Changing Expectations in the Pharma Outsourcing Market

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While demand for outsourcing services remains strong in the pharmaceutical industry, spending is down and further decreases are expected. Service provides are faced with increasing competition and growing pressure to differentiate.

Pharmaceutical Market Remains Strong…

The global pharmaceutical market is currently expanding at a healthy compound annual growth rate (CAGR) of 6.3% according to EvaluatePharma. In addition, global pharma R&D spending is increasing at a CAGR of 2.8%. As a result, by 2022, the research firm expects 50% of added revenues to be derived from new products currently in the R&D pipeline.[1] The market for active pharmaceutical ingredients (APIs) is growing at a similar CAGR (6.5%) and will reach $225 billion in 2021, according to Mordor Intelligence.[2]

Not surprisingly, healthy growth rates are also predicted for the global pharmaceutical contract manufacturing and research markets. Mordor Intelligence predicts the contract manufacturing sector will expand at a CAGR of 6.4% to reach $84 billion in 2021[3], while Grand View Research estimates the global healthcare contract research industry will grow at greater than 6.0% annual and be valued at $45.2 billion by 2022[4].

But Is Changing…

While growth remains strong, the pharmaceutical industry is faced with pricing pressure and expectations for new medicines that provide measureable added value. Drug manufacturers are challenged to be first to market with highly efficacious, cost-effective and demonstrably safe products and are consequently seeking efficiencies in all aspects of their operations. Reasons for outsourcing to contract development and manufacturing organizations (CDMOs) and contract research organizations (CROs) are thus changing.

While outsourcing activities were initially driven by the desire to reduce costs, for respondents to the 2016 Nice Insight CDMO Outsourcing survey, the top five drivers for outsourcing were improving quality and efficiency, gaining competitive advantage and operational / technical expertise and reducing the risk of supply shortages.[5] In 2017, the top reason for participants in **2017 Nice Insight Contract Development and Manufacturing Survey** is access to specialized technologies.[6] The other top four reasons are improving quality, gaining expertise, outsourcing is seen as a strategic activity and cost.

Similarly, for respondents to the **2017 Nice Insight Preclinical and Clinical Contract Research Survey**, access to specialized technologies is the main driver for partnering with research firms.[7] Other top reasons include improving quality, incorporating outsourcing in their strategic plans, and gaining access to operational, subject matter and regulatory expertise.

Contract service organizations that serve as long-term partners, act as extensions of their customers' businesses and provide comprehensive, efficient, responsive and affordable support combined with access to novel and proprietary technologies will achieve the greatest success under these conditions.

With Continued M&A Activity …

Merger and acquisition (M&A) activity has occurred at a healthy pace in the pharmaceutical industry in recent years, including in the contract services sector. A total of 76 transactions involving service organizations were announced or completed in 2016, according to Capstone Partners, with sellers achieving high valuations with an average EBITDA multiple of 113.2x.[8] Notably, nearly three quarters of the deals were made by strategic buyers.

In the CDMO segment, Capstone reports that emerging and small pharma companies, which account for a growing percentage of pipeline candidates, require support across the full pharma development cycle from discovery through commercialization, which is driving M&A activity.[8] The number of US CDMOs acquired in 2016 totaled 14.

The increasing complexity of clinical trials is driving demand for sophisticated CRO partners that have a broad range of advanced capabilities, according to Capstone.[8] This need is a key driver of M&A activity in the CRO space.

CROs and CDMOs, as well as diversified testing, inspection and certification companies and private equity firms have also been busy acquiring analytical testing laboratories in order to meet the growing demand for cost-effective testing in the face of increasing regulatory requirements and the need to rapidly evaluate large numbers of pipeline candidates, according to Capstone.[8]

And Decreased Spending

Despite the healthy state of the market, the Nice Insight survey results for both the CDMO and CDMO sectors indicate a measurable decrease in spending by pharmaceutical companies on outsourcing activities.

Notably, the percentage of respondents to the 2016[5] and 2017[6] Nice Insight CDMO Outsourcing surveys with annual outsourcing expenditures of $50 million or more dropped from 71% to 56%, respectively. In addition, more respondents to the 2017 survey expect their companies to decrease (52%) rather than increase (39%) spending on contract development and manufacturing services over the next five years[5] compared to 75% and 4%, respectively, in 2016[6].

A decrease in spending was also noted in the CRO sector; the number of drug manufacturers spending more than $50 million/year on contract research services dropped noticeably from 56% in 2016[9] to 47% in 2017[7], according to the Nice Insight CRO surveys. Also similarly, in 2016 nearly 75% of respondents expected spending on contract research services to increase[9], while in 2017 that number was just 40%, with 50% predicting a decline in spending over the next five years[7].

The reduced spending matches well the significant drop in the number of new drugs approved by FDA in 2016 – down from 41 in 2014[10] and 45 in 2015[11] to just 19 in 2016[12] as of November 29, 2016.
On a positive note, around half of the respondents to the 2017 Nice Insight CDMO (55%)[6] and CRO (48%)[5] Outsourcing surveys expect their companies the number of CDMOs they partner with to increase.

Overall, however, the high level of M&A activity and the results obtained for the Nice Insight surveys suggest that competition in the CDMO and CRO marketplaces appears to be tightening, making it increasingly important for outsourcing partners to meet the quality, reliability, timeliness and other expectations of sponsor firms looking to outsource research, development and manufacturing activities.

BUT... Equipment spending Is Up!

Although they are decreasing spending on outsourcing, pharmaceutical companies appear to continue spending on equipment. Over one-third of respondents (38%) to the **2017 Nice Insight Pharmaceutical Equipment Survey** have equipment budgets that exceed $100 million, a remarkable increase from 2016.[13] In addition, 73% of respondents project budget increases in the coming years. A desire to increase productivity, lower costs, shorten the development timeline and access specialized technologies is driving the increased investment in equipment. The budget increases in 2017 may also indicate growing investments by small and emerging pharma companies to expand their in-house manufacturing capabilities.

References

1. EvaluatePharma, "World Preview 2016, Outlook to 2022," September 2016. http://info.evaluategroup.com/rs/607-YGS-364/images/wp16.pdf.
2. Mordor Intelligence, "Global Active Pharmaceutical Ingredients Market - Growth, Trends & Forecasts (2016 - 2021)," September 2016. https://www.mordorintelligence.com/industry-reports/global-active-pharmaceutical-ingredients-api-market-industry.
3. Mordor Intelligence, Global Pharmaceutical Contract Manufacturing Market - Trends and Forecasts (2016 - 2021) August 2016. https://www.mordorintelligence.com/industry-reports/global-pharmaceutical-contract-manufacturing-market-industry.
4. Grandview Research Inc., "Healthcare CRO Market to Reach $45.2 Billion by 2022," January 2016, http://www.grandviewresearch.com/press-release/global-healthcare-cro-market.
5. The 2016 Nice Insight Contract Development & Manufacturing Survey.
6. The 2017 Nice Insight Contract Development and Manufacturing Survey.
7. 2017 Nice Insight CRO survey,
8. Capstone Partners, "Pharmaceutical Outsourcing: Q1 2017." March 2, 2017. http://www.capstonellc.com/sites/default/files/Capstone%20Pharmaceutical%20Outsourcing%20M%26A%20Report_Q1%202017_0.pdf.
9. 2016 Nice Insight CRO survey,
10. FDA, "New Molecular Entity and New Therapeutic Biological Product Approvals for 2014" http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm429247.htm
11. FDA, "New Molecular Entity and New Therapeutic Biological Product Approvals for 2015" http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm430302.htm,
12. FDA, "New Molecular Entity and New Therapeutic Biological Product Approvals for 2016" http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm483775.htm
13. The 2017 Nice Insight Pharmaceutical Equipment Survey