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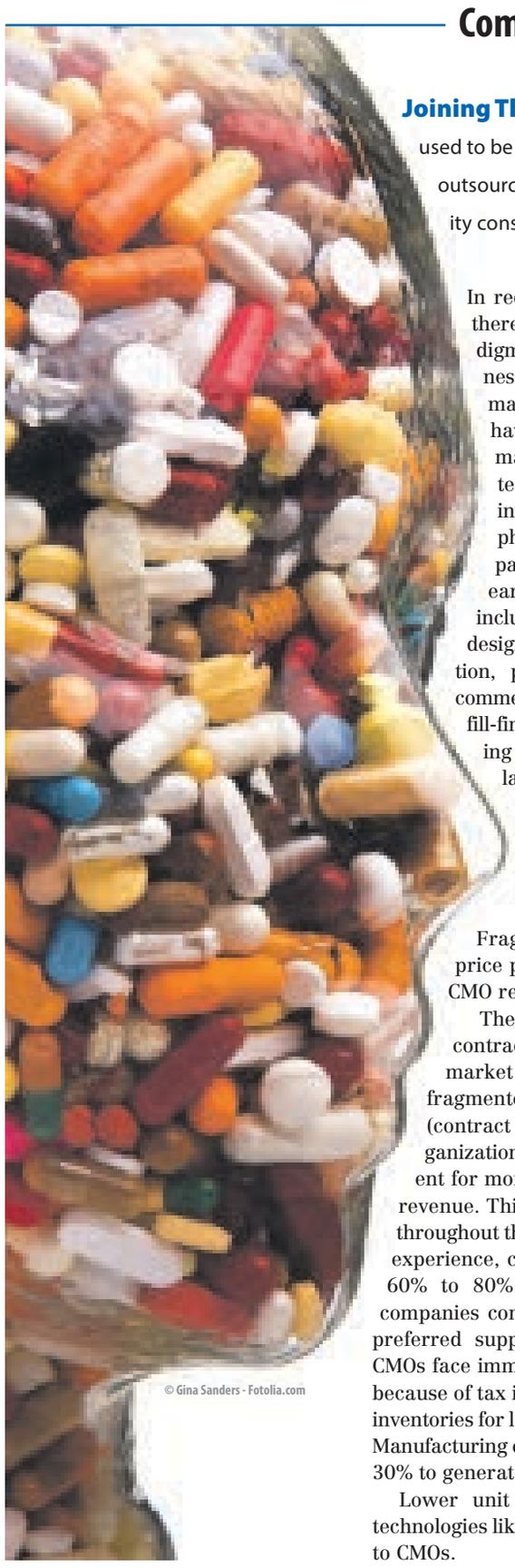
Expanding CMOs

Companies Aim to Stand Out in Global Pharmaceutical Contract Manufacturing Market



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Joining The Supply Chain – Pharmaceutical contract manufacturing used to be viewed as a one-off activity where a pharmaceutical company outsourced a drug for manufacturing predominantly because of capacity constraints.

In recent times, however, there has been a paradigm shift in the business model of contract manufacturers. They have gone from one-off manufacturing to integrating themselves into the supply chain of pharmaceutical companies, right from the early-stage activities, including preformulation design, process optimization, preclinical stage to commercial manufacturing, fill-finish services, packaging and logistics, regulatory, analytical, and marketing support.

Challenges of the Existing CMO Business Model

Fragmented market and price pressure drive down CMO revenues.

The pharmaceutical contract manufacturing market remains highly fragmented, with many CMOs (contract manufacturing organizations) relying on one client for more than 50% of their revenue. This suppresses prices throughout the industry. Based on experience, cost and size, nearly 60% to 80% of pharmaceutical companies consider going back to preferred suppliers. Furthermore, CMOs face immense price pressure because of tax incentives and lower inventories for low-volume products. Manufacturing costs must drop up to 30% to generate tax savings.

Lower unit volumes and new technologies likely will pose a threat to CMOs.

Low-volume products such as niche products, orphan drugs and generics as well as emerging markets present poor profit margins and lower inventories for CMOs, thereby resulting in price pressure and increased competition. The existing CMO business model can address only the basic requirements of global pharmaceutical companies such as unit cost, technology, IP protection, cost flexibility, and security of supply. This model does not cater to the restructuring costs (compensation arrangements and disposal of old facilities), financial effects (tax implications, government subsidies and exchange rate exposure) and commercial demands (local market approvals, portfolio and brand).

Lack of venture capitalist (VC) funding for early-stage companies will result in lower expenditures than prerecession levels.

A majority of VC firms prefer investing in companies with promising late-stage (phase II and phase III) drug candidates than in early-stage companies. The United States and Asia seem to be more attractive targets for VC firms than Europe, as Europe has been comparatively slow in regaining financial stability. In 2011, pharmaceutical R&D spending decreased for the first time in more than a decade in major markets such as the United States. Overall, VC investments in the pharmaceutical contract manufacturing market seem to be on a declining curve over the next five years as investors back away.

Injectable-Dose Formulations Likely to Spur the Growth of CMOs

Despite the current dominance of solid-dose formulations, injectable-dose formulations have experienced strong growth in the past five years, with a compound annual growth rate (CAGR) of 18.7% from 2007 to 2012. The significant growth for injectable-dose formulations is expected to continue in the next five years attributed to the following key factors:

The highly sterile and aseptic conditions and skilled personnel required for manufacturing injectable-dose formulations fuel demand for outsourcing as it appears to be a viable alternative to additional manufacturing capacities for pharmaceutical and biotech companies.

Cytotoxics are expected to be the key growth driver for the injectable-dose formulations segment because of the robust demand for oncology and other high-potency drugs such as antibody conjugates, steroids and IV fluids that require quick onset of action.

Pharmaceutical and biotech companies prefer prefilled syringes for existing and new products as prefilled syringes eliminate issues with overfilling of expensive drugs, thereby resulting in significant cost-savings. This likely will be a major driver for outsourcing to CMOs.

Other factors driving the growth of the injectable-dose formulations segment include rapid onset of action, better therapeutic efficacy and greater return on investments to manufacturers.

Unmet Market Need	Potential Game-Changing Strategy
An integrated, end-to-end business model on a risk-sharing basis with clients	Increased focus on preclinical development services such as formulation development, process support, process development, clinical trial manufacturing, analytical service and regulatory support in addition to the core custom manufacturing services is necessary to integrate into the value chain at early life-cycle stages and to build long-term relationship with clients. To attract more clients, certain CMOs likely will adopt a differentiation strategy that includes repositioning themselves among clients by promoting more services such as formulation improvements, alternate dose formulations, real-time order tracking, and logistics support. Patheon and DPT Laboratories have been two such leading CMOs that have positioned themselves as development service providers capable of transitioning from offering clinical services to commercial manufacturing.
Instilling new capabilities and anticipating capacity demand for careful outweighing of benefits and risks	Industry consolidation by means of acquisitions and strategic alliances to expand capabilities in new product and service segments as well as new geographies has made Aenova one of the fastest-growing companies. Aenova's foray into the liquid and semi-solid dose formulations segment by the acquisition of the Temmler Group in 2012 has resulted in a significant increase of market shares and capacities to meet global demands.
Demand for next-generation biological therapies such as vaccines, anti-cancer therapies, gene therapies, specialized antibiotic treatments and recombinant proteins	Because of increased focus of big pharma companies on biologics to address unmet needs in therapeutic areas such as oncology, the injectable-dose formulations segment — which is a low-volume, high-margin business — will likely be the growth driver for CMOs. Key focus areas in sterile manufacturing of injectable-dose formulations include vaccines, anti-cancer therapies, antibodies, gene therapies, specialized antibiotic treatments and proteins. Hence, investments and capacity expansions in injectable-dose formulations manufacturing will help CMOs, particularly the small and medium-sized, to grow and sustain their businesses in the market. Cytotoxics and lyophilized products dispensed as injectable-dose formulations are expected to be a significant source of revenue for CMOs; therefore, more contract manufacturers likely will develop these capabilities.

Unmet Market Needs and Potential Game-Changing Strategies

Given the challenges and complexities of the existing business model of CMOs globally, market participants must adopt potential game-changing strategies, both to address unmet market needs as well as to grow in the highly competitive global pharmaceutical contract manufacturing market.

Conclusion

Quality, timeliness and cost remain the top three factors in choosing a CMO. But differentiation strategies such as repositioning themselves among clients, capturing projects at early life-cycle stages and entrenching an integrated end-to-end business model are likely to pave the way for growth and sustenance in a market as highly fragmented and regulated as pharmaceutical contract manufacturing.

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