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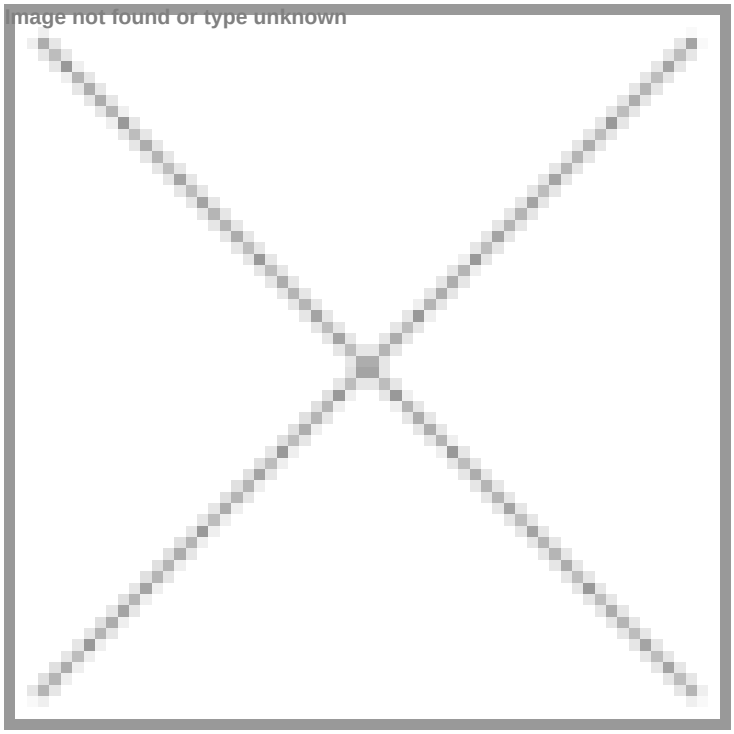
"CDMOs must demonstrate robust quality systems and technological advancement"

06 March 2025 | Views | By sanjiv.das@mmactiv.com

India’s first specialty pharma CDMO OneSource Specialty Pharma recently got listed on the National Stock Exchange (NSE). The company provides seamless end-to-end offerings across all verticals (biologics, drug-device combinations, sterile injectables and Softgel capsules). They are among the few global players to offer both drug substances and drug products and has posted Q3FY25 revenues at Rs 392 crore. Neeraj Sharma, CEO & Managing Director, OneSource Specialty Pharma while being upbeat about the CDMO sector reveals more about the company's major highlights in coming years during an interaction with BioSpectrum India.



What have been the major highlights for this fiscal? What are the revenue projections for FY 24-25?

For FY 24-25, we have guided a revenue range of $160–180 million and are on track to meet our projections. This fiscal has been marked by significant milestones e.g., the successful merger of the three incoming businesses, fundraising with participation from marquee investors, successful listing on the NSE and the BSE and significant addition to our customer base.

The listing of OneSource Pharma on the NSE and BSE this year marks a significant milestone in our journey, one that began with a vision to build a one-stop shop for the CDMO sector. Listing will increase our visibility among partners and stakeholders, opening more opportunities for strategic collaborations and business ventures. It will also support the recruitment of talent from around the globe. The group is known for its strong corporate governance.

We now have over 60 customers across all modalities. We now collaborate with 20 customers in the GLP-1 space and have initiated our first new biological entity (NBE) programme with a top three animal health company. Additionally, we are supporting seven potential NCE-1 programmes.

What are the major plans in store for 2025 and beyond, to strengthen your position in the CDMO sector?

As we look ahead to 2025 and beyond, we remain fully committed to reinforcing our position as India's first Specialty Pharma CDMO by expanding our capabilities, advancing quality standards, and strengthening customer partnerships.

A key strategic focus is our leadership in drug-device combination (DDC) fill-finish and assembly, particularly as several customers prepare for commercial-scale GLP-1 supplies between 2025 and 2026. To support this, we are making significant investments to expand our manufacturing capacity, ensuring we are well-positioned to meet the needs of our partners.

Additionally, we are broadening our sterile injectable capabilities, both by scaling existing infrastructure and introducing new capabilities to support a wider customer base.
In biologics, we are leveraging our deep expertise and robust infrastructure in the microbial segment to position ourselves as a key player in this high-growth segment with limited CDMO providers.
In line with our commitment to expansion and innovation, we have already tripled our soft gel manufacturing capacity to 2.4 billion capsules per year and launched CDMO offerings for this segment.

Beyond capacity expansion, quality and compliance remain at the core of our operations, demonstrated by 36 successful regulatory and customer inspections of our sites in 2024. Our flagship site operates with digitalised, paperless systems, allowing us to enhance efficiency, ensure regulatory excellence, and scale operations seamlessly. We are driving a transformational shift in quality management, evolving from quality as a compliance necessity to quality as a competitive differentiator.

Through these strategic initiatives, we are strengthening our leadership position, expanding into high-growth areas, and reinforcing our commitment to delivering world-class CDMO solutions to our customers globally.

What are the major challenges facing the CDMO sector in India? How do you plan to address those?

The CDMO sector in India is experiencing strong growth, driven by increasing outsourcing trends, a highly skilled talent pool, and a well-established track record in pharmaceutical manufacturing.

India's capabilities in drug development, manufacturing, and regulatory compliance have positioned it as a preferred partner for global pharmaceutical and biotech companies. Additionally, the rising demand for specialised areas such as drug-device combinations (DDCs) and biologics presents significant growth opportunities for well-invested CDMOs.
However, evolving regulatory requirements, heightened scrutiny from regulatory agencies, and geopolitical uncertainties pose challenges to the industry. To navigate these complexities, CDMOs must demonstrate robust quality systems, technological advancement, and operational excellence.

At OneSource, we have proactively addressed these challenges by investing heavily in technology, talent, and processes, ensuring that we remain ahead of regulatory expectations. Our comprehensive compliance framework is designed to meet global regulatory standards, allowing us to maintain operational excellence and deliver high-quality solutions across all stages of production.

Our focus on quality and compliance not only ensures business continuity but also strengthens our position as a trusted CDMO partner in the global market.

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