



ADAPTING TO CHANGE *in* CONTRACT PHARMA

How can pharma outsourcing partners overcome the challenges of a rapidly changing industry?

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SUMMARY

PROBLEM:

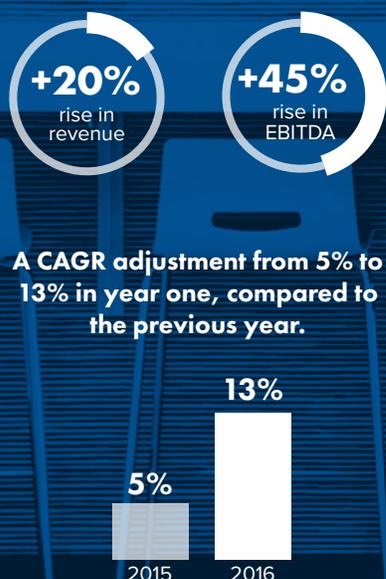
A pharmaceutical contract development and manufacturing organization (CDMO) recognized that their business model had not kept up with modern market realities.

SOLUTION:

Grounded in a comprehensive assessment, Clarkston worked closely with the client to develop an actionable market strategy and a prioritized series of critical operational initiatives to transform the business and prepare for the future.

RESULTS:

The initiatives unlocked the capacity for a 20% rise in revenue, a 45% rise in EBITDA, and a CAGR adjustment from 5% to 13% in year one, compared to the previous year.



A contract development and manufacturing organization (CDMO) found itself wondering how it could continue to be competitive in a rapidly evolving industry. Traditionally, contract pharmaceutical manufacturing had focused on the large-scale manufacturing of drugs for commercialization. Over time, these organizations began to capture value further upstream in the drug development lifecycle, pushing into pre-formulation and clinical supply. As the contract pharma model advanced into the late 2000s, customers were increasingly interested in a strategic outsourcing partner – one company that could offer any number of services from candidate selection to commercialization.

At the same time, the pharmaceutical outsourcing market was experiencing a tremendous amount of change. Cornerstone services were maturing, driving profit centers towards commoditization. Consolidation of outsourcing players was impacting the way that CDMOs went to market. The industry also had to prepare for growth, as the emergence of biologics and biosimilars had begun to take pharma by storm, each requiring their own set of capabilities to capture the opportunity.

As a result, these intermediaries faced an unprecedented number of challenges.

- *How could they simultaneously operate their multi-dimensional business and ensure that each service offering was optimized?*
- *How could they balance product-focused “white glove” services with services that require extreme operational excellence?*
- *How could they determine capabilities to add for the future and which to prioritize for investment today?*
- *How could they maximize the value that they offer to their clients at each part of the drug development lifecycle?*

Management knew that answering these questions was critical to maintain competitive advantage in a new business reality. They chose to partner with Clarkston Consulting, a leading strategy, operations, and implementation consulting firm to help them transform their business to succeed in a dynamic market.

CHANGE DRIVERS and CHALLENGES

Trends impacting the pharmaceutical outsourcing market

ACCELERATING M&A ACTIVITY

The consolidation of companies within the pharmaceutical outsourcing space has become more prevalent as industry players seek to quickly expand capabilities. These organizations aim to offer more value to their customers via interconnected services along the drug development cycle. Successful partners will provide true end-to-end solutions and successfully operationalize them. The ability to scale operations and maintain effective technology transfer between stages remains essential.

80

Number of M&A deals by pharma outsourcers projected in 2017, a 25% increase.

COMMODITIZATION OF MATURE SERVICE OFFERINGS

Continued commoditization of common services has resulted in diminishing profit margins. Customers no longer see these services as differentiators and seek organizations who offer them at the best price point. It remains critical, however, for diversified contract organizations to continue to provide these services as part of broader service bundles for their customers. The need for strategic customer relationships remains crucial. Brand equity in commoditized services will continue to erode as customer choices shift in real time.



Compendial Testing is an example of a service that has become commoditized.

PATIENT CONSUMERIZATION DRIVING NEW R&D MODELS

Digital has informed and increased patient's modern expectations across all dimensions of healthcare. This market-driven evolution puts additional pressure on manufacturers to accelerate their speed to market. Traditional R&D models are beginning to evolve - pharmaceutical companies will increasingly rely on stable outsourcing relationships to increase speed to market in the patient-centric landscape.

\$242.6 BILLION

Global life sciences R&D spend in 2017; small molecule, large molecule, generic, government.²

GROWTH IN BIOLOGICS / BIOSIMILARS

The growth in the market for biologics and biosimilars has created additional demand for contract organizations in research, development, and manufacturing. Large molecule complexity is also on the rise in biologics, driving greater demand for outsourcing. Technology, operations and technical knowledge must work in concert to respond to these growing demands and capture the biologics opportunity.

Biologics market is expected to grow **10.9% CAGR** over the next 7 years.³

PRICING PRESSURES ON CORE CUSTOMERS

Increasing pricing pressures on pharma, driven by growing buyer leverage and additional regulatory attention, will continue to make outsourcing attractive to customers. Cost constrained pharma and biopharma companies will look to outsourcing partners for creative terms and bulk agreements. To succeed, contracted organizations must also be increasingly flexible to work with amplified demands of many different customer types

80%

of pharma outsourcing customers we spoke with mentioned "flexibility" as a key attribute they desire

FOUR CRITICAL SUCCESS FACTORS

Working in close collaboration with the client, the team took a holistic approach to address the four areas most critical for future success in pharmaceutical outsourcing.

KEYS TO SUCCESS IN MODERN PHARMA OUTSOURCING

1. Creating an optimal sales mix that aligns with strategic goals and market growth realities.
2. Optimizing the end-to-end business processes to sustain consistent, high-quality service.
3. Constantly incorporating customer feedback for continuous improvement, while also investing in the services of tomorrow.
4. Making pragmatic investments in technology and automation, built by capable teams on solid processes.

THE MARKET

The pharmaceutical outsourcing market is expected to grow at a CAGR of 7.3% and be valued at \$352.8B by 2020.⁴

+7.3%



\$352.8B

SALES AND MARKETING

A modern sales mix for a modern organization

As the CDMO industry has grown, so had the number of services that our client offered to their customers. Flexible to their customers' requests, the client was now faced with an unmanageable menu of services, many of which were not hitting profit targets. In response, Clarkston brought together disparate data about service line market growth offering differentiation, group profitability, and capacity models to create an optimized sales portfolio. The new sales targets, now aligned with the business strategy, indicated to the sales organization which areas to focus investment, reposition, or consolidate.

With new guiding principles in place, the team went to work to operationalize the new sales targets. They worked closely with the sales & operations planning group to improve demand planning and project coordination. They created processes to better involve SMEs in technical sales, and streamline the sales process for common services. With new models in hand, the client could now drive down variability, decrease the amount of time required for project intake, and improve pricing to match market realities.

Recognizing the importance of sustainability in sales and marketing changes, the team worked with the client to appropriately update the business development team incentives to better align the sales team and sales strategy. A deal filter was developed that allowed sales reps to utilize a simple process to ensure that sales opportunities aligned with the sales strategy. Updated marketing materials were developed to fill critical gaps in service promotion. With the right foundations in place, the project shifted focus to internal business processes.

OPERATIONAL EFFICIENCY

Driving down variability, freeing up capacity and reliably executing

The client's operations team knew that their business processes had to be improved, from project origination through delivery. While their current procedures promoted quality above all else, their efficiency suffered. Sluggish practices amplified problems, and re-work often competed with scheduled new work. The Clarkston team set out to identify the most critical pain points in the process and assess the most important areas to improve for maximum impact.

The team focused on identifying and reducing non-value-add

activities to, in turn, free up billable capacity in the labs.

- Manual activities were measured and analyst's time was assessed.
- Recommendations were developed for optimizing operations from the ground level up.
- Processes were improved to ensure teams had the correct resources, at the right time, for their piece of the end-to-end process.
- The team developed a robust scheduling tool that enhanced the client's finite planning.
- A bridge was built between the recommendations in sales & marketing and operations to ensure efficient handoff between sales and operations.

As a result of these changes, the organization is now able to reliably complete a greater volume of work per year. Paired with increasing demand growth across CDMO services, the client was now positioned for profitable growth. Customers recognized the improvement, as the organization could now complete projects more quickly and adhere to tighter deadlines. Most importantly, these changes unlocked the ability to meaningfully scale the business and accelerate growth.

CUSTOMER FOCUS

Becoming the Partner of Choice

Along with the comprehensive internal fact-finding, the Clarkston team conducted a

series of customer interviews, speaking with a representative cross section of customers to gather additional perspectives. This type of customer input is highly valuable and critical to incorporate into strategic and operational initiatives. The time was spent discussing the client's performance, outlining areas for focus, and exchanging ideas about the future.

In combining this external data with internal analysis, the team provided recommendations to enhance quality systems, aimed at decreasing investigations, minimizing rework, and improving customer interactions. A comprehensive plan was developed to reduce the volume of documentation required, decrease instances of 'not right first time', enhance standardization, and develop quality mindset training. Opportunities also existed to enhance customer collaboration processes and systems. This was delivered via a customer portal that is able to offer different capabilities based on the stage of customer relationship (development, analytical testing, and/or manufacturing).

Combined with Clarkston's industry perspective, the customer interviews also served as a basis for analysis around future capabilities and technologies that were not currently offered, but could be subjects for future investment. Some of these technologies were tagged as 'quick wins', and client teams were activated to assess the viability of the

AVERAGE INDUSTRY

CMO	→	16.7%
CRO	→	20.2%
CDMO	→	19.5%
Other	→	18.3%

Given the state of the industry, pharma outsourcers stand to improve average EBITDA margins by 3-5% by 2020 through sustained effort in sales and operations

WHAT ARE CUSTOMERS LOOKING FOR IN A PHARMA OUTSOURCING PARTNER?

1. High quality of service and delivery
2. Consistent on-time delivery.
3. Industry leading scientific capabilities
4. Competitive pricing
5. Effective lines of communication
6. Strong history of compliance with GxP
7. Expanding capabilities for future needs

service and its alignment to the corporate strategy. In addition, more than a dozen emerging scientific capabilities were assessed and primed for strategic consideration and future investment. Joint planning and execution along emerging services can serve as a powerful gesture in long term strategic partnerships.

TECHNOLOGY AND AUTOMATION

Investing in differentiation for the future

As with any asset heavy business, it is critical to target areas for investment in technology, equipment, instrumentations, and automation. In the contracting business, significant equipment downtime can lead to missed deadlines and strained client relationships. Superior technology can serve as a differentiator in sales and in execution. Refresh plans are a core piece of this strategy, but companies must also take a broader look at their strategic goals and future capabilities to plan for the future appropriately.

Selective automation, on top of solid business processes, can serve to effectively accelerate numerous manual tasks. Misplaced technology, or automation 'for the sake of automation' can wreak havoc on teams, processes, and budgets. With this in mind, the Clarkston team helped the client develop a strategic automation road map that synced with their business strategy and current budgets.

Alongside their process recommendations, the teams jointly made decisions about foundational technologies and tools.

CONCLUSION

As pharma companies have evolved, so have the challenges facing outsourcing partners. CDMOs are positioning to extract more value along the pharma value chain, which is unlocking new opportunities and posing new challenges. While the addressable market continues to grow for the foreseeable future, it's more important than ever to optimize the business to position for profitable growth.

This client knew that basic operational initiatives and standalone strategic assessments were not enough to exploit the change going on in the market. Working together, Clarkston and the client were able to develop a sequenced series of operational improvement initiatives, built on their new market-driven strategy. These worked in concert with one another to help the organization transform. Tomorrow's market leaders will be hyper-adaptable and able to flex their strategy and operations to meet the many challenges that tomorrow will hold.

QUESTIONS TO CONSIDER

While grappling with the shifting landscape in Pharma outsourcing, we recommend asking yourself the tough questions about both your capabilities and environment.

- *Do we understand the implications of the major market trends for outsourcers and are our people equipped to interpret and leverage them?*
- *Do we have a proven approach to evolve our market strategy to meet modern demands? Does our strategy connect downstream with our core operations?*
- *Are our business processes efficient and effective in helping us deliver predictably and consistently? Are we hitting profitability targets?*
- *Are we simultaneously improving efficiency in our core services and adequately planning investment in future scientific and technical capabilities?*
- *Are we strategically and operationally equipped to serve the needs of our customers across all our services, consistently and profitably into the future?*

To learn more about Clarkston Consulting's contract pharma services and experience, contact Michelle Tartalio at michellet@clarkstonconsulting.com

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