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Speaker Spotlight

Jim Miller

Exploring Trends in Contract Manufacturing
Tue 05/11/19 10:30-11:40
ICSE Theatre 120D40

We catch up with Founder & Former President of PharmSource, Jim Miller to find out the latest insights affecting the CDMO sector.

Q: How is life post-PharmSource?
Since retiring from PharmSource, the market intelligence company I co-founded in 1996 and sold to GlobalData in 2016, I have remained engaged with the CDMO industry in a variety of ways. I have advised a number CDMOs on business strategy, and have been working with DCAT on education programs for DCAT Week. I continue to write industry trends, and serve as an ex-officio board member for the CDMO industry's trade association in the US, the Pharmaceutical and Biopharmaceutical Outsourcing Association.

Q: What are the most significant trends impacting CDMOs at the moment?
CDMOs have benefited mightily from the explosion in new drug development, which has been driven by advances in clinical science and robust support from financial markets. It can be said that the CDMO industry has enabled the dramatic growth in the drug development pipeline by making it much less expensive and much faster to get candidates into the clinic, significantly reducing the risk to investors. All segments of the CDMO industry – small and large molecule API manufacturing, drug product manufacturing and supporting services – have benefitted from the rapid market growth.

Q: Are there any particular services which are particularly in demand? What's driving this?
Thanks to the large and growing new product pipeline, demand for nearly all capabilities is quite robust. This includes custom small molecule drug substance manufacturing, which many observers had assumed would decline as the pipeline mix shifted toward biologics; while the number of biologics in the pipeline has grown rapidly, small molecule drugs still comprise at least 50% of the pipeline and the supply of capacity is very tight. Highly potent small molecule APIs are a particularly strong sub-segment. Cell and gene therapy are the hot new therapies and demand for viral vector manufacturing capacity appears to greatly outstrip available supply.

Q: We've seen significant M&A activity in the past year, what's the impact of so much consolidation?
M&A has created a growing number of "mega-CDMOs", CDMOs with revenues in excess of $1 billion with broad capabilities. The four largest CDMOs now have the

manufacturing scale of Big Pharma companies. CDMOs of such scale and breadth of capability can supply products of all types at a global scale, including the ability to be a single supplier for drug substance and drug product. There are also several CDMOs within striking distance of the $1 billion threshold, i.e., in the $500 million to $1 billion size range, but they will need to make some additional sizeable acquisitions to push them over the $1 billion mark.

Q: What are the challenges facing the sector?

Trade tensions threaten global supply chains and if they persist they could force a restructuring of current bio/pharma industry manufacturing and supply networks. Most bio/pharma companies have just one or two manufacturing sites providing the global supply for their major products whether they are captive facilities or contract manufacturers. While US-China and Brexit trade tensions dominate the headlines, other trade disputes involving the US and the EU and India are also simmering. Quality and compliance issues have already impacted sourcing from India and China, but tariffs and non-tariff barriers could potentially impact suppliers operating from Europe as well. Bio/Pharmaceuticals have not been impacted much as yet, but the situation bears watching.

Bipartisan consensus on lowering drug prices is emerging in the US, the last major holdout on government-mandated drug prices. While the industry has successfully fought off government efforts to control prices up to this point, Congress and the administration appear ready to use the government's buying power to impact prices on drugs purchased through Medicare. If this were to happen, not only would there be increased pressure on bio/pharma company cost of goods, but pinched margins could also impact spending and investment on new drug development.

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Q: What's your outlook for 2020?

I would expect 2020 to be another strong year for the CDMO industry, barring any major crises like an all-out trade war or financial crisis. New product approvals are at a record high, and new financing continues to flow into emerging bio/pharma companies at record levels. Even if a financial crisis were to hit the broader macroeconomy, many emerging bio/pharma companies have substantial cash on hand, and the cash-rich global biopharma companies would make sure the most promising new products are funded.

Jim Miller is the founder and former president of PharmSource, the pharmaceutical outsourcing industry's premier collection of market intelligence about contract manufacturing. Jim has consulted to many of the top bio/pharmaceutical companies and contract research and manufacturing organizations. He previously served as a consultant in corporate strategy with the Boston Consulting Group and as an executive with several healthcare information companies.

Hear Jim speak at CPhI Worldwide on the panel session Exploring Trends in Contract Manufacturing on Tuesday 5th November at 10:30 in the ICSE Theatre.