# Norman Stoffregen â?? SVP and Site Head, Enzene

We provide the infrastructure, expertise, and manufacturing flexibility to help bring biologics to market quickly and cost-effectively

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*Norman Stoffregen, SVP and Site Head at Enzene Inc., explains how the US arm of Indiaâ??s Enzene Biosciences is introducing its cost-efficient, continuous manufacturing model to the US CDMO market. With a state-of-the-art facility in Hopewell, New Jersey, Enzene supports mid-sized biopharma clients with flexible, small-footprint biologics production. By combining global expertise, local talent, and close client partnerships, Enzene aims to advance innovation and affordability across both human and animal health.*

**For our international readers who might not be familiar with Enzene, could you provide some background on the organisation?**

Enzene operates under Alkem Laboratories, one of Indiaâ??s largest pharmaceutical companies. Within India, the biologics division functions as Enzene Biosciences. Several years ago, Enzene Biosciences made the strategic decision to expand into the US, leading to the establishment of our American affiliate, Enzene Inc.

Enzene was founded around 2015 with a mission to lower the cost of medicine for patients in India, where most healthcare expenses are paid out of pocket. Our CEO, Himanshu Gadgil, set out to achieve this by embracing disruptive technologies rather than simply building large manufacturing facilities. This vision gave rise to the EnzeneX$^{TM}$ platform, which enabled us to significantly reduce

production costs for existing medicines and apply those efficiencies to new drugs.

To date, Enzene has developed and launched eight proprietary biosimilars. While we do not commercialise products under our own brand, but rather develop and manufacture them for licensing partners. Building on that expertise, about half of our business in India today consists of CDMO services, primarily focused on monoclonal antibodies.

The decision to establish a US presence was driven by the goal of expanding the CDMO side of the business internationally. That decision brought us to Hopewell, New Jersey, where Enzene Inc. now operates exclusively as a CDMO. Here, we work with clients in two main ways: either by manufacturing their existing processes at our facility, or by leveraging our India site for further process development before transferring production to the US.

**Can you introduce the Hopewell facility and describe your capacity and service offering?**

In 2024, we began construction of our new facility here in Hopewell, New Jersey. Having leased a previous Bristol Myers Squibb (BMS) facility, the site initially spanned 54,000 square feet of manufacturing space, utilities, process development, and quality control laboratories. The first phase of our redevelopment efforts has focused on building two drug substance manufacturing suites, each operating at the 500-litre scale. We have also established centrally located supporting areas for media and buffer preparation, equipment cleaning, and column packing.

From the beginning, we designed the facility with scalability in mind. Roughly one-third of the second floor is reserved for future expansion, allowing us to replicate our initial suites and increase scale up to 1,000 litres. This is what we refer to as phase two, and we are already in active discussions and planning for that next stage.

As phase one nears completion, we are preparing to move directly into phase two. During construction, we also made strategic decisions to allow for further expansion on the first floor, either for additional drug substance suites or to establish a mid-sized drug product fill-finish capability.

In addition to the original construction, we secured an extra 26,000 square feet of space. This expansion houses new process development labs, quality control areas, and office space. It became operational earlier this year, and we have already completed our first engineering batches for a client, even before the main facilityâ??s construction was fully complete. This is a true testament to our agility and adaptability as an organisation.

**As Enzeneâ??s first global expansion, what was the rationale for choosing the US and what advantages does New Jersey have as a base for manufacturing?**

While India has a strong reputation for both development and manufacturing, many clients expressed the importance of having US-based production capabilities. Therefore, establishing a physical presence in the worldâ??s largest biopharmaceutical market was an important strategic decision for Enzene to better serve customers.

The leadership team evaluated multiple potential locations from Boston to San Diego and down into the Carolinas, but ultimately chose New Jersey as the best location. As a former BMS facility, this particular campus provided exceptional existing infrastructure, including extensive electrical capacity, wastewater management, and other essential utilities. It was ideally suited for redevelopment as a

brownfield project, allowing us to customise the facility for phased growth.

Beyond the infrastructure, New Jerseyâ??s long-standing reputation as a pharmaceutical and biologics hub was a key factor in the decision. The state offers access to a deep pool of industry talent, with many major biopharma companies based here, and there are strong academic partnerships available as well. We are actively collaborating with Rutgers University for technology improvements and local community colleges that are developing bioprocessing training programs. New Jerseyâ??s historically strong life science ecosystem gives us both the expertise and the talent pipeline needed to support Enzeneâ??s long-term growth in the US.

**How would you describe Enzeneâ??s customer base?**

From a CDMO perspective, Enzeneâ??s focus is distinct. While we collaborate with some large players, our primary clients are small to mid-sized biopharma companies. With larger CDMOs serving big pharma, Enzene is uniquely positioned to support companies that need a more flexible, tailored approach.

From early-stage start-ups and virtual biotech firms to more established mid-sized companies, we specialise in helping smaller innovators scale efficiently. Our goal is to be a trusted partner that provides the infrastructure, expertise, and manufacturing flexibility they need to bring their biologics to market quickly and cost-effectively.

Another important aspect is that Enzene operates in both human and animal health. We have signed contracts with animal health providers and are closely navigating both FDA and USDA requirements, ensuring compliance while expanding our capabilities.

**How is Enzeneâ??s service offering adapted to fit the precise needs of small to mid-size biopharma organizations?**

Enzeneâ??s strategy is based on a clear division of focus: our Indian operations lead cell line and process development, analytical testing, and related technical services, while our US facility currently focuses on manufacturing excellence. As our US operations mature, we will continue expanding this model to offer more comprehensive, end-to-end development services locally.

We have already established a process development laboratory here in Hopewell, which will allow us to support clients from early-stage process optimisation through full-scale production. Over the past two years, weâ??ve seen growing demand from US-based companies to perform development work domestically. Many clients prefer to work closely with our teams on-site, visit the facility, and participate in the tech transfer process directly.

While our India team continues to provide deep technical expertise and development resources, our US site offers hands-on accessibility and operational flexibility. Together, this integrated global model allows Enzene to provide clients with the best of both worlds: world-class scientific capability with the responsiveness of a local partner.

**Enzeneâ??s offering is based on the EnzeneX$^{TM}$ platform. Can you over a brief overview of the capabilities of this technology?**

Our technology platform, EnzeneXâ?¢, is an advanced, fully connected continuous manufacturingâ?¢ (FCCM) system that optimises perfusion to achieve continuous biologics production. The platform allows for uninterrupted loading and processing of materials which results in added efficiency and cost-effectiveness.

This method allows us to operate production bioreactors of 500 to 1,000 litres that produce amounts equivalent to a traditional 10,000 to 15,000-litre bioreactor. This intensified perfusion, fully integrated with our continuous downstream process, allows us to run smaller bioreactors and significantly reduce facility footprint. For example, our manufacturing suites require roughly 1,500 square feet of classified space, compared to thousands of square feet in conventional models. Overall, EnzeneXâ?¢ reduces processing costs by half, giving our clients access to more cost-effective manufacturing while maintaining high standards of quality.

**Evolving customer needs and expectations are you observing in the CDMO sector? What key factors do you believe will best align with client priorities and set successful partnerships apart?**

At a recent industry event I attended a few weeks ago, there was a lot of discussion around what it means to be a true partner. Traditionally, CDMOs are largely order-driven. An innovator places an order, and the CDMO executes, but there is limited deeper collaboration. At Enzene, we differentiate ourselves by becoming experts in our clientsâ?? processes. We collaborate with them across the entire lifecycle from development, supply chain, and purchasing to manufacturing at any scale. This deep integration allows us to be connected with our customers at every level of their organisation. This is what I see as the true meaning of partnership, and it sets us apart.

Our team is fully engaged with each project, and because we assign teams to each client, we can provide what I would describe as a â??white gloveâ?• level of service. This approach ensures that we are not just executing orders, but actively partnering with clients to deliver solutions that align with their needs and drive mutual success.

**We are seeing major trends around digitalisation, optimisation, and sustainability as considerations. Are these reflected in client demands, and how is Enzene leveraging those specific categories?**

Our platform has evolved into EnzeneX 2.0, and we are already discussing future versions. Each iteration brings enhanced capabilities such as process analytical technology, machine learning, and increased automation. Like many companies, we are working to integrate these tools online and are exploring AI applications in data analytics, supply chain, and related areas.

AI is a topic of considerable discussion in the industry. While it is often seen as a buzzword, its value depends entirely on the expertise of the people interpreting and validating the results. At Enzene, we are cautious about relying solely on AI. For technical applications, human oversight remains a priority, as deep process knowledge is critical to ensuring accuracy and quality.

Sustainability is also a key consideration. One major advantage of the EnzeneXâ?¢ platform is the small facility footprint it allows. By running production in smaller bioreactors and leveraging single-use technology, we reduce resource consumption and environmental impact. Unlike traditional setups that require extensive clean-in-place and steam-in-place systems, our approach minimises waste while also lowering costs. This combination of efficiency and environmental responsibility is

increasingly important to our clients.

**Looking ahead, how do you see Enzeneâ??s Hopewell site evolving in capacity and capabilities?**

As I mentioned, the facility was designed with future expansion in mind from the start. Our first phase of construction involved building two drug substance manufacturing suites at the 500-litre scale, and we have identical space at the front of the building that can be replicated to scale up to 1,000 litres. We have already set a goal of completing this expansion within the next two years to bring on additional clients while better supporting our current ones.

Our large process development laboratory has also attracted client demand for additional work. Over the next year, we plan to expand this space to offer cell line development, upstream and downstream process development, and conversion from fed-batch processes to the EnzeneXâ?¢ FCCM platform.

We also have additional space in the facility that could accommodate at least two additional drug substance manufacturing suites, or potentially mid-sized drug product filling capabilities. While Enzene is fully focused on continuous manufacturing, we are exploring ways to accommodate clients who rely on fed-batch processes for potentially up to 2,000-litre bioreactors in fed-batch mode.

Ultimately, our platform is designed to be flexible. A client may start with a fed-batch process and transition to fully connected continuous manufacturing when the timing is right. This adaptability is part of the value we offer, ensuring we can meet immediate needs while supporting long-term innovation.

**From an organisational perspective, what kind of culture are you developing within the Hopewell site to best position Enzene as a partner of choice?**

Our team is currently around 60 people, and we expect to reach approximately 80 by March 2026 with continued growth as we bring on additional manufacturing suites.

We are also building a strong, collaborative culture within the organisation. Our local team includes talent from large pharmaceutical companies, small start-ups, and other CDMOs. We have also brought in key talent transfers from Enzene in India, who bring years of experience in fully connected continuous manufacturing, ensuring we carry knowledge and expertise across locations. This creates a unique blend of cultures that combines global perspectives with local talent. Our workforce ranges from individuals fresh out of college to professionals from large pharmaceutical companies or even start-ups. It is a diverse, dynamic group, and that diversity is central to the culture we are building here in the US.

**What final message do you have on behalf of Enzene to your customers, clients, and the broader ecosystem?**

What Enzene is doing right now is very exciting. Our facility in India has already proven the technology through the development and launch of eight different biosimilars, and now we are bringing that expertise to the US through our CDMO offering. This is a particularly exciting time in

New Jersey and across the US, as many companies are onshoring their operations. While that will fill some existing capacity, our position as a relatively new player also allows us to pursue new clients and opportunities.

What I believe is most significant about Enzene is the true partnerships we can build with clients. By combining the knowledge gained from our Indian development operations with decades of US manufacturing experience among our staff, we are able to offer a level of expertise and collaboration that is genuinely unique in the market.

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