOs have been among the big winners of the demand for outsourced vaccine supply, and with booster shots already underway and more approvals to come (over 30 to date for COVID-19 vaccines and therapies), demand will likely remain strong for several years to come.

Barry, reflecting on how CMOs have gained due to the sudden need for additional capacity, commented: *“The CMOs benefiting most from Covid-19 vaccine development by number of contracts are Catalent, Lonza, and Emergent BioSolutions – though the latter may now suffer as a result of its well documented FDA inspection difficulties. Emergent’s contracts skew toward vaccine manufacture, whereas Catalent and Lonza’s contracts are more evenly split between vaccines and therapies. But other large contract development and manufacturing organizations (CDMOs) have also benefited greatly.”*

In fact, many of these supply Covid supply contracts are not only for large volumes, but also run over long periods of time – for example, Lonza signed a ten-year active pharmaceutical ingredient agreement with Moderna.

Orhan Caglayan, Brand Director at CPhI Worldwide, commented: *“When we look at the collective findings of Dawn and Fiona, we see that biotechs may continue to face some challenges in accessing available capacity at the right time. Many of the more established CMOs have large Covid contracts and capacity is shifting away from the US. This means that biotechs and pharma partners without sufficient inhouse capacity are going to have to widen their networks of potential partners. What we see at CPhI Worldwide is that proactive companies are looking ahead now for new partners and how they can ensure continuity and flexibility in supply.*

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