SEAMLESS RNA PRODUCTION—FROM DISCOVERY TO DELIVERY—WITH HIGH-QUALITY (HQ) ENZYMES

Adopt HQ-grade enzymes early during preclinical studies and process development to transition seamlessly to large-scale mRNA manufacturing with GMP-grade enzymes.

Using the appropriate grade of enzyme for each stage of development helps you scale up faster and within budget

Research-grade

Manufactured under ISO 9001:2015, the enzymes are high quality and provide reliable performance for routine research applications.

HQ-grade

Enzymes manufactured to many of the same quality standards as GMP-grade reagents under ISO 3485:2016 but not in a GMP facility.

GMP-grade

Enzymes manufactured and quality controlled in compliance with strict guidelines, including ISO 13485:2016 Quality Management System, that operates in accordance with GMP guidelines.

Drawbacks of scaling up mRNA production with research-grade enzymes

- Small package sizes are not ideal for large-scale reaction workflows
- Lot-to-lot variability in production can impact reproducibility
- Inconsistency with GMP-level quality assurance may slow down your scale-up process

Although research-grade and GMP-grade enzymes are chemically identical, they can differ in material sources, purity, or stability, which can impact assay performance and necessitate workflow revalidation when scaling up.

GMP-grade

Research-grade

Taking the leap from small-scale research to large-scale clinical production can be complex and time consuming, oftentimes requiring reassessment and revalidation of workflows.

HQ-grade enzymes, manufactured to many of the same quality standards as GMP-grade enzymes, facilitate a seamless transition from discovery phase with small-scale research use to manufacturing with GMP-grade.

Compare the three grades of enzymes

Research-grade +
Purity HQ-grade ++
GMP-grade +++

Research-grade <1 ml
Size HQ-grade ≥1 ml
GMP-grade 1 ml ~100 ml

Research-grade \$ HQ-grade \$\$ GMP-grade \$\$\$

Cost

How HQ-grade enzymes help

√ Documented purity and rigorous testing to support preclinical studies

√ Streamlined scale up and lot testing with larger package sizes

√ Compliance with many GMP-grade quality standards while maintaining a lower cost

HQ-grade enzymes are the perfect solution for scaling up to therapeutic development stages—whether preclinical testing or process development—when GMP-grade reagents aren't required

		Therapeutic development stage		
		Research	Development	Manufacturing
Quality feature	Evaluation stage	Research-grade	HQ-grade	GMP-grade
Exonuclease and endonuclease free	Final formulation	J	J	J
Purity testing • Endotoxin, bioburden • Host cell-derived DNA/ RNA contamination	Final formulation	-	J	J
AOF: animal- and human- origin free	Final formulation	-	J	J
	Raw materials	-	-	J
ß-lactam free	Final formulation	-	J	J
	Raw materials	-	-	J



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