

# We are well-aligned to capitalize on the CDMO opportunity

Dr Abdelaziz Toumi, CEO, Lupin Manufacturing Solutions (LMS), in an interview with Viveka Roychowdhury, Express Pharma

**In light of the BioSecure Act and the PILLS Act, aimed at reducing dependencies on other countries and incentivising manufacturing of pharma products in the U.S., how is Lupin Manufacturing Solutions adjusting to the policy changes?**

The pharmaceutical industry is inherently dynamic — constantly evolving and adapting to scientific breakthroughs, market needs, and policy shifts. Change has become a norm in our business, driven by compelling reasons such as supply chain security, access to innovation, and the need for resilient healthcare systems.

The COVID-19 pandemic was a wake-up call that exposed vulnerabilities in global supply chains, especially in the life sciences sector. It emphasized the urgent need to build robust, future-ready systems — not just for potential pandemics, but to support the increasing complexity of a globally interconnected pharmaceutical landscape. Pharmaceuticals are developed, manufactured, and distributed across borders, making supply chain reliability and quality control more critical than ever.

At the same time, we are witnessing major demographic and economic shifts. Populations around the world are aging — India included — and healthcare access is expanding. These trends are accompanied by rapid medical innovation and rising expectations from patients. However, with longer life expectancy and access to advanced therapies comes increased pressure on healthcare budgets. The challenge lies in delivering broader access to cutting-edge treatments while maintaining cost-efficiency. This requires innovative solutions that can serve more patients sustainably.

Geopolitical shifts are also shaping our strategy. For instance, the U.S. Biosecure Act aims to safeguard sensitive health data and bolster domestic manufacturing capacity. It is not a protectionist measure, but rather a response to legitimate concerns around data privacy and national resilience. The PILLS Act similarly promotes U.S.-based manufacturing — an understandable move given its economic implications.

We're closely monitoring these developments and aligning our long-term strategies accordingly. As a global organization, we must be close to our customers. The U.S. remains the largest pharmaceutical market, and proximity — geographic and operational — is key to delivering best-in-class service. That's why co-locating select activities closer to our clients makes strategic sense, especially when considering time zones, logistics, and regulatory expectations.

We have always taken a long-term view. Our commitment to quality, compliance, and ESG principles reflects our ambition to build a top-tier, globally respected organization. In our role as a Contract Development and Manufacturing Organizations (CDMO) partner, our goal is to be known for deep expertise and unwavering quality. While regulatory changes like the Biosecure Act may trigger shifts, our broader objective is to build resilient, future-ready systems that allow us to serve our customers — whether in the U.S., Europe, Japan, China, or India — with excellence.

Innovation is no longer limited to the West. China is fast emerging as a powerhouse in pharmaceutical R&D, and India is poised to follow. At Lupin Manufacturing Solutions, we're not here for short-term gains — we are investing for the long haul, building capabilities that align with global trends and customer needs.

### **Where does India fit in the global API CDMO space as compared to other countries like China, Korea, etc?**

India has long held the reputation of being the “pharmacy of the world,” especially in the generic pharmaceutical segment — where it leads in volume and cost-efficiency. However, when it comes to CDMO — the service-driven side of the pharmaceutical industry — India still plays a relatively small role on the global stage, accounting for less than 2–3% of the market today.

At Lupin Manufacturing Solutions (LMS), we see this as a major opportunity. The global CDMO space is expanding rapidly, particularly as it supports not just large pharmaceutical companies, but a growing base of innovative biotech firms and academic entrepreneurs. In fact, more than 70% of drug discovery today originates from small to mid-sized enterprises. These innovators often rely on CDMO partners to help advance their molecules from early-stage development to commercial production.

India’s current CDMO market is valued at around \$3.5 billion and has the potential to grow to \$25 billion, according to the Boston Consulting Group — an impressive CAGR of over 21%. Despite India’s current underrepresentation, we believe the country is well-positioned to take on a far more significant role in this space, thanks to its robust manufacturing foundation, world-class scientific talent, and evolving infrastructure.

At LMS, we are capitalizing on this opportunity with purpose. We are building on Lupin’s five decades of expertise in small molecule manufacturing. We are carefully selecting and repositioning key assets within our network. We’ve begun with two strategic manufacturing sites — at Vizag and Dabhosa — supported by our centralized R&D hub in Pune focusing on all API research under LMS.

Furthermore, global policy shifts, such as the U.S. Biosecure Act, which calls for more secure and diversified supply chains, present an important tailwind. The Act is not just about domestic production — it reflects a broader push for supply chain resilience and data protection, both of which play to India’s strengths in scale, reliability, and compliance.

Sustainability is also at the heart of our strategy. Across Europe and the U.S., regulatory frameworks are increasingly focused on ESG compliance — not only environmental factors like renewable energy and waste management, but also social and governance standards. Modern manufacturing must be green, automated, and AI-enabled. We are investing significantly in these areas to meet the evolving expectations of our global customers.

India's API ecosystem is another strength we're leveraging — from raw materials and intermediates to a strong supplier base and top-tier universities. Our ecosystem is vast and interconnected, supported by an exceptional talent pool and an increasingly innovation-driven outlook.

While profitability in the CDMO space can be nuanced, India undoubtedly enjoys a structural cost advantage compared to Western markets and several of its Asian peers. This positions us competitively — especially when paired with Lupin's global scale, robust quality systems, and longstanding customer trust.

In a market as competitive as CDMO, we welcome the challenge. Competition drives excellence — and our differentiation lies in a combination of deep expertise, global outlook, and a culture of quality and transparency. We are committed to building a sustainable, innovation-aligned business that serves the future needs of our international client base with consistency and purpose.

## **Tell us more about Lupin Manufacturing Solutions**

Lupin Manufacturing Solutions (LMS) was officially incorporated in November 2023. We moved swiftly to define our core purpose and positioning within the global CDMO landscape. In the months that followed, Lupin carved out manufacturing assets at Vizag and Dabhosa, marking the operational start of LMS. These facilities are integral to LMS' ambitions and were carefully selected for their proven track record and future scalability.

As with any strategic initiative, having the right leadership in place was the critical first step in setting the direction and building the foundation for long-term success. I joined as the CEO of this company around mid-June 2024. Over the past nine months, our primary focus has been on building a world-class team and operational structure. I'm proud to share that we at LMS have successfully assembled our full leadership team, collectively bringing decades of CDMO experience with Indian and international world-class CDMOs. Given the global nature of this business, we have also established dedicated business development capabilities across the U.S. and Europe, ensuring proximity to our clients and agility in our response.

A key strategic milestone was our recent integration of API R&D under LMS, which we announced earlier this month. We have consolidated more than 200 scientists and over 20 labs into a dedicated R&D centre in Pune. This move significantly enhances our development capabilities and gives us the flexibility to offer tailored, high-quality solutions to our CDMO partners. We have also moved into LMS' new headquarters in Mumbai, further consolidating our operations and enhancing connectivity with clients and partners.

This has been an exciting start. We are growing rapidly, attracting exceptional talent, and building the capabilities that will define the future of Lupin Manufacturing Solutions as a trusted, innovation-led CDMO on the global stage.

**How does LMS differentiate its offerings in the CDMO space? And, since most of the future growth will come from biologics and biosimilars, how will India make its mark as a global biosimilar CDMO market?**

At Lupin Manufacturing Solutions (LMS), we can fully leverage the world-class capabilities of our parent company Lupin, while building a focused CDMO platform that caters to the evolving needs of global innovators. Our facilities in Vizag and Dabhsa represent strong foundations — proven sites with more than five decades of operational experience. These sites are already approved by all major global regulatory authorities, including the US FDA, EMA, WHO, TGA, and ANVISA. Recently, we hosted a WHO audit at our Vizag facility, which went exceptionally well — another affirmation of our compliance and quality-first mindset.

Today, LMS has a portfolio of over 25 APIs being supplied to various pharmaceutical companies in more than 50 countries. Our track record in delivering high-quality APIs at scale gives us a strong foundation for our CDMO journey.

At LMS, while our core focus is on small molecules, we bring deep technical expertise across a broad technology spectrum. This includes complex chemical synthesis, high-potency manufacturing, and specialized platforms like peptides, iron-based formulations, and both non-recombinant and recombinant fermentation. In Vizag, we already operate a high-potency facility, positioning us to support oncology, the largest therapeutic category globally with over 3,000 active drug candidates.

We are lining up investments in the new modalities — ADCs, Peptides — as these will be driving the industry growth. Importantly, we approach CDMO partnerships as platform-agnostic. Our clients don't define themselves by modality — they define their mission by therapeutic need. Whether that involves small molecules, biologics, mRNA, or a combination like antibody-drug conjugates (ADCs), we aim to be the agile partner that enables them to succeed.

ADCs, for example, represent a highly complex and growing category where we already have the foundational capabilities — protein development, linkers, toxins

Being a part of Lupin, LMS has access to adjacent capabilities beyond small molecules, including biologics and injectables, which we can extend to our clients depending on their needs. This flexibility allows us to act as a true solutions partner — whether the client is a large pharma company or an emerging biotech driving early-stage innovation. For biologics, our group capabilities extend to CDMO services for large molecules, including monoclonal antibodies and proteins. Additionally, our advanced chemistry portfolio includes capabilities like high-pressure hydrogenation and low-temperature transformations — critical for solving complex development challenges.

Furthermore, our regulatory expertise is a critical asset. Many of the biotech clients are science-driven organizations that rely on strong partners to navigate the complex, global regulatory landscape. Our ability to combine scientific understanding with compliance rigor is what sets us apart.

We're not just building a CDMO — we're building a trusted, globally relevant manufacturing platform designed for the future of pharmaceutical innovation.

**You mentioned about sustainability as part of the manufacturing processes. However, following sustainable and environmentally responsible practices add to CapEx and operational cost, and pharma companies are constantly on the lookout to lower the cost of medicines. So how does LMS approach this challenge of adhering to sustainability guidelines while keeping the costs and budget in check?**

At Lupin Manufacturing Solutions, sustainability isn't a project or a box to check — it's deeply embedded into the way we operate. It is not viewed as a cost element, but rather as an essential investment in the future of our business, our communities, and the planet. This is not a discussion point — it's a non-negotiable principle. It is how we think, how we plan, and how we act.

We've adopted a wide range of green manufacturing practices aimed at minimizing environmental impact — not just in terms of global sustainability, but also in how we operate within local ecosystems and communities. Our processes are designed to reduce and recycle waste, including solvent recovery systems, minimal-waste chemical reactions, and innovative packaging design. We continuously assess and re-engineer our operations to ensure minimal resource usage without compromising quality.

We're particularly proud to be pioneering enzymatic processes and biotransformation for the synthesis of some of our APIs. These are routes that reduce the use of chemicals and dramatically improve the environmental footprint of manufacturing operations. In parallel, we're actively transitioning select processes to aqueous fermentation, replacing conventional solvent-based approaches where possible. And when solvents are essential, we ensure maximum recovery and reuse to maintain circularity.

LMS's efforts are fully aligned with Lupin's broader sustainability goals, including the carbon neutrality targets for 2030. As of now, more than 40% of our energy consumption in Dabhsa for instance is sourced from renewable sources like solar and wind — putting us ahead of many global benchmarks, including in several developed markets. Additionally, we are embedding clean chemistry principles into our R&D workflows, while investing in advanced technologies like continuous flow reactors to reduce both energy use and waste.

Sustainability also extends to diversity and inclusion, which we view as vital to long-term success. We're actively working to promote more women in leadership roles and ensuring that our teams reflect the global nature of the CDMO business. This is not just an ESG imperative — it's about unlocking the full potential of talent across regions and backgrounds.

And the numbers speak for themselves — Lupin's ESG score has jumped from 17 to 76 over just four years, making us one of the leading organizations in India and beyond on several critical ESG parameters.

We don't just see sustainability as a responsibility — we see it as a competitive advantage and a driver of innovation, job creation, and long-term resilience. Simply put, if a business isn't sustainable, it isn't built to last.

This interview was first published in the Express Pharma (print), May 2025 Edition