How Can Contract Manufacturers Grow When Operational Performance does not Meet Expectations?

A QAD Leadership White Paper for Life Sciences Manufacturers

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HOW CAN CONTRACT MANUFACTURERS GROW WHEN OPERATIONAL PERFORMANCE DOES NOT MEET EXPECTATIONS?

Contract manufacturing organizations (CMOs), like yours, want to grow rapidly. Fortunately, as established pharmaceutical and medical device firms continually increase focus on their core strengths, they also increasingly outsource manufacturing to contract firms, resulting in robust growth in the CMO sector. At the same time, the contract manufacturing space is consolidating from a heretofore fragmented field.

Who will thrive and who will fail as the sector consolidates? One thing's clear: The winners will be the companies that operate most effectively and efficiently, raising questions for Chief Financial Officers and Chief Operating Officers. How can today's disappointing operational performance metrics support the ambitious growth objectives of their firms?

Industry research suggests that CMOs are struggling with three key challenges:

- **Excessive inventory** indicated by low inventory turns
- **Poor capacity utilization** indicated by low utilization levels
- **Underperformance on client deliverie**s indicated by poor delivery in-full on-time metrics

Unaddressed, these challenges can become threats to your existence. At the very least, they can render you vulnerable in an era of growing client and shareholder expectations.

That's why a growing number of companies are exploring next-generation business solutions that promise to strengthen operational performance. Read on to learn how CMOs like yours can thrive in the coming years by capitalizing on these visionary approaches.

MEGA-TRENDS AND MARKET DRIVERS

The March Toward CMO Sector Consolidation

Certain market drivers and trends threaten to make status quo approaches to contract manufacturing unprofitable and unsustainable. Consider some of the issues in play:

- The first mega-trend is the **expiration of blockbuster patents and the rise of generic pharmaceuticals.** Big brand drug companies have, so far, proved unable to replace the giant sellers that drove growth over the past few decades. As they confront the "patent cliff," they experience financial turbulence and turmoil, and turn to CMOs for help. Contract manufacturers, in turn, are challenged to operate more efficiently than ever in order to profitably meet the demands and expectations of these clients.
- The demand for heightened efficiency is exacerbated by overarching patterns in today's healthcare markets. **Payers are less willing than ever to reimburse for brand-name drugs** when proven generics are widely available. As a result, everyone is forced to operate in a more focused, lean and efficient fashion to prosper in a relatively harsh market environment.
- **Regulatory demands** have also put pressure on the industry. The Drug Quality and Security Act (DQSA) increased the FDA's regulation, monitoring, and enforcement of drug supply chain activities and includes serialization down to the unit level.

These trends have contributed to the growth of the contract manufacturing sector – encouraging drug companies to step back and concentrate on discovery, marketing and other core competencies. Indeed, vertically integrated business models have given way to a global network of dynamic suppliers in pursuit of market share and profitable growth.

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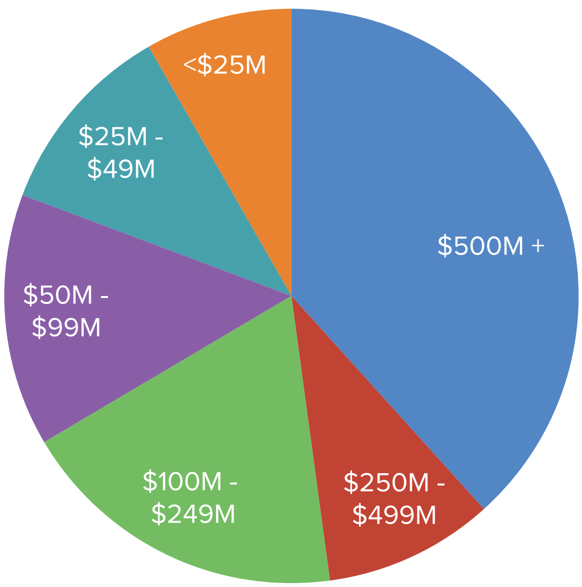
With these patterns in play, CMOs are engaged in a frenzy of M&A. “Consolidation is the name of the game for CMOs, (see Figure 1) with 18 acquisitions of one drug-product CMO by another drug-product CMO in the past three years,” according to Pharmaceutical Technology.

Figure 1: Dose CMO market share by company size (based on 2014 revenues).



Source: PharmSource, Contract Dose Manufacturing Industry by the Numbers, July 2015

CMOs, however, are confronting increasing expectations from their clients, regulators, boards and other stakeholders. That fact exposes today’s operational limitations and weaknesses, forcing CMOs to continually raise operational capabilities and performance levels.

“During these turbulent times, the need to find cost savings, operational economies and competitive advantage prompted drug-owning companies to want more from contractors, seeking deeper and more meaningful business relationships to help speed their products to market,” according to Pharmaceutical Manufacturing magazine.

Couple this fact with the fragmented nature of the CMO marketplace. Of the top 10 CMOs by revenue, not one controls more than 3% market share, according to research firm Visiongain (see Figure 2). With client expectations climbing, the likelihood that aggressive consolidation will continue is high.

That raises questions for you as an executive leader: in the shakeout of CMO players that appears inevitable, will your company be the hunter or the hunted? Will your valuation and cash position be strong or will operational flaws and inefficiencies drive drown shareholder value, rendering you vulnerable to serial acquirers?

Pharmaceutical Contract Manufacturing Organizations

Rank	Company	Revenue ($M)	Market Share (%)
1	Catalent	1,458	2.7
2	Lonza	1,355	2.5
3	Evonik	1,110*	2.0
4	Royal DSM	1,026	1.9
5	Patheon	1,023	1.9
6	Baxter BioPharma Solutions	992	1.8
7	Boehringer Ingelheim	862	1.6
8	Fareva	755	1.4
9	Aenova	712	1.3
10	Teva	692	1.3
	Overall World CMO Market	54,907	100.00

Source: Visiongain, 2016

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CONFRONTING PAIN POINTS

The Costs and Consequences of the Status Quo

C-Level executives – particularly CFOs and COOs – are intent on driving revenue growth, strengthening profitability and achieving operational excellence in an era of rapidly increasing expectations. They are presently experiencing three critical challenges that impede their ability to meet these objectives, specifically excessive inventory, poor capacity utilization and underperformance on client deliveries. Let's examine these challenges one by one.

Excessive Inventory. Stock-outs are unacceptable in today's environment. Should an important customer be told that there's insufficient supply to meet its demand, then that customer is liable to go elsewhere, undercutting your revenue projections.

Unfortunately, risk-aversion around this issue also presents a threat, where inventory levels will grow and inventory turns will remain limited. This ties up your working capital, which otherwise could be used to fuel growth. It prevents you from investing in innovative initiatives such as differentiated packaging, more complex formulations, cold chain services and clinical trial management capabilities that can set you apart in a hyper-competitive market. It is an illusion if high levels of inventory levels feel safe. It is an indicator that your sales and operations planning capabilities – your limited ability to reconcile available supply with emerging demand – are confining you.

Sometimes inventory bottlenecks are related to a process breakdown. Some companies don't have full visibility into their inventories until it hits the docks. Sometimes they lack full line of sight into in-process goods moving through manufacturing. You may lack forecasting and demand planning visibility to ensure labor and material availability in line with production.

Whatever the cause, you may be experiencing inventory turns of just one or less when industry best practice may be three or more, depending on the sub-segment. Existing industry research suggests the current range of inventory on hand can run anywhere from 45 days to 185 days. Being at the high end of this range risks being eclipsed by rivals running at higher levels of performance.

Low Capacity Utilization. If you have 10 manufacturing suites and you are only using half on a weekly, monthly or annual basis, then your utilization rates are low. Industry best practice points to 70% utilization rates or higher. It is common, however, for CMOs to report utilization rates in the 30-40% range – an abysmal level by today's standards.

There are plenty of explanations for weak performance levels: Managers report that equipment is down during production runs, or they may lack sufficient material or it may be the wrong material. Specialized operators may be required, yet be unavailable at the point of production. These explanations are just excuses in the eyes of customers. Due to the inefficiencies associated with capacity underutilization, CMOs are in danger of not meeting their contract obligations to customers. Responsiveness is low and turnaround times are in jeopardy.

Financial metrics – the concerns of a watchful CFO – also are at stake. Consider the impact on return on invested capital when half or more of your equipment is sitting idle. You have mixers, blenders and dryers that are unused 60 to 70% of the time. What happens to profit margins when half your highly trained, highly paid staff members are sitting on the bench waiting to be deployed?

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Underperformance on Client Deliveries. Today, CMOs are measured by their sponsor clients on Delivery in-Full On-Time (DIFOT). Companies, however, struggle to fully meet the terms of an order – in-full or on-time, or both – in a growing number of instances. This can be a powerful blow to customer satisfaction and loyalty. Client expectations are escalating. Will they be met? Suppose you can deliver 100 cases by April 30 or 60 cases by April 15, but not 100 by April 15 as agreed. What's the impact on a customer relationship? Considering that payments are often tied to milestones, what's the impact on cash flow and profitability?

One factor contributing to the DIFOT problem is the vast array of quality tests that must be conducted in the manufacturing process. Each process step may introduce new layers of quality control. You may end up with shipments – finished goods inventory – awaiting release due to an unperformed quality control; the goods are just sitting there on the dock. Perhaps the client has observed a process deviation or that documentation lacked appropriate sign-offs. Then there's a cold chain issue because the product hasn't been kept at a precise temperature.

Whether it's a lack of upstream visibility into the supply chain, tracking of in-process inventory or downstream assurance that a batch has been appropriately handled, your struggle to gain line of sight can end in huge losses. It may be a customer penalty due to an unmet milestone or a scrapped batch that carries enormous expense. DIFOT is essential to customer success and profitable growth. Under the circumstances, any indicators that DIFOT performance levels are not being met should be treated with alarm.

Such challenges paint a grim vision of the future that some CMOs will inevitably experience. A new trajectory, however, is possible for companies that conquer the status quo. In fact, a growing number of CMOs have begun shifting their thinking and investments in pursuit of operational excellence.

NEXT GENERATION BUSINESS SOLUTIONS OFFER A PATH TO OPERATIONAL EXCELLENCE

Top performers in the CMO sector have learned you can strike a balance between risk management and inventory management. They have increased inventory turns and reduced inventories, but not to the point where they are vulnerable to stock- outs. They have freed working capital. Some have dramatically increased capacity utilization. They have ensured they are meeting customer commitments in terms of delivery.

What if you could do the same?

You can. As world-class CMOs are discovering, next-generation business solutions can provide powerful gains in terms of operational and financial performance. What does a next-generation business solution encompass?

- **Deep domain expertise tied to customer engagement.** You need a partner that enables you to optimize and streamline operational processes. Drawing on best practices and skilled expertise, you can map your processes, enhance them and automate them for maximum performance. Working with experts who understand your business, you should be armed to take on issues such as quality management, serialization and supply chain management.

- **Future-facing insight.** You should have a window into your supply chain and your demand chain so that you can plan ahead and act decisively. Rather than be surprised by process breakdowns, you should anticipate problems and prevent them. Rather than be blindsided by events, you preempt them or influence them. You should be able to strengthen decision-making.
- **Full-spectrum suite of applications.** A cloud-based ERP solution built for manufacturing should incorporate demand planning, supply planning, quality management and a full mix of financial capabilities. Collectively, thesemodules should enable you to gain full control of your manufacturing processes while remaining compliant with global GMP regulations. You can avoid risks and continuously improve and modernize your operational processes, and ensure you are fully aligned with your business strategy and objectives.

Finally, you need a partner capable of delivering a solution that's fully matched to your business model. Your solution should reflect the kinds of investments you need to make and map to the scale at which you operate. Your solution should support your ambitions while enabling you to maximize your ROI.

Of course, a big part of the ROI equation is the "I." Is the investment appropriate and matched to the return or are you in danger of getting overrun or overwhelmed by excessive offerings that exceed your available resources?

This is the reason executive decision-makers like you are moving beyond the status quo in terms of existing operating approaches. Next-generation ERP solutions promise to deliver support for profitable and sustainable growth while meeting your objectives for operational excellence. This is why companies like yours are no longer willing to stand still. Fortunately, you don't have to. You now have an opportunity to:

- Optimize, streamline and modernize your business processes
- Automate quality functions
- Gain greater visibility into your supply chain
- Serialize your products
- Ensure you have a compliant solution in a qualified cloud environment

By ensuring you have a business partner that can provide valuable guidance and best practices while supporting the system-level transitions you face, you can achieve the operational performance results necessary to reach your goals. You'll address increasing performance demands for inventory, capacity and delivery. That's how you can reconcile your growth aspirations with operational performance.

Your Strategic Assessment: to find out how you can obtain an assessment that clarifies where you stand today on operational performance, contact a client adviser at QAD at info@qad.com. With decades of Life Sciences manufacturing experience, we can clarify your path to operational excellence.

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