

# PRODUCT SUPPORT FOR SCIENTISTS DEVELOPING, MANUFACTURING & ANALYZING BIOTHERAPEUTICS

THE FOUNDATION FOR YOUR INNOVATION.





## SUPPORTING BIOTHERAPEUTIC DISCOVERY, MANUFACTURING & ANALYSIS

Innovative biotherapeutics, including gene therapies, protein/antibody treatments, and nucleic acid therapies, are revolutionizing disease treatment. These cutting-edge therapies offer targeted and personalized approaches to a wide range of diseases, from genetic diseases to cancer. By harnessing the power of molecular biology, scientists are developing revolutionary new treatments which precisely target disease-causing molecules.

At New England Biolabs, we are dedicated to creating advanced molecular biology tools to support the discovery of these transformative therapies. Our extensive range of high-quality reagents are designed to meet the rigorous demands of the biotherapeutic industry. From the initial stages of discovery to the complexities of large-scale manufacturing and

detailed analysis, our products and expertise are integral to every step of the therapeutic development process. With a commitment to innovation and collaboration, we work with scientists like you to push the boundaries of biotherapeutics, ultimately bringing life-changing therapies to people across the globe.





At NEB, we have over five **decades of experience** in practicing molecular biology, which has led to the introduction of a broad product portfolio that has the potential to touch almost every stage of today's biotechnology discovery and development processes. With this expertise in hand, we are ready and able to **collaborate with biotech companies**, large and small, to support your discoveries and help them move through clinical testing, manufacturing, and quality control, and into regulated markets around the world.

## BIOTHERAPEUTIC DISCOVERY / DEVELOPMENT

NEB supports the discovery and development phase of biotherapeutic development with a comprehensive range of high-quality enzymes and reagents. Our extensive product portfolio includes tools for cloning, protein expression, *in vitro* transcription, nucleic acid amplification, and nucleic acid purification, all of which are essential for early-stage research. Our reagents can be used in high throughput automated methods for enhanced efficiency.

## MANUFACTURING / SCALE-UP

In the manufacturing and scale-up phase, NEB offers RUO and GMP-grade\* reagents that meet stringent regulatory standards, ensuring consistency and reliability with every order. Our scalable solutions and technical support help streamline the transition from small-scale experiment to large-scale production, maintaining product performance, integrity, and quality throughout the transition process.

## ANALYTICAL ANALYSIS

NEB provides a suite of advanced tools and enzymes designed for precise and accurate biotherapeutic characterization. Our products support various analytical methods, including next-generation sequencing and mass spectrometry, enabling detailed analysis of biomolecules.

## FACILITIES & QUALITY CERTIFICATES



**NEB Headquarters**  
Ipswich, MA USA

### Capabilities

Formulation, Filling, Dispensing, Kitting, Packaging, Fermentation, Purification

### Quality Systems

ISO 9001, ISO 13485



**NEB Headquarters Expansion**  
Ipswich, MA USA

### Capabilities

Formulation, Filling, Kitting, Packaging, Warehousing, QC Laboratories

### Quality Systems

ISO 9001, ISO 13485



**Rowley Production Facility**  
Rowley, MA USA

### Capabilities

Formulation, Dispensing, Kitting, Packaging, Fermentation, Purification, QC Laboratories, Warehousing

### Quality Systems

ISO 9001, ISO 13485, GMP-grade\*



**Rowley Packaging Facility**  
Rowley, MA USA

### Capabilities

Formulation, Filling, Dispensing, Kitting, Packaging, Fermentation, Purification

### Quality Systems

ISO 9001, ISO 13485



**NEB Lyophilization Sciences**  
Oxford, UK

### Capabilities

Lyophilization, Kitting, Packaging, Warehousing, QC Laboratories

### Quality Systems

ISO 9001, ISO 13485

NEB Headquarters Expansion photo credit: © Robert Benson Photography

\* "GMP Grade" and "GMP-grade" are branding terms NEB uses to describe reagents manufactured at our Rowley, MA facility, where we utilize procedures and process controls to manufacture reagents under more rigorous conditions to achieve more stringent product specifications, and in compliance with ISO 9001 and ISO 13485 quality management system standards. NEB does not manufacture or sell products known as Active Pharmaceutical Ingredients (APIs), nor do we manufacture products in compliance with all of the Current Good Manufacturing Practice regulations.

# PRODUCTS SUPPORTING BIOTHERAPEUTIC DISCOVERY

Molecular biology tools and techniques are at the heart of the discovery and pre-clinical development of groundbreaking biotherapeutics, including gene, protein/antibody, and nucleic acid therapies. These molecular tools empower scientists to dive deeper into the genetic and molecular foundations of diseases, leading to the creation of targeted and effective treatments. Techniques such as CRISPR gene editing, recombinant DNA technology, and next generation sequencing are indispensable for identifying therapeutic targets, engineering therapeutic proteins and antibodies, and developing nucleic acid therapies. By offering precise control over biological processes, molecular tools not only accelerate the discovery phase but also enhance the understanding of a biotherapeutics specificity and efficacy.

Our growing and diverse portfolio of products is designed provide the tools needed by researchers investigating new biotherapeutics.



## GENE THERAPY DISCOVERY

Traditional methods like recombinant DNA technology and modern advancements such as CRISPR gene editing are pivotal in the discovery of new gene therapies. These techniques enable precise manipulation of genetic material.

### FEATURED PRODUCTS:

CONSTRUCTION	TRANSFORMATION	NUCLEIC ACID REMOVAL (AAV)	DNA PURIFICATION & ANALYSIS	TEMPLATE GENERATION
NEBuilder® HiFi DNA Assembly Cloning Kit (NEB #E5520)	NEB® 5-alpha Competent <i>E. coli</i> (NEB #C2987)	NEBExpress® Salt Active Nuclease (NEB #M0764)	Monarch® Spin Plasmid Miniprep Kit (NEB #T1110)	NEBuilder HiFi DNA Assembly Cloning Kit (NEB #E5520)
NEBridge® Golden Gate Assembly Kit (NEB #E1601, #E1602)	NEB 10-beta Competent <i>E. coli</i> (NEB #C3040)	NEBExpress Salt Active Nuclease, GMP Grade (NEB #G8024)	Monarch Spin PCR & DNA Cleanup Kit (NEB #T1130)	BspQI (NEB #R0712)/ BspQI-HF® (NEB #R3712)
	NEB Stable Competent <i>E. coli</i> (High Efficiency) (NEB #C3040)		NEBNext® Ultra™ II DNA Library Prep Kit (NEB #E3325)	Q5® Hot Start High- Fidelity 2X Master Mix (NEB #M0494)
			NEBNext Companion Module v2 for ONT (NEB #E7672)	phi29-XT WGA Kit (NEB #E1604)/ phi29-XT RCA Kit (NEB #E1603)
				TelN Protelomerase (NEB #M0651)
				T5 Exonuclease (NEB #M0663)



## PROTEIN/ANTIBODY DISCOVERY

Tried and true methods such as cloning and protein expression combined with modern next generation sequencing are essential for discovering new protein and antibody therapies. These methods enable the precise manipulation and production of therapeutic proteins.

### FEATURED PRODUCTS:

CONSTRUCTION	CONSTRUCTION (CONT'D)	EXPRESSION	NUCLEIC ACID REMOVAL	PURIFICATION
NEBuilder HiFi DNA Assembly Cloning Kit (NEB #E5520)	phi29-XT WGA Kit (NEB #E1604)/ phi29-XT RCA Kit (NEB #E1603)	PURExpress® <i>In Vitro</i> Protein Synthesis Kit (NEB #E6800)	NEBExpress Salt Active Nuclease (NEB #M0764)	NEBExpress Ni-NTA Magnetic Beads (NEB #S1423)
NEBridge Golden Gate Assembly (NEB #E1601, #E1602)	NEB 5-alpha Competent <i>E. coli</i> (NEB #C2987)	BL21 (DE3) Competent <i>E. coli</i> (NEB #C2527)	NEBExpress Salt Active Nuclease, GMP Grade (NEB #G8024)	NEBExpress Ni Resin (NEB #S1428)
		NEBExpress Cell-free <i>E. coli</i> Protein Synthesis System (NEB #E5360)		NEBExpress Ni Spin Columns (NEB #S1427)



## NUCLEIC ACID THERAPEUTICS

Key molecular biology methods, such as *in vitro* transcription (IVT), are essential for the discovery of new nucleic acid therapies. These techniques enable the precise synthesis and manipulation of RNA, driving advancements in nucleic acid therapy discovery.

### FEATURED PRODUCTS:

TEMPLATE GENERATION	IN VITRO TRANSCRIPTION	RNA CAPPING	POLY(A) TAILING	RNA PURIFICATION & ANALYSIS
NEBuilder HiFi DNA Assembly Cloning Kit (NEB #E5520)	HiScribe® T7 High Yield RNA Synthesis Kit (NEB #E2040)	Faustovirus Capping Enzyme (NEB #M2081)	<i>E. coli</i> Poly(A) polymerase (NEB #M0276)	Monarch Spin RNA Cleanup Kits (10, 50, 500 µg) (NEB #T2030, T2040, T2010)
BspQI (NEB #R0712)/ BspQI-HF (NEB #R3712)	HiScribe T7 mRNA Kit with CleanCap® Reagent AG (NEB #E2080)	Vaccinia Capping Enzyme (NEB #M2080)		Monarch Spin RNA Isolation Kit (Mini) (NEB #T2110)
Q5 Hot Start High-Fidelity 2X Master Mix (NEB #M0494)	<u>Companion Products</u> DNase I (NEB #M0303)  DNase I-XT (NEB #M0570)  RNase Inhibitor, Murine (NEB #M0314)	mRNA Cap 2'-O-Methyltransferase (NEB #M0366)		Luna® Probe One-Step RT-qPCR 4X Mix with UDG (NEB #M3019)
phi29-XT WGA Kit (NEB #E1604)/ phi29-XT RCA Kit (NEB #E1603)				
TelN Protelomerase (NEB #M0651)				





## BIOTHERAPEUTIC SCALE UP AND MANUFACTURING



NEB's portfolio of research-grade (RUO) and GMP-grade\* products enables bench to commercial-scale production batch sizes. When it is time to scale up and optimize reaction components, our standalone enzymes and buffers are readily available in formats (ml to kl), enabling a seamless transition to large-scale manufacturing.

- Over 50 years of experience in enzymology and reagent manufacturing
- A collaborative relationship where we prioritize a deep understanding of your goals and future needs, all while we continuously innovate products you may need in the future
- The ability to manufacture and package products at the scale and format you need (ml to 1000's of L)
- ISO 9001- and 13485-certified manufacturing facilities and global warehousing capabilities
- A purpose-built, 43,000 sq ft. production facility for GMP-grade\* enzyme manufacturing
- Direct access to our Customized Solutions Team who is committed to your growth and success



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## FEATURED PRODUCTS FOR BIOTHERAPEUTIC SCALE UP & MANUFACTURING:

PRODUCT NAME	DESCRIPTION	GENE THERAPY	PROTEIN/ ANTIBODY	mRNA	AVAILABLE GMP-GRADE*
<b>BspQI</b>	Type IIS restriction enzyme and Isoschizomer of LguI and SapI used to linearize plasmid DNA for mRNA therapeutics			●	●
<b>NEBExpress Salt Active Nuclease</b>	Engineered nuclease that leverages high salt (500 mM NaCl/KCl) conditions to remove nucleic acids in protein, adeno-associated virus (AAV) manufacturing and other biopharma workflows	●		●	●
<b>TEV Protease</b>	Highly specific cysteine protease with a recognition sequence with the highest catalytic efficiency of ENLYFQ* <sub>S</sub>		●	●	
<b>Thermolabile Proteinase K</b>	Recombinant, heat-inactivated Proteinase K, engineered for complete inactivation at 55°C in 10 minutes, with broad protease activity for digestion of proteins in nucleic acid preparations and other applications		●		
<b>Q5 Hot Start High-Fidelity Master Mix</b>	Q5 is composed of a novel polymerase that is fused to the processivity-enhancing Sso7d binding domain, improving speed, fidelity and reliability of performance. Note that the formulation of the GMP-grade product is different than the catalog product	●		●	
<b>HiScribe T7 High Yield RNA Synthesis Components</b>	The HiScribe T7 High Yield RNA Synthesis Kit is an extremely flexible system for <i>in vitro</i> transcription of RNA using T7 RNA Polymerase. Separate components available in GMP-grade format			●	●
<b>T5 Exonuclease</b>	Double-stranded DNA specific exonuclease and single-stranded DNA endonuclease, initiates at the 5' termini of linear or nicked double-stranded DNA	●			●
<b>TeIN Protelomerase</b>	Cuts dsDNA at a TeIN recognition sequence and leaves covalently closed ends at the site of cleavage	●		●	●
<b>phi29 DNA Polymerase</b>	Replicative polymerase from the <i>Bacillus subtilis</i> phage phi29 and has exceptional strand displacement and processive synthesis properties with inherent 3'-5' proofreading exonuclease activity	●		●	●
<b>DNase I-XT</b>	DNA-specific endonuclease used for removal of contaminating genomic DNA from RNA samples and degradation of DNA templates in transcription reactions			●	
<b>RNase Inhibitor, Murine</b>	Specifically inhibits RNases A, B and C			●	●



To find out how NEB can help,  
visit [www.neb.com/GMP](http://www.neb.com/GMP)



## PRODUCTS FOR ANALYTICAL ANALYSIS



NEB offers a comprehensive catalog of products designed to support scientists performing analytical analysis of biotherapeutics. In the realm of protein and antibody therapies, our mass spectrometry-compatible reagents facilitate precise and efficient protein characterization, enabling detailed analysis of protein structure and function. NEB also provides a portfolio of enzymes designed for the precise and efficient characterization of glycan structure.

### FEATURED PRODUCTS:

#### LC-MS/MS NUCLEIC ACID ANALYSIS

RNase 4 (NEB #M1824)  
RNase 4 Digestion and  
3' End Repair Mix  
(NEB #M1288)  
Nucleoside Digestion  
Mix (NEB #M0649)

#### PROTEIN ANALYSIS

IdeZ Protease  
(IgG-specific)  
(NEB #P0770)  
Trypsin-ultra™, Mass  
Spectrometry grade  
(NEB #P8101)

#### GLYCAN ANALYSIS

PNGase F  
(NEB #P0704, #P0710,  
#P0708, #P0711)



To learn more, visit  
[www.neb.com/applications/  
glycobiology-and-proteomics/products](http://www.neb.com/applications/glycobiology-and-proteomics/products)



# CUSTOMIZED SOLUTIONS CAPABILITIES

SUPPORTING SCIENTISTS ADVANCING THERAPEUTIC INNOVATION AND MANUFACTURING THROUGH NEB'S CUSTOMIZED SOLUTIONS CAPABILITIES

Contact our Customized Solutions Team to build your personalized solution.

With 50 years of experience in enzymology and reagent manufacturing, NEB's Customized Solutions Team will help you access novel products, meet quality specifications, speed time to market and streamline your supply chain, allowing you to focus more on what matters most – **innovation**.

## AREAS WE SERVE:



Large Volume Packaging



Custom Formulations  
& Concentrations



Aliquoting, Kitting,  
Packaging & Private Label



GMP-grade Reagents



Learn more or get started at  
[neb.com/customizedsolutions](http://neb.com/customizedsolutions)

# NOT SURE WHETHER YOU NEED RESEARCH-GRADE (RUO) OR GMP-GRADE PRODUCTS?

		RUO	GMP*
 <b>mRNA PRODUCTION</b>	Ability to produce gram to kilogram quantities of mRNA		✓
	Support production of commercially approved mRNA product(s)		✓
	Comparability reports supporting migration from RUO to GMP-grade products for clinical production		✓
 <b>PRODUCT CUSTOMIZATION</b>	<i>Examples include but are not limited to:</i> High-concentration enzymes, formulation, fixed protein concentrations, packaging and fill size	✓ Contact our Customized Solutions Team to discuss	✓ Contact our Customized Solutions Team to discuss
 <b>INFRASTRUCTURE</b>	Animal-free facility		✓
	Risk-based Validation Programs	✓	✓
	Expanded validation requirements for facility/utilities/environment/cleaning/process equipment/computer systems		✓
	ISO 8 Clean Rooms, ISO 5 Filling Hoods		✓
	Multiple production sites for business continuity	✓	✓
 <b>MANUFACTURING PROCESSES</b>	Ampicillin-free processes	Contact our Customized Solutions Team to discuss	✓
	Animal-free processes and final formulation	Contact our Customized Solutions Team to discuss	✓
	Characterized master cell banks		✓
 <b>PRODUCT ATTRIBUTES/ TESTING</b>	Comprehensive panel of product contamination assays performed and Terminal filtration of final product	✓	✓
	Validated assays with quantitative results		✓
	Compendial assays applied to all products, including bioburden and endotoxin levels, where applicable		✓
	TSE/BSE statements		✓
	Animal-free raw materials, processes and formulation	Contact our Customized Solutions Team to discuss	✓
 <b>QA &amp; REGULATORY</b>	ISO 9001 and ISO 13485 certified	✓	✓
	Batch history files/batch history records	✓	✓
	Consolidated batch history file/batch records and defined critical quality attributes and critical process parameters and QA reviews		✓
	Change management and lot disposition by Quality Unit	✓	✓
	Regulatory support package including but not limited to the following risk statements – melamine, antibiotic, mutagenic and elemental impurities, nitrosamine and residual solvents		✓
	Validated shipping configurations	✓	✓
	Temperature tracking devices for all GMP-grade shipments		✓
 <b>SUPPORTED APPLICATIONS</b>		Research use or preclinical applications	For further processing in clinical or commercial cGMP applications



## BEYOND THE NEB CATALOG

OVER 40 YEARS OF SUPPORTING CUSTOMERS  
WITH CUSTOMIZED SOLUTIONS

We recognized long ago that our customers' needs sometimes extend beyond the traditional list of products found in our catalog. For over 40 years, we have employed a collaborative approach to discover, plan, and ultimately deliver custom products that fit our customers' unique requirements. From larger quantities of existing products, to custom packaging and labeling, or even custom formulations and formats, we are here to help.

### Large Formats for NEB Products

The most frequent request we receive is for larger quantities of our catalog products. Over the years, we have expanded our production capabilities and can easily support these requests. In fact, this capability became even more important during the COVID-19 pandemic, during which we were able to support customers developing diagnostics and vaccines. Large volume requests can be fulfilled in a single vial, bottle or plate for high-throughput applications, or dispensed into pre-determined aliquot sizes to meet your specific need.

### Product Quality

As with any product that you purchase from us, the reagents and products that we supply through our Customized Solutions Team are manufactured in compliance with our Quality Management System. Our Quality team utilizes a

two-tiered approach to ensure product quality. Tier one focuses on compliance, specifically our ISO 9001 and ISO 13485 certificates. The second tier incorporates a variety of cutting-edge quality controls that assess a product's physical attributes, performance, and purity. We are committed to achieving the highest level of product quality regardless of whether you purchase a product from our catalog or through our Customized Solutions Team.

In all of these situations, our Customized Solutions Team is ready to help and serves as a bridge to the support and resources you need to ensure your success.



Learn more or get started at  
[neb.com/customizedsolutions](https://neb.com/customizedsolutions)

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