

Breaking down boundaries with our new biologics manufacturing site

Located in New Jersey, USA



Welcome to **Enzene's state-of-the-art manufacturing site**

Our first manufacturing site in New Jersey is at the heart of the US Northeast Corridor, providing easy access for many of our customers, and positioning us in a prime location for forming partnerships with new companies.

Spread over 54,000 sq ft, this plant holds the distinction of being one of the only biologics-focused continuous manufacturing bases in the US.

The site will also host multiple processing lines of our continuous manufacturing technology platform, EnzeneX™.

'Bringing our patented and innovative technology into North America will help to streamline supply chains, accelerate turnaround times, and provide greater control of the overall manufacturing process, hosted under one roof.'

Everything you need in a partner

We understand the unique challenges faced by small and mid-sized biotech companies in securing clinical phase and commercial capacity for their novel molecules. Our state-of-the-art facility is here to cater specifically to your needs.

New Jersey is ideal for us to serve emerging innovative, US-based biotech firms looking to benefit from our in-depth expertise in continuous manufacturing. This expansion marks a significant milestone in our commitment to delivering affordable and innovative solutions that positively impact the global healthcare ecosystem.

We are committed to bringing the best to your project, comprising of a world-class team with deep scientific and technical expertise across a wide range of modalities. New Jersey offers an abundant pool of highly skilled talent, which will ensure that we have the resources we need to achieve the full potential of your product.

We are confident that this expansion enables us to continue providing our clients with the exceptional manufacturing services they have come to expect from Enzene.



Service offerings

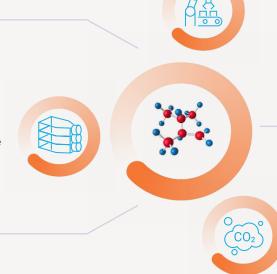
Our New Jersey plant is not just a production site but also a testament to our commitment to quality and compliance. The facility has been designed to meet the stringent GMP requirements of the USFDA and the USDA. We are dedicated to ensuring the highest standards of safety, efficacy, and quality in all our products.

Our continuous manufacturing technology platform, EnzeneX™, hosted at this site, optimizes quality, efficiency, and flexibility to ensure the maximum value is delivered. 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 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



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/multispecific antibodies, cytokines)



Increased productivity

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



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



Cost effective manufacturing

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



Reduced emissions

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

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

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

From cell line to finish line, we offer everything you need for a streamlined route to market.



Our wide range of modalities can meet your every need

From monoclonal antibodies to conjugated and bispecific proteins, our technical expertise spans a wide range of complex biologics. With the support and experience of our pioneering scientific experts, there's no challenge we're unwilling to take on.

	Upstream capabilities				Downstream capabilities				
Modality	Perfusion and fed-batch process development	Process characterization	Tech transfer and scale-up	Integrated continuous manufacturing	Downstream process development	Process characterization	Tech transfer and scale-up	Continuous manufacturing	Refolding methods
Monoclonal antibodies (mAbs)	O	O	C	O	O	O	C	C	
Recombinant proteins	O	O	C	0	O	O	O	O	O
Recombinant enzymes	O		O		O		O		O
Conjugated proteins	O				O				
Bispecific proteins	O	O	O	O	O	O	O	O	
Fusion proteins	O	C	C	O	O	C	O	C	O
Synthetic peptides					O	C	O		
Plasmid DNA (pDNA)	C				O				
Phytopharmaceuticals					С				

What does the future hold?

The launch of our New Jersey site coincides with our ambitious expansion plans and will play a central role in our future growth. This expansion into North America enhances our manufacturing capabilities to better serve North American companies and facilitate faster delivery of products to the market. This growth will pave the way toward achieving our objective of increasing healthcare availability, leading to better patient outcomes.

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. Enzene's onshoring of manufacturing capacities at the New Jersey plant ensures access equity for early-stage biological assets by providing cost-effective, yet quality local manufacturing.

How can Enzene Biosciences help you?

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.

With Enzene, you can expect unparalleled quality, exceptional service, and innovative solutions. Discover the power of continuous manufacturing technology and partner with us to bring lifechanging biologics to patients around the world.

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. This facility provides a solid base in North America to offer 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.

Discover how we could support you at our New Jersey facility.

Get in touch at: www.enzene.com/ contact-us



