Approvals of COVID-19 biologics will put huge pressure on large-scale bioprocessing networks, according to CPhI Annual Report

Oct. 15, 2020 by Abdul Khalifeh

Tightening of bio-manufacturing capacity expected to occur after 2024, whilst Europe forecast to equal North America in total capacity

The third part of the 2020 CPhI Annual Report – released during the second week of the CPhI Festival of Pharma (5-16 October, 2020) – predicts, that if approved, COVID vaccines and therapeutics will cause an impending biomanufacturing capacity challenge, particularly for large scale reactors.

CPhI Annual Report expert, Dawn M. Ecker – Managing Director of bioTRAK Database Services at BDO – explores the medium- to long-term implications of supply and demand for biologics manufacturing. Her findings show that short-term capacity concerns have eased, but beyond 2024 we may see capacity challenges. The primary variable in future commercial capacity needs will be the progress of Alzheimer's drugs, PDL/PDL-1 checkpoint inhibitors and Covid therapeutics currently in late stage development.

Ecker reports that global bio-manufacturing capacity will increase to 6500kL by 2024 at a CAGR of 6.4% – up from 4700kL in 2019 – but capacity demand is rising faster and will reach 4700kL in 2024 at a CAGR of 12%.

"Should indications such as treatments for Alzheimer's disease or broad cancers obtain regulatory approval, a significant increase in demand for manufacturing capacity could occur, potentially leading to a serious capacity shortage. We also face an additional challenge of incorporating demand for recombinant proteins to combat COVID-19. We conservatively estimate that the demand for these products could require approximately 30 metric tonnes per year – so this potential demand will add significant pressure to manufacturing networks with large-scale capacity," commented Ecker.

The report also explores the continuation of recent manufacturing trends with geographical shifts underway; a changing demand in the scale of reactors; and how capacity is moving from big pharma towards CMOs and hybrids (those that make internal excess capacity available to outside developers).

Current reactor scales coming online reflect previous priorities for R&D and small volume products. As such, only 20% of the new bioreactors projected by 2024 will be of 10,000L size, whilst 50% will be of 2000L scale. Yet Ecker's models suggest the most probable scenarios will see half of phase II and III products requiring a bioreactor capacity of 10,000L to meet demand – and COVID-19 products will undoubtedly require multiple large-scale bioreactors. The challenge here is that much of the new bioreactor installations reflect a pre-pandemic demand profile.

In terms of access, currently around 70% of bioprocessing capacity is owned by product developers, with CMOs and hybrid companies providing the remainder. This potentially means innovators without in-house manufacturing may have difficulty accessing capacity as their products move towards commercial scale.

Ecker states that the distribution of capacity will continue to change over the next four years, with CMO/hybrid capacity share increasing to 36%. In terms of geographic spread of capacity, Europe will equal North America for total bio-manufacturing capacity by 2024, with Asia also expanding.

"Over the last five years there has been modest capacity growth in North America and Europe, with significantly greater growth in Asia. The next few years, however, will see significant growth rates projected in both Asia (~7%) and Europe (~12%), and by 2024 Europe will have equivalent capacity to the USA for the first time," added Ecker. "Looking deeper at the country level, particularly Korea, Singapore and Ireland, we see that growth here reflects government incentives and tax advantages, amongst other factors."

Tara Dougal, head of content at CPhI Festival of Pharma added: "What this report highlights is that the partnerships early-stage innovators establish now with CMO and hybrid companies will become increasingly important as new capacity challenges emerge in the next few years. With capacity also now spread globally, it means that pharma companies need to be increasingly international in their approach to sourcing and I would encourage the industry to use the CPhI Festival of Pharma to start building those vital connections. The event's digital nature has enabled us to bring increased insights in a variety of formats, as well as partners from all corners of the globe. Our event and the findings in the annual report will help deliver competitive advantages for all stakeholders in the pharma supply chain."

Download a copy of the CPhI Annual Report on Global Pharma Insights. An in-depth analysis of this year's CPhI Annual Report is also provided in a podcast debate featuring Dawn Ecker, as well as Fiona Barry, Associate Editor, PharmSource, a GlobalData Product, and Dan Stanton founder and editor of BioProcess Insider.

Summary of findings

Dawn M. Ecker, Managing Director of bioTRAK Database Services, BioProcess Technology Group – Bioprocessing trends overview 2020 – 2024

- Demand for biologics manufacturing by volume is projected to reach over 4700kL, a 5-year growth rate of over 10% per year
  - If Alzheimer's drugs and PDL/PDL-1 checkpoint inhibitors are approved, demand could be much higher resulting in capacity shortages in a typical forecast. However, if approved, COVID 19 therapies and monoclonal antibody-based infection preventatives could cause significant pressure to large-scale manufacturing networks
- Global biologics manufacturing capacity will increase to 6500kL by 2024 from nearly 4700kL in 2019
  - CMO/hybrid companies increase their control of capacity from 33% in 2019 to 36% in 2024 and by 2023, Europe will have capacity equivalent to North America. Capacity in Asia continues to grow.
- Half of the typical products in late phase development can be met by a single 2000 or 5000L bioreactor, but half of these products, as well as COVID-19 therapies, will require large-scale bioreactors of 10,000L
- Overall, capacity should experience some loosening in the short-term, but may tighten after 2024 – the approval of COVID-19 therapeutics and preventatives would also place significant pressure on large-scale manufacturing facilities
- Despite some shift in capacity distribution the majority of capacity will remain in-house, which may cause capacity issues for product developers that lack internal manufacturing capabilities

-ENDS-

Notes to editors

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