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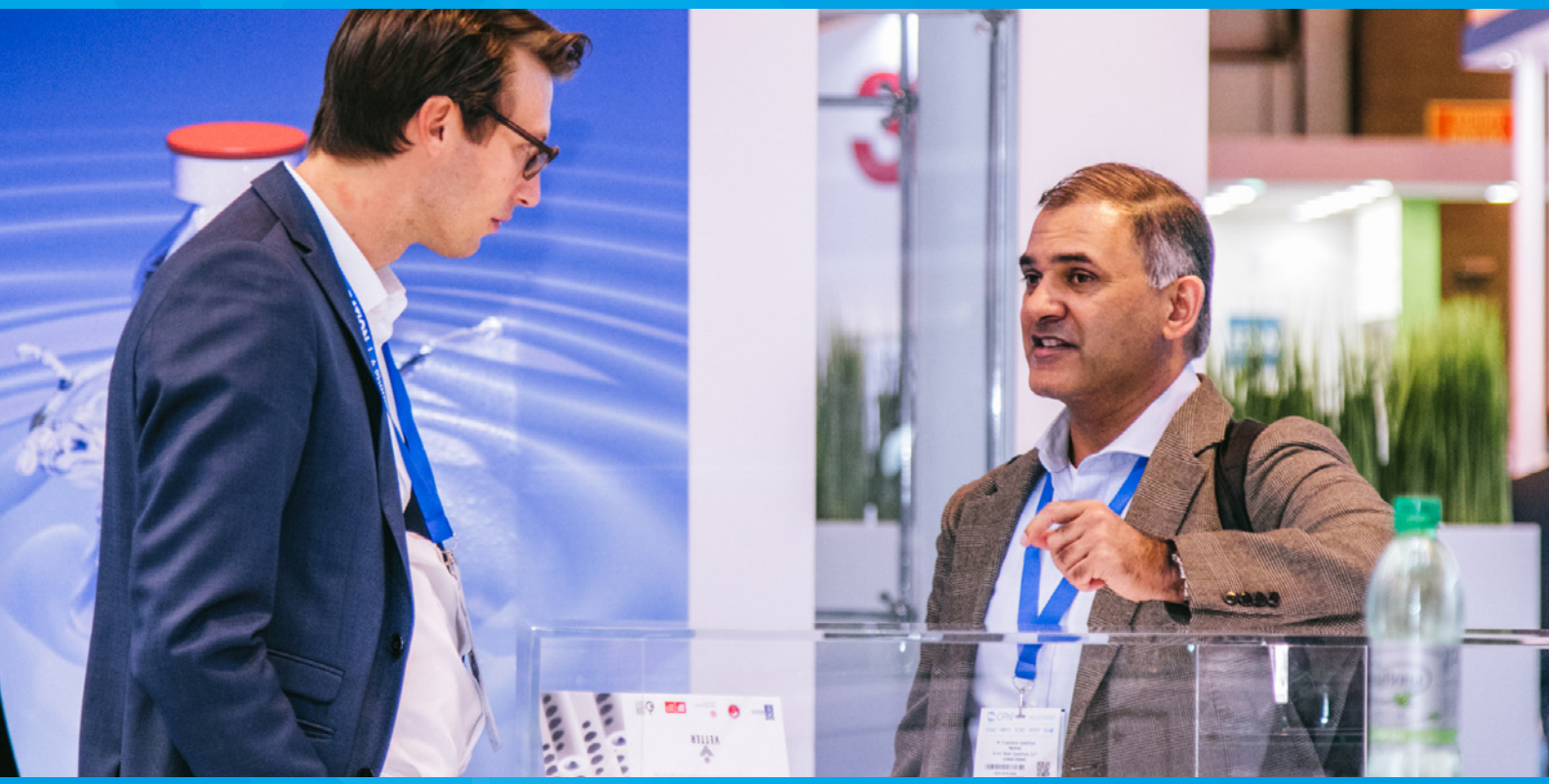

The dynamics driving CDMOs
Biopharma bottlenecks & competition

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Contents

03 CDMO business strategies
03 Large molecule bottlenecks
04 Competitive edge and consolidation
04 Finding CDMO talent
06 About ICSE

> Drug firms are outsourcing more work than ever, which is both fuelling competition in the CDMO sector and highlighting areas where capacity is unable to keep up with demand say experts.

Executive Summary

The demand for outsourced manufacturing continues to increase, driven by pharma's desire for cost efficiency. In addition, efforts to streamline and shed in-house capacity means some drug companies now have no option but to outsource.

- There is a lack of biopharma outsourcing capacity – particularly the skills required for cell and gene therapy production. This represents a real opportunity for CDMOs willing to invest in the expertise and technical capacity required to undertake such projects. Skills in viral vector production are in particular demand.
- Demand for biopharma capacity is also driving the development of technical solutions. Accessing these technologies will be critical for all CDMOs interested in capturing market share.
- It is also important that CDMOs are able to add expertise in line with innovation in drug development.
- Finding skilled staff is a global challenge. It is important that CDMO hiring strategies focus on emphasising the range of work undertaken and their technical capabilities in order to attract top talent.

Drug firms are outsourcing more work than ever, which is both fuelling competition in the CDMO sector and highlighting areas where capacity is unable to keep up with demand say experts.

CDMO business strategies

The contracting industry owes its existence to small molecule drugs. It was pharma's willingness to cut internal capacity and hand production to third parties – often staffed by former in-house teams – that established the sector.

Initially, only simple operations like fill/finish and packaging were outsourced. However, in subsequent years small molecule firms farmed out a broader range of manufacturing activities.

In recent years this trend has continued to the point where there are now "virtual pharmas" that do not have any manufacturing capacity and instead rely on contractors 100% [1].

A similar shift is being seen in large molecule outsourcing, at least as far as active pharmaceutical ingredient (API) production is concerned says Fiona Barry, associate Editor at PharmSource, a GlobalData product.

"Among FDA and EMA novel and biosimilar drug approvals in 2018, outsourcing of API production was roughly the same between biologics including cell and gene therapies, and small molecules, at approximately one third, according to the GlobalData Pharma Intelligence Center."

Large molecule bottlenecks

While the proportion of small and large molecule API production outsourced may be comparable, there is a marked difference in the volume of formulation work handed over to third parties.

Barry told us, "When it comes to dose manufacture, the gap widens: approximately 10% more small molecule novel approvals had their dose production outsourced than biologics.

She suggested that, "This difference between biologics and small molecules may reflect that there are fewer CMOs offering biologic services than small molecule services," citing GlobalData Pharma Intelligence Center data.

There is also a lack of biopharma-specific manufacturing capabilities in the CDMO sector,

particularly in areas like cell and gene therapy, which Barry believes is holding back growth.

She told us, "Analysis shows there is insufficient capacity for viral vectors to meet the demand for cell therapy manufacturing, an extremely promising sector that is heavily reliant on viral vectors."

This lack of capacity has already delayed some cell therapy production projects Barry says, explaining that, "These delays are caused by a lack of scalability and cost-effectiveness, quality issues, and process consistency.

"Our report shows that while the current scale of viral vector manufacturing is sufficient to supply clinical trials, this volume will not meet commercial needs in the near future."

Fortunately, there are signs the technology sector is responding. In recent months, G-CON Manufacturing has formed separate collaborations with GE Healthcare and Pall for viral vector manufacturing platforms [2,3].

CDMO's have also recognized the opportunity according to Barry, who said, "On the contract manufacturing side, we've seen Novasep, Symbiosis Pharmaceutical Services, Brammer Bio, Oxford BioMedica, and other CMOs make viral vector manufacturing investments over the last year."

Competitive edge and consolidation

Technical bottlenecks aside, the continued increase in pharmaceutical industry demand for outsourced manufacture means the CDMO sector is still highly competitive.

This has seen contractors adopt a range of strategies to gain market share. Some specialize while others, referred to as "full service" firms, offer a broad range of services.

The development of "full service" CDMOs has been accompanied by a wave of consolidation in recent years. Larger contractors have acquired smaller specialists to add capabilities in line with evolving market demands.

This trend is set to continue according to Kevin Bottomley, partner at Results Healthcare, who cites the fragmented nature of the market as well as sponsor desire to streamlined pipelines as key dynamics.

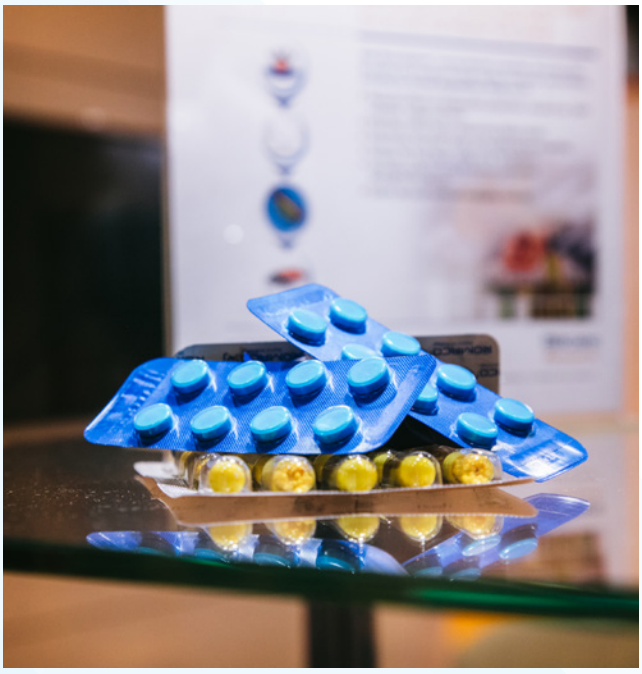
"M&A will be driven by a need to consolidate a highly fragmented business sector; large pharma continues to outsource more and more of its manufacturing activity and wants to simplify its outsourced manufacturing supply chain by having larger integrated suppliers."

Finding CDMO talent

But while CDMO business strategies may differ, ultimately, it is in-house manufacturing expertise that determines whether a contractor will succeed or fail.

As a result, finding staff is a major focus for contractors according to Lucinda Denney from Concilium Search, who says the globalised nature of the industry makes recruitment and retention a considerable challenge.

"The CDMO sector has not escaped the consequences of recent globalization trends, more recently feeling increased competitive pressures from CDMO's in India and China.



"The need for CDMOs to respond adequately to this new market pressure is high to ensure such anxieties do not stunt the ability to secure and retain local talent."

The keys to attracting staff, Denney says, are a CDMOs reputation as an employer and the work with which it is involved.

"Candidates are often attracted by the fast-paced, agile and dynamic nature of the industry and the challenges that come with meeting stringent customer demands."

Another point to consider when hiring is that, somewhat ironically given the origins of the CDMO sector, pharmaceutical companies are a very good source of potential employees, according to Denney.

"For candidates considering making the jump from the pharmaceutical industry to a CDMO, previous experiences of customer satisfaction and successful project delivery can particularly influence the reputation of a CDMO as a potential future employer, not just contracting partner."

For such people, the need for state-of-the-art technologies on site and a particular focus on investment in laboratory and production facilities is key, something CDMOs need to keep in mind according to Denney.

"Emphasising the competitive nature of CDMOs, the quest for new techs and the opportunities that come with the ever-growing international market can help attract and retain high-value talent in the industry."

Competing in the CDMO sector also relies on being able to retain talent and expertise to ensure services can be offered in a consistent and reliable manner.

Therefore, according to Denney, "Long term retention of top-talent in the CDMO industry is a considerable focus area of HR professionals in the sector.

References

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