



**Enzene**

An innovation-driven  
biotech and CDMO

[www.enzyme.com](http://www.enzyme.com)



Passion. Innovation. Life

# 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 discovery to fill & finish on even the most complex projects. With a strong biosimilar portfolio and unique proprietary fully-connected continuous manufacturing™ (FCCM™) 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?

Enzene Biosciences is a leading global contract development and manufacturing organization (CDMO). The company was founded on a belief that we have a responsibility to positively impact healthcare around the world by providing the technological expertise, passion for innovation, and dedication to helping clients bring accessible and affordable products to market. Built on a proven history of successful commercial launches and a strong early-stage product pipeline, Enzene continues to disrupt the CDMO industry with novel processes that improve quality and productivity while reducing costs and carbon footprint.

We operate a state-of-the-art R&D facility equipped with advanced technologies, alongside our cGMP manufacturing facilities, which feature six suites. These suites encompass fed-batch, semi-continuous, and our patented fully-connected continuous manufacturing™ process, EnzeneX™, positioning us among the few global pioneers in this field. Our microbial and mammalian DS plants, as well as our sterile fill & finish plant in India, have received EU-GMP certification.

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 80,000 sq ft, this plant will also hold the distinction of being one of the only biologics-focused fully-connected continuous manufacturing™ (FCCM™) based 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 10 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.



## What CDMO services do we offer?

Discovery	Development	Manufacturing	Other capabilities
Peptide services	Cell line engineering and development	Tech transfer and scale-up	Product characterization
Protein services	Cell banking	Drug substance manufacturing	Method development, qualification and validation
Assay services	Upstream process development and characterization	Fed-batch	Stability studies
Advanced modalities	Downstream process development and characterization	EnzeneX™, fully-connected continuous manufacturing™	Dynamic process screening
Antibody discovery	Downstream refolding methods	Drug product manufacturing	Bioassay capability
Antibody engineering	Formulation and drug product development	Lyophilization	Quality assurance and control
			Regulatory affairs

## Enzene modalities at a glance:

Modality	Upstream capabilities				Downstream capabilities				
	Perfusion and fed-batch process development	Process characterization	Tech transfer and scale-up	Fully-connected continuous manufacturing™ (FCCM™)	Downstream process development	Process characterization	Tech transfer and scale-up	Fully-connected continuous manufacturing™ (FCCM™)	Refolding methods
Monoclonal antibodies (mAbs)	●	●	●	●	●	●	●	●	
Recombinant proteins	●	●	●	●	●	●	●	●	●
Recombinant enzymes	●		●		●		●		●
Conjugated proteins	●				●				
Bispecific proteins	●	●	●	●	●	●	●	●	
Fusion proteins	●	●	●	●	●	●	●	●	●
Synthetic peptides					●	●	●		
Plasmid DNA (pDNA)	●				●				
Phytopharmaceuticals					●				

## We are proud to launch an extensive range of biosimilars

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	●	●	●	●
Pertuzumab	HER2-positive metastatic Breast Cancer	●	●	●	



## Enzene in the USA



- Brownfield development in New Jersey
- 80,000 sq. ft.



- Multi-staged, Phased growth
- Phase 1 Launch – Q1, 2025



- Drug Substance
- Drug Product
- CMC

## We offer modular and manufacturing flexible capacity



**2**

Bioreactors (200L & 500L)



**2**

Manufacturing suites



**CHO GMP-grade modality agnostic**  
manufacturing (mAbs, recombinant proteins,  
fusion proteins, bispecific proteins)



**Clinical and phase  
GMP supply**

using fed-batch and  
FCCM™



**2-4**

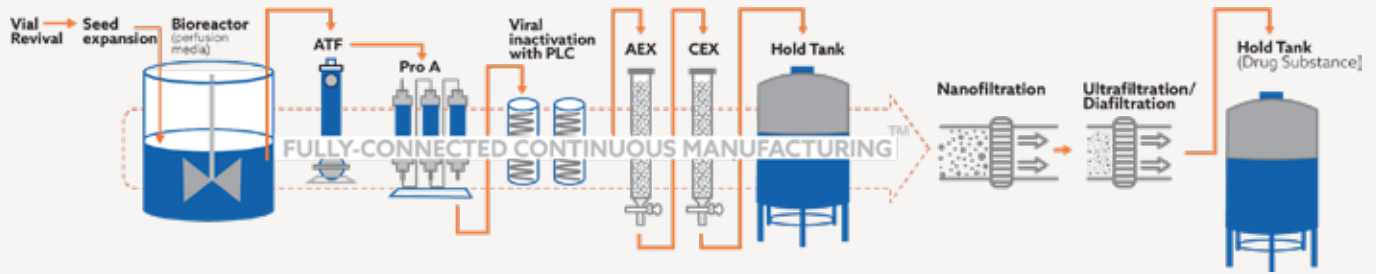
additional DS suites (500L  
& 1000L), with a possibility  
of a DP filling line



**EnzeneX™**

Scale-on and scale-out

# Our patented and validated fully-connected continuous manufacturing™ platform



A key asset in our commitment to delivering maximum value is our fully-connected 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.

## 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 fully-connected continuous manufacturing™ (FCCM™)



### Increased productivity

Upstream processing productivity is increased ~10x



### Cost effective manufacturing

A lower cost of goods translates to a ~50% reduction in processing costs



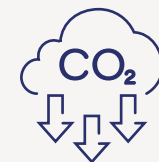
### High quality products

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

We are committed to delivering high-quality, cost-effective manufacturing solutions to support your drug development programs. Our team offers everything you need to progress through from cell line development to fill and finish. Spanning R&D, analytical and operations support, our rigorously refined, fully integrated approach represents a single, direct and streamlined route to market.

### Contact us

To learn more about Enzene and discover how we can support you, please get in touch at [www.enzyme.com/contact-us](http://www.enzyme.com/contact-us) or [bd@enzyme.com](mailto:bd@enzyme.com)





**Global R&D and Manufacturing\*,  
Pune, India**

\*Our microbial and mammalian DS plants as well as our sterile fill & finish plant in India have received EU-GMP certification



**USDA Designed Facility,  
New Jersey, USA**



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