

Vivek Sharma - CEO, Piramal Pharma Solutions (PPS)



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Vivek Sharma, CEO of Piramal Pharma Solutions (PPS), one of the world's leading CDMOs with a presence in North America, Europe, and Asia, provides insights into the main trends shaping the global demand for contract development and manufacturing services. He also highlights the company's customer-centric business model, the strength of its global manufacturing footprint its M&A strategy, as well as how he aims to establish PPS as a best-in-class organization in terms of quality compliance.

The global CDMO market amounted to USD 65.8 billion in 2016 and is set to experience a sustained growth moving forward to eventually reach USD 85 billion by 2020. What do you identify as the main drivers behind this strong demand?

When looking at the macro environment, all Big Pharma companies want to increase the speed-to-market of their life-changing products while at the same time reduce development and manufacturing costs. They strive to apply this approach to an ever-increasing number of products in the pipeline but they do not hold the in-house capacity to reach this objective. In this context, they are left with no choice but to look for external partners that can enable a streamlined and faster go-to-market model and this is precisely where the CDMO industry enters the picture.

Nevertheless, many pharmaceutical companies that already rely on outsourcing still struggle to fully rationalize their supply chain, for the simple reason that the number of suppliers and providers

they rely on has soared tremendously over the past years. As a result, there is an ever-growing demand for integrated, one-stop-shop service providers which can offer a larger set of services across the value chain.

Although Big Pharma companies play a critical role in fostering the demand for CDMO services, one should not overlook the growing importance gained by biotech companies in this paradigm. The overall number of biotech companies operating worldwide has tremendously increased over the past years, and the majority of them do not hold in-house development and manufacturing capacities. For these biotech companies too, the only way to bring products to the global market is to partner with CDMO companies.

In this context, there is no doubt that the global CDMO market will continue to grow and expand in the coming years, but only players with comprehensive and well-targeted offerings will fully benefit from this fast-increasing demand.

Don't you think that rising protectionism - as it seems to materialize in some strategic markets - could eventually alter the demand for outsourcing services?

First and foremost, the pharmaceutical sector is a global market: healthcare needs know no borders and most companies are committed to cater to the healthcare demand worldwide.

Although one can expect that current or expected trade policies could eventually encourage US companies to favour US-based service providers, this would not change the overall equation: pharmaceutical companies do not hold the in-house capacity to streamline their go-to-market strategy by themselves, and they must rely on external partners.

In this regard, a company like PPS which holds operations in Europe, North America, and Asia is perfectly positioned to continue servicing these three strategic hubs, regardless of any protectionist policies that might be enforced in a given country or region.

We see a variety of business models being implemented by CDMO companies, ranging from specialty focus, capacity consolidation to vertical integration. How would you describe the development approach that PPS has embraced over the past years?

Our overarching approach is extremely clear: we must concentrate our efforts on meeting customers' needs. Piramal is a company that sees our customers' success as the only way to

nurture our own growth. In this regard, all investments are conducted in a way that can bring more added-value to our partners.

We closely engage with the latter and jointly invest capital in projects and capabilities. As CEO of the company, my first and foremost objective is to develop the company to make it the most customer-centric firm – and to be recognized by our customers for this commitment – rather than instinctively building up production capacities and capabilities

At the end of the day, PPS shares the exact same objective as its partners: bring life-changing products to the patients. At Piramal, we are very passionate about this overarching mission, and this is precisely why we consider pharmaceutical companies our partners rather than mere customers.

Isn't a challenge to aim for customer-centricity while in the meantime you strive to move up the value chain and provide more and more complex products to your customers?

This is actually what makes our endeavour to be a customer-centric company so exciting while forcing us to be innovative. As a matter of fact, some of our customer-centric initiatives have inspired our current partners, who look at replicating these processes within their own operations.

For example, we have set up a unique model to collect, analysis, and integrate customers' feedbacks. As part of this program, the performance of our different sites is measured according to feedback given by our customers. In the meantime, I personally review all customer feedback, which allows me to closely monitor our strengths and areas for improvements.

Under your tenure, PPS has so far favoured niche acquisitions (including Coldstream Laboratories and Ash Stevens), while some of your direct competitors recently conducted multi-billion deals to grow their capacities. Is there room for such large-scale investments in the strategy of Piramal Pharma Solutions?

There is always room for large acquisitions in our growth strategy. Large or small, we look for acquisitions that fit well with our need: these would include expanding our geographical footprint, complementary or new capabilities that are synergistic, and technologies that fit well with our customers' future requirements, to name a few. We also look for companies that fit our culture,

have a stellar quality record, and have strong management. The key is that – post-acquisition – we must be in a better position to serve our customers.

To the difference of many of your peers in the global pharmaceutical and healthcare sector, you honed a two-decade-long experience holding operations and finance positions prior to taking over a pharma-focus company. To what extent has this experience revealed itself a great asset when operating on the global CDMO stage?

I do believe that holding a different background has revealed in itself a very precious advantage, as I was able to assess our operations from a different standpoint than if I had always worked in this industry. Since I took over, we divested assets that were not perfectly aligned with our development vision while integrating new capabilities through a handful of acquisitions. In the meantime, we re-organized our teams with the objective to increase our commercial performance, and I truly believe that my background has helped me successfully driving our company through these structural changes.

As a matter of fact, our recent results speak for themselves. Although there are plenty of ways to measure success, I would mention that we almost doubled the size of our business over the past three years, and we added more customers during this period than over the preceding eight years. I am humbled by the fact that I was recognized as “CEO of the Year” by CPhI awards in 2015, while our company has earned countless industry recognitions and customer awards, and these are an acknowledgement of our remarkable commitment to exceeding customers’ expectations.

In the grand scheme of things, PPS’s eye-catching performance is above all due to the outstanding efforts of our 4,000+ employees. My role is to steer our people’s energy and expertise to the right direction, so we present a united front when pursuing our main goal: ensuring patients can benefit from medicines developed and manufactured by Piramal.

Leveraging your expertise in finance and M&A, what are the main aspects you look at when evaluating a potential acquisition?

Targeted capabilities emerge as a key parameter to look out for, but I believe that human capital is the most crucial aspect to consider. In this context, I assess if the mindset of the people heading the targeted company could fit within Piramal’s customer-centric model, so we can operate as one single organization moving forward. At the end of the day, in terms of operations, the capabilities

you may acquire are just as good as the people that have been managing these assets...

...but on the other hand, you can also “change the people,” once you have acquired a given asset?

Not really. The service industry is above all a relationship business: customers choose and remain loyal to a given partner because the latter has earned their trust. This aspect is particularly important in a regulated industry like the pharmaceutical sector, where compliance and reliability are absolutely paramount. To be a successful service provider in the pharmaceutical sector implies fostering subtle chemistry both internally and externally – that’s the main driving force behind customer acquisition and retention.

On one hand, it seems that pharmaceutical companies are increasingly transferring risks and cost pressure to their service providers, while - on the other hand - we see eye-catching alliances being forged between pharmaceutical companies and CDMO players, such as the recent co-investment agreement inked by Sanofi & Lonza in the biologics arena. What is your take on the evolving relationship between pharmaceutical and CDMO companies?

First of all, I want to highlight that the quality of this relationship is absolutely crucial, and both sides must acknowledge that we depend on each other. In this regard, my perception is that only a greater integration between pharmaceutical companies and CDMO companies can usher higher outcomes to both parties.

There is no doubt that the cost pressure coming from our partners is continuously increasing, but they do not disregard the added value generated by their partners either. In some situations, we even could increase our prices because – as part of our company’s continuous improvement process – we proved ourselves being able to generate a higher value for our customers, which they fully acknowledged.

In the meantime, one should bear in mind that cost pressure also stands as a great innovation driver, which can – again – reveal itself beneficial to both customers and CDMO companies. Let me give you a concrete example: a customer once asked PPS to manufacture a complex small molecule, whose production costs were particularly high. Piramal leveraged its unique R&D capacity to significantly decrease the manufacturing cost of this product, which ultimately enabled

our customer to gain substantial market shares.

As per Piramal, we are in constant discussions with pharmaceutical companies' vis-à-vis transformative alliances, in the likes of the one you just mentioned. As a matter of fact, we are also evaluating with some customers the opportunity to embark on even more creative partnerships.

Without disclosing ongoing discussions, what forms could take on such creative alliances?

Capital constraints, reduced internal bandwidth to drive development projects, and a need for reducing cost and clinical timelines, are all realities in the new pharma world. As a CMO we continue to look at creative alliances that can address these issues. Innovative business models may include pharma site divestiture to a CMO with committed volumes for a set number of years, risk-share models that reduce upfront costs, with potential for a higher payout for the CMO, on success tied to milestone events, and fixed price early development projects.

Some India-based manufacturers have recently engaged into a frenzy of asset acquisitions in regulated markets to come closer to their customers and hedge themselves from protectionist policies. In the meantime, regulatory issues have recently hit a large number of Indian plants while the country's manufacturing cost advantage is slowly waning. How do you take into consideration these aspects when evolving PPS' manufacturing footprint?

PPS has been conducting significant investments in Europe and North America, where we hold five cutting-edge assets overall. Some of our customers are looking for products specifically developed and manufactured in these regions, and we have been continuously strengthening the capacity of these facilities to meet their expectations.

Nevertheless, PPS is partnering with a large variety of customers, which all express very different needs. As part of this diversity, some customers – including US and Europe based companies – are reaching out to us for projects where cost efficiency holds a crucial importance, and they want to rely on our world-class facilities located in India, where production costs will remain largely lower than in the US or Europe in the foreseeable future. This is particularly true for PPS' customers, as our company truly strives to pass all benefits of Indian's manufacturing cost advantage to the latter.

In the meantime, one should not overlook the fact we are today able to deploy cost-competitive R&D-driven projects in India, because talent and structural resources are more largely and easily available than some years ago.

In the grand scheme of things, we do not plan to radically alter the balance of our manufacturing footprint in the coming years and we will continue investing in all our sites, whether they are located in the US, in Europe, or India.

As mentioned, some India-based manufacturers were severely affected by increasing regulatory scrutiny over the past three years, and even some of the country's powerhouses received warning letters from the US FDA. As Piramal displays one of the best track records in this regard, what has been your approach to keep the company away from compliance issues?

My approach is extremely simple: quality is everyone's responsibility. When operating in an industry with stringent requirements and regulations like the pharmaceutical sector, quality compliance cannot be an endeavour that only weighs on the shoulders of a few people or divisions. As a matter of fact, the quality was integrated as a Key Result Area (KRA) for all our 4,000 employees, regardless of the function they belong too. In my eyes, risk exposure in terms of quality compliance is actually the most crucial metric for our organization, and we have conducted huge investments to ensure our company remains ahead of the curve.

As a leading CDMO operating in the most stringent markets and working hand-in-hand with prestigious partners, our facilities are continuously audited by regulatory authorities from all around the world as well as by our customers. Furthermore, we also set up our own internal quality teams which tirelessly monitor our sites, while external consultants regularly conduct surprise inspections of all our facilities.

Finally, we also strive to instil 'Quality as a culture' within the firm that is directly inspired by the standards set up by our customers. In this regard, we hired quality experts that used to supervise our customers' sites, which provides us with great support when it comes to aligning our practices with those of our partners.

PPS received the prestigious 'Regulatory Procedures and Compliance' award at the CPhI Pharma Awards (2017), and Head of Compliance & Quality at Piramal was recently ranked among the world's top 50 quality experts by World Quality Congress.

What will be your final message to our international readers?

PPS wants to be known as the best customer-centric organization in the global industry and as a firm that our partners can trust. To propel the success of our customers, we will continue growing our capacity accordingly while maintaining an utmost focus on quality compliance. Piramal Pharma Solutions is the partner of choice of pharmaceutical and biotech companies, and we share the same mission as our partners: bringing reliable, high-quality, and life-changing products to the patients.

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