



Enzene Biosciences: An Innovation-Driven Biotech and CDMO

www.enzyme.com



Who are we?

Enzene is a dynamic biotech company that brings together innovation and technology to deliver cutting-edge solutions in the biopharmaceutical industry. Our mission is to provide end-to-end CDMO services for biologics, offering a comprehensive platform of services from cell line development to fill & finish on even the most complex projects. With a strong biosimilar portfolio and unique proprietary continuous manufacturing capabilities, we are committed to redefining the healthcare landscape through our unwavering dedication to quality, innovation, and accessibility.

Our mission is to provide affordable, quality medicine to aid lives with debilitating conditions

We have always been committed to delivering trusted and affordable solutions that can positively impact the global healthcare ecosystem. We will continue to create access for early-stage biological assets by providing cost-effective, yet quality local manufacturing.

How can we help you?

An Alkem Laboratories subsidiary and venture capital-backed firm, Enzene is a leader in the Indian biotech industry. Our successful commercial launches and robust early-stage products make us a trusted partner for global pharmaceutical companies.

We operate a state-of-the-art R&D facility equipped with advanced technologies, alongside our cGMP manufacturing facilities feature five suites. These suites encompass fed-batch, semi-continuous, and our patented continuous manufacturing process, EnzeneX™, which places us among the few global pioneers in this field.

We also have a new manufacturing site in New Jersey, US, housing several lines of EnzeneX™, with a GMP facility and supporting lab. This strategic location provides easy access for customers, and helps form more global partnerships. Spread over 54,000 sq ft, this plant will also hold the distinction of being one of the only biologics-focused continuous manufacturing bases in the US.

Our commitment to excellence is exemplified by our impressive track record of delivering over 30 projects at various stages, from cell development to commercialization. This includes achieving a remarkable milestone of advancing complex proteins from gene to Phase 1 clinical trials within approximately 12 months.

Our services

At Enzene, we pride ourselves on our technical expertise, flexibility, and bespoke solutions. The comprehensive range of fully integrated services is designed to meet the unique needs of each client across the entire product lifecycle, from early-stage discovery to commercial manufacturing. Our services support the development and manufacturing of high-quality biopharmaceuticals in a timely and cost-effective manner to maximize accessibility.

Enzene services at a glance:

We offer a suite of fully integrated services across the product lifecycle

R&D Pre-clinical

- **Cell line development**
- Media optimization
- **Process development** (USP & DSP)
- QTPP, Liquid / lyophilization formulation development (**PFS, pens, vials & cartridges**)
- Clone stability
- Process & method transfer

Analytical Clinical (Phase 1-3)

- **Advance analytics & bio-assays** for clone selection, compound identification & product characterization
 - Primary structure analysis
 - Intact and reduced mass analysis
 - Secondary, tertiary & high order structure analysis
 - Impurity profiling and characterization
- **Process characterization**
- **Analytical & bio-analytical qualification**

Manufacturing

- **GMP cell banking** (Mammalian & Microbial)
- Pre-clinical manufacturing of DS & DP
- **Method validation**
- **Pharmacokinetics & immunogenicity assays**
- **Scale-up, clinical & cGMP manufacturing of DS & DP**
- DS and DP testing, release and stability studies
- **Liquid / lyo fill finish** (PFS, pens, vials & cartridges)
- **Regulatory support**
- **Quality assurance & control**



We are committed to delivering end-to-end solutions that accelerate drug development and commercialization.

Our capabilities encompass a broad spectrum of biology, chemistry, and GMP manufacturing operations. With our expertise and cutting-edge technologies, we deliver innovative and high-quality solutions to meet the diverse needs of our clients.

Enzene capabilities at a glance:

Discovery and development

- Cell line engineering and development
- Cell banking
- Upstream process development and characterization
- Downstream process development and characterization
- Downstream refolding methods
- Formulation and drug product development

Manufacturing

- Tech transfer and scale-up
- Drug substance manufacturing
- Fed-batch
- EnzeneX™ continuous bioprocess manufacturing
- Drug product manufacturing
- Lyophilization

Other CDMO capabilities

- Product characterization
- Method development, qualification and validation
- Stability studies
- Dynamic process screening
- Bioassay capability
- Quality assurance and control
- Regulatory affairs



Molecule (Originator)	Marketed indications	Development	Pre-Clinical	Clinical	Launch
Teriparatide	Osteoporosis	●	●	●	●
Denosumab	Postmenopausal osteoporosis Giant cell tumor of bone	●	●	●	●
Romiplostim	Immune thrombocytopenic purpura (ITP)	●	●	●	●
Adalimumab	Rheumatoid arthritis	●	●	●	●
Cetuximab	Squamous cell cancer of the head and neck	●	●	●	●
Bevacizumab	Metastatic colorectal cancer	●	●	●	●
Ranibizumab	Neovascular (Wet) age-related macular degeneration	●	●	●	●
Liraglutide	Type II Diabetes Mellitus	●	●	●	
Pertuzumab	HER2-positive metastatic Breast Cancer	●	●		
Tocilizumab	Rheumatoid arthritis	●			

We are proud to launch an extensive range of biosimilars

By leveraging one of the world's strongest biosimilar product pipelines — with molecules at various stages of the development life cycle — exclusive licensing opportunities give you the chance to bring trusted and affordable biosimilar products to patients quickly.

Our proprietary continuous manufacturing technology

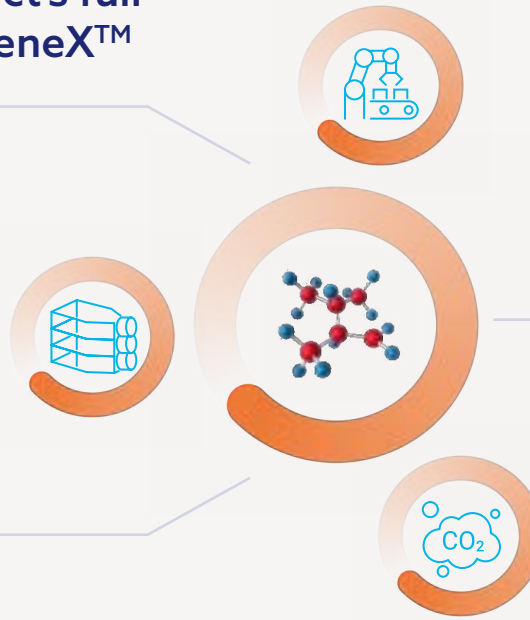
A key asset in our commitment to delivering maximum value is our continuous manufacturing technology platform, EnzeneX™, which will be hosted at our US site to optimize quality, efficiency, and flexibility in delivery. It also supports the cost-effective, and sustainable production of high-quality biologics, making them more accessible to patients worldwide. With multiple manufacturing lines at the new site, we are poised to meet the growing demand for biologics and biosimilars in the US.



Unlock your product's full potential with EnzeneX™

Primed for product scaling

Scale-on using the same size bioreactors with higher process duration and scale-out using multiple same size suites to enable right-first-time transfer.



Patented and validated quality manufacturing

Intensified perfusion using alternate tangential flow (ATF) and automated multi-column chromatography means EnzeneX™ delivers high-quality, efficient and cost-effective manufacturing.

Designed with flexibility in mind

Greater flexibility, lower cost and higher sustainability (lower carbon and facility footprint) compared to traditional stainless steel bioreactors.

EnzeneX™ delivers higher productivity, quality, and sustainability at a significant cost advantage



Fully validated method

Proven manufacture of commercial mAbs and conversion of biologics from fed batch to continuous manufacturing



Increased productivity

Upstream processing productivity is increased ~10x, and downstream processing productivity is increased 25-50%



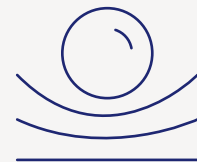
Cost effective manufacturing

A lower cost of goods translates to a ~40% reduction in processing costs



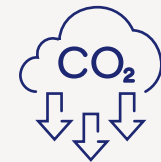
High quality products

Minimized product contact with cell culture fluid reduces aggregation and degradation (clipping, oxidation, deamination, glycation) and means high quality products, even for less-stable and difficult-to-express proteins (fusion proteins, bi/multi-specific antibodies, cytokines)



Flexible design

Clinical phase GMP supply in as low as 30-50L scale and modular design with variable bioreactor capacity accelerates development with scale-on and scale-out approaches



Reduced emissions

Smaller equipment and single-use bioreactors reduce carbon footprint up to 50%

Benefits of partnering with Enzene

We are dedicated to realizing your vision to bring accessible, high-quality treatments to patients around the world. Our scientific and technical experts are ready to take on any challenge, with a problem-solving mindset to tackle even the most complex of projects.

Partnering with Enzene offers several benefits, including:

Unparalleled expertise:

Our senior leadership team has a wealth of experience in biopharmaceutical development and manufacturing, with a cumulative 100+ years of knowledge and expertise.

Innovative solutions:

We are committed to innovation, as shown by our proprietary EnzeneX™ platform, and are constantly developing new and improved technologies to meet the evolving needs of our clients.

Flexibility and scalability:

Our flexible and scalable approach, supported by 22 bioreactors and 5 manufacturing suites, enables us to cater to the unique demands of every project.

Quality and compliance:

We adhere to the highest quality and compliance standards to ensure the safety and efficacy of our products, as shown by the development of 15+ new biologic entities and biosimilar products for regulated markets.

Exceptional customer service:

We are dedicated to providing exceptional customer service and building long-lasting client partnerships and have successfully delivered 31 projects at different stages from cell line development to commercial at accelerated rates.



Changing the world one biologic at a time

A key asset in our commitment to delivering maximum value is our continuous manufacturing technology platform, EnzeneX™. This patented technique optimizes quality, efficiency, and flexibility in delivery. It also supports the cost-effective and sustainable production of high-quality biologics, making them more accessible to patients worldwide. In addition to EnzeneX™ manufacturing lines at our existing facilities, multiple lines will be hosted at our new site in New Jersey, enabling us to meet the growing demand for biologics and biosimilars in the US.

Contact us

To learn more about Enzene and discover how we can support you, please get in touch at www.enze.com/contact-us



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