The pharmaceutical industry is undergoing dramatic change. Pricing pressures, pipeline challenges, and emerging global markets are reshaping the way these companies operate. Providers to the pharmaceutical industry, such as contract manufacturers, will need to transform as well. In the year to come, contract manufacturers that differentiate their offerings and capabilities will be able to retain customers and grow their business within this highly competitive marketplace. Those that are able to adapt quickly, by taking advantage of the transformative nature of the industry, will position themselves as market leaders.

We will highlight four trends that are shaping the contract manufacturing industry, providing guidance on how companies can successfully navigate each.

**2014 Contract Manufacturing Trends**

- **Putting the D in CMO**
  Will your company make the shift to support development and other “upstream” services? And if so, are you positioned to execute on this strategy?

- **Emerging Markets**
  How will your company help pharmaceutical companies meet their global supply chain demands?

- **Increased Need for Differentiation**
  What value-added capabilities and services will your company provide in order to evolve with your customer base and differentiate you from your competition?

- **Consolidation**
  How will your company remain competitive, profitable, and positioned for growth in a market increasingly dominated by large players?
In the year ahead, more contract manufacturing organizations (CMOs) will consider opportunities to provide services and support further “upstream” in the drug development process. With intensive margin pressures on the core business of commercial manufacturing and packaging, some CMOs are offsetting costs by offering more project based consulting and development activities. And where this has clearly worked for some of the larger CMOs, transforming them to what industry calls contract development and manufacturing organizations (CDMO), many companies have impaired their entry into this market by over-leveraging their current offerings.

**Saturated Market**
The increase in the number of offshore contract manufacturing alternatives has left CMOs struggling to maintain profit margins and differentiate themselves in an already competitive marketplace. The market has become increasingly driven by price rather than value, making it incumbent upon CMOs to provide value outside of the traditional commercial manufacturing phase of the drug product lifecycle.

**Research and Development Opportunities**
Outsourcing early-stage analytical, formulation, and development activities has become a growing trend for the pharmaceutical industry. This shift offers CDMOs more opportunities to partner and offer services within the drug product lifecycle. However, to accomplish this, contract manufacturers need to evaluate their talent and capabilities. Cannibalizing people and assets from the core contract manufacturing business can lead to difficulties in both ventures.

**Rise of the Emerging Biotechs**
A third reason for increasing opportunity in contract development services is found in the growth of emerging biotechs. Many of these companies are heavily focused on the development of drug compounds to address a specific therapeutic area. They lack infrastructure in the areas of formulation, clinical and regulatory agency submission. Often times, the desired end state for these companies is to sell to a big pharma or a biotech company. However, if the appropriate level of funding exists, partnership with a CDMO can provide another viable option. By working together, an emerging biotech, an established “donor” company, and a CDMO can move a product through approvals and into the market.

**Navigating this Trend**
- If you want to start or expand your development business (which is not for every CMO), create a strategy that, whenever possible, will be executed by separate leadership with a separate P&L, separate assets, and separate personnel.
- Plan to hire sales, marketing, and scientific personnel with specific backgrounds and experience in these areas. Do not rely on your legacy personnel to help you make the shift.
- Plan to keep a close eye on progress. You will need to get customers signed up for projects. Be aggressive about working with existing customers and securing new ones. Canvass the smaller startups and their funding sources. Consider unique gain sharing arrangements with other companies, especially as you are getting the business off the ground.
In 2014, companies providing services and support to pharmaceutical companies, including contract manufacturers, contract packagers, and contract development organizations, will look to establish assets in “Rest of World” (RoW) and “pharmerging” markets. The aim is to become part of the global supply networks for both branded and generic pharmaceutical companies, while also turning to emerging markets for the greatest growth in prescriptions and revenue.

**Market Shifts**
Regardless of what statistics you review, the continued shifts in growth from the US, Europe, and Japan to pharmerging and RoW markets is evident. IMS Health reports that in 2012, the Brazilian and Chinese markets grew by 16 percent and 21 percent respectively compared to an average market growth of minus two percent (-2%) for the five major European markets, and minus one percent (-1%) for the US market.1 We expect this global shift to be a driving trend for the pharmaceutical industry over the next decade. Paralleling this trend will be the continued movement of key areas of the pharmaceutical supply chain (both manufacturing and distribution) into these emerging areas.

**Demographics and Patient Access**
While revenue and prescriptions are growing within the RoW and pharmerging markets, they continue to struggle with infrastructure to support basic healthcare. For example, Frost and Sullivan reports that the average number of hospital beds and doctors in countries such as India and China is a fraction of those available in more developed countries (i.e., India has .7 hospital beds per 1,000 people, and .6 doctors per 1,000 people; China has 2.2 hospital beds per 1,000 people, and 1.4 doctors per 1,000 people).2 As healthcare infrastructure expands in these massive global markets, the patient population served by branded and generic pharmaceutical manufacturers will also increase. This, in turn will fuel opportunity for CMOs and other contract service providers.

**Navigating this Trend**
- CMOs will need to balance entrepreneurial “land grab” acquisitions in advance of customer contracts, and collaboration with existing customers, determining how they will work together as part of a global supply chain. Contract manufacturers who saw a competitive advantage in having all their manufacturing and packaging capabilities in one facility will need to rethink this strategy.
- CMOs should look to hire or contract experts with experience in local country regulations and business practices. There will be first mover opportunities for companies that look to expand; however, these opportunities will come with inherent challenges and risks that need to be clearly understood in advance.
- Examine opportunities in the areas of reconfigurable and disposable manufacturing. There will be a market opportunity for CMOs that are able to provide flexibility in what they manufacture and where they manufacture it.
Commoditization of Core Offerings
As competitive pressures continue to drive profit expectations lower and lower for traditional contract manufacturing offerings, these companies need to consider new ways to increase margins. The typical lower margin manufacturing and packaging of commercial products will continue to see price competition, especially from previous US providers with lower labor costs and locations that are closer to emerging markets.

More and more contract manufacturers will also look to offset this trend by adding in support for formulation and development activities. These project based activities operate with a different profit-to-labor model and can help CDMOs create longer term relationships with their customers earlier on – contributing throughout the full product lifecycle, rather than just during the commercial manufacturing stage. To execute on this strategy, however, it will require capital investment and changes to skills and core competencies. These are activities that traditional contract manufacturers have been hesitant to do in advance of having a paying customer or signed contract.

Lackluster Service Creates Opportunity
Traditional contract manufacturers have struggled with the infrastructure necessary to scale up their operations and manage multiple customers and multiple products. The typical approach has been to add labor, which is not sustainable to support continuous growth. The result has been degradation in customer service, as requests get lost within larger and larger organizations that usually have silos between sales, manufacturing, quality, packaging, production planning, and finance/accounting.

This lackluster performance can create opportunity for CMOs willing to invest in reengineering their processes and implementing automation, especially for some of the more routine requests they receive. CDMOs willing to invest in implementing customer portals and even employing dedicated customer care professionals can potentially take business from underperforming competitors, and attract new business by creating a better overall customer experience and value proposition.

Navigating this Trend
- Create a differentiation strategy as part of your normal business planning. Take the opportunity to gather input on emerging industry trends, and by talking to your customers.
- Look for ways to organize and redeploy labor in order to increase customer satisfaction. Try to standardize and automate wherever possible. This will require up front investment, but will pay dividends as your volume of manual work decreases – allowing you to support increases in your customer base without adding personnel.
- Look for first mover opportunities to differentiate and make an impact. This has been something traditional contract manufacturers have been hesitant to do. However, emerging trends such as biosimilar development, unit-dose serialization and traceability, and changes to regulations governing the global pharmaceutical landscape, provide additional business avenues for CMOs. Contract manufacturers that can offer solutions to these challenges will attract customers and set themselves apart from the competition.

In the coming year, CMOs will continue to seek out ways to differentiate their offerings, assets, and value-added services. CMOs are under enormous pressure to achieve financial results. In an environment where margin pressures and competition from new entrants are increasing, contract manufacturers are often vying for the same customers. These factors make the need to differentiate all the more pressing; the CMOs that win this battle will attract the best customers and remain viable in the future.
In 2014, industry mergers and acquisitions will continue. The contract manufacturing market is characterized by several large companies, and hundreds of smaller companies with limited capabilities and capacity. Many of these smaller companies have emerged to serve just a few of customers as part of a particular product supply chain. A variety of factors restrict their ability to scale up to handle multiple products and customers. As with the merger of DSM and Patheon in the fourth quarter of 2013, additional mergers and acquisitions will occur, particularly as companies aim to expand global assets and capabilities to manufacture and package specialty drug and biologics.

Size and Ability to Scale Provide Competitive Advantage
As outlined throughout this report, the addition of development capabilities, the ability to increase global reach, and the ability to further differentiate products and services are all enhanced by size and the ability to scale. On the flip side, it will be harder and harder for smaller, traditional CMOs to compete for new business. To combat commoditization and further differentiate their offerings, new manufacturing capabilities in new geographic locations will become more and more important.

Supplier Consolidation
Supplier consolidation has been a trend for pharmaceutical companies for years. This consolidation will continue to impact the contract manufacturing market as the big players drive towards the “one stop shop” suite of offerings. There will still be opportunities for smaller CMOs that specialize in specific manufacturing processes or that offer unique technologies. Nevertheless, it will become increasingly more difficult for these companies to “sign the next deal” as their people and capacity are focused on meeting current customer demands.

A Saturated Market Leads to Other Ventures
In addition to the consolidation of traditional CMOs to share assets and gain economies of scale, there will continue to be crossover where large contract research organizations (CROs) invest in manufacturing capabilities. CMOs who have traditionally operated autonomously should explore partnerships to fill gaps in their offerings along the entire drug development and commercialization life-cycle. As CROs look to expand their portfolio, CMOs will face new competition from companies that have clear and established relationships with the same customers. There will be market opportunities for CMOs and CROs that can further benefit their joint customers and their own businesses.

Navigating this Trend
• If you plan for acquisition or consolidation, make sure you have a strategy to quickly realize economies of scale and profitable growth. You need to clearly understand how the customer is being served, and who in your organization is providing this service. It is not enough to say you will “consolidate back office functions” and then offer the same level of service; in doing so, you will risk customer satisfaction, which will ultimately impact your sales.
• Look at partnership opportunities with CROs. If nothing else, you will likely share some of the same customers. From an account planning standpoint, examining relationships and alliances will be valuable. Consider ways to collaborate, and the types of value-added offerings that will leverage the capabilities of your organizations – particularly those supporting the handoff between clinical development and commercial manufacturing. Large CDMOs will face challenges in making this handoff seamless. For smaller companies with specialization in these core areas, there can be a short-term competitive advantage.
Continue the Discussion

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Putting the D in CMO

- Insights Paper: Biosimilars are Coming. Are You Ready?

Emerging Markets

- VIEWpoint: Optimizing Financial Planning and Consolidation for Global Expansion

Increased Need for Differentiation

- Insights Paper: Serialization in a CMO Environment: Strategic Approaches for Becoming Serialization-Ready
- Case Study: World-Class Solution Injects Consistency & Efficiency in Supply Planning

Consolidation

- Insights Paper: Contract Manufacturing Partnerships: Identifying the “Best Mix” of the Right Partners

For more information, contact Joe D’Ambrosio: jdambrosio@clarkstonconsulting.com Access Joe’s blog here.

References


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