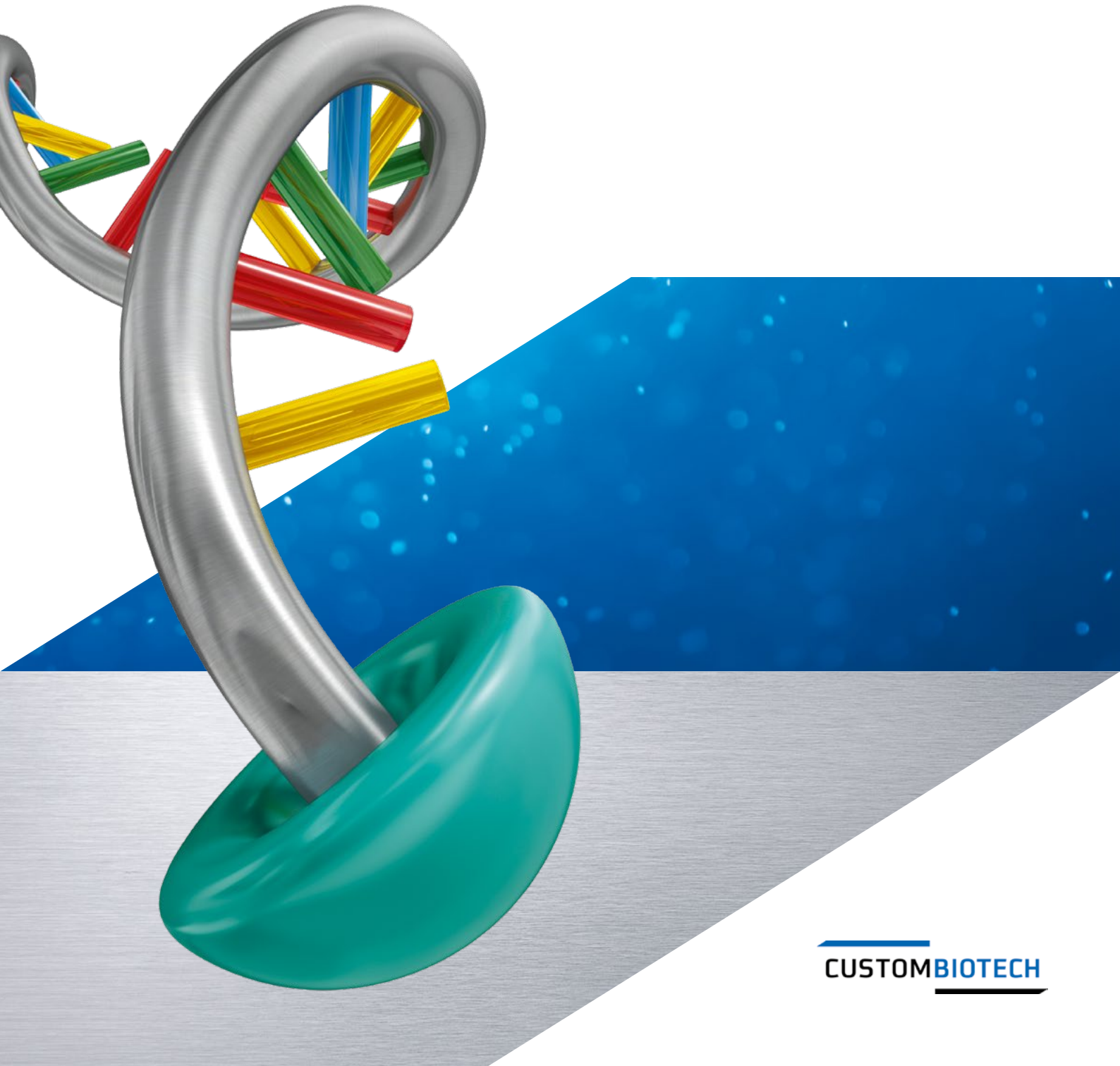
Roche

Quality and security that empower breakthroughs

Raw materials for mRNA therapeutics



CUSTOMBIOTECH

Our pledge at CustomBiotech

To reduce uncertainties

mRNA therapeutics – from development to manufacturing

Though discovered over 50 years ago, mRNA has only recently entered the limelight as a therapeutic agent. *In vitro* transcribed mRNAs are engineered to elicit protein expression either in immune cells as a new front to treat cancer and combat infections, or in other tissues to improve replacement therapies.

Critical decisions in drug development

Not all causes for setbacks or deviations during technical development of a new drug can be anticipated. We believe, however, that variations in raw materials or limitations in scale up should not be a reason for delays of development or commercialization of your mRNA drug.

Therefore, selecting fit-for-purpose critical raw materials from the beginning with the foresight to smoothly transition into a routine manufacturing process is a pivotal decision.

Fit-for-purpose raw materials comply with the following standards

- Manufactured under Good Manufacturing Practice (GMP) quality standards
- Highly consistent from lot to lot
- Available in scale and quality for commercial production
- Produced free of animal-derived components and beta-lactam antibiotics
- Tested for critical impurities, e.g. endotoxin, bioburden, residual metals, as well as host cell DNA and host cell protein

Reliable partner for industrial production

We merge the experiences, knowledge and lessons learned over 30 years of industry leadership to offer a partnership that goes far beyond supplying raw materials. Our experts understand the industry and thus can anticipate and resolve issues before they become a problem. Count on our products to support your scale-up and regulatory approval.

Gain peace of mind

Let our raw materials and their traceable quality control, change and deviation management contribute to your standardized, robust manufacturing processes. Make the right sourcing decisions early in your development to minimize risk of project delays and to drive the fast market launch of your drug.

Foresight
The effective path to market

We are growing with you

The CustomBiotech portfolio of raw materials evolves alongside the therapeutic mRNA market. Even with increasing requirements you can focus on the development of your drug. Let us focus on providing critical raw materials in quality and scale needed for your commercial mRNA production.

In ongoing projects CustomBiotech optimizes the entire portfolio to meet fit-for-purpose standards. The specifications are determined by the intended use of manufacturing therapeutic mRNA.

Product Portfolio

Product	Catalog number	Pack size	GMP Grade	Animal-free[1]	ß-Lactam-antibiotic-free	Tested for RNase / DNase activity	Extended impurity testing[4]
T7 RNA Polymerase,rec., GMP Grade	08 140 669 103	10 ml (ca 10 mg)	Yes	Yes	Yes	Yes	Yes
Pyrophosphatase,rec., GMP Grade	08 140 677 103	20 ml (ca 40 mg)	Yes	Yes	Yes	Yes	Yes
RNase Inhibitor, rec., GMP Grade	In development	2 MU 100 kU	Yes	Yes	Yes	Yes	Yes
DNase I,rec., RNase-free	03 539 121 103	200 kU	Yes	No[2]	Yes	Yes	In development
Proteinase K, rec.	03 654 672 103	850 mL	Yes (except for Hb assay)	No[2]	Yes	Partially	No
Ribonucleotides, 100 mM:							
ATP	04 980 824 103	100 mL	Yes	No[2,3]	Yes	Yes	No
CTP	04 980 875 103	100 mL	Yes	No[2,3]	Yes	Yes	No
GTP	04 980 859 103	100 mL	Yes	No[2,3]	Yes	Yes	No
UTP	04 979 818 103	100 mL	Yes	No[2,3]	Yes	Yes	No
On-going project							
N1-Methyl-Pseudo-UTP	09 188 991 103 09 522 409 103	100 mL 1.0 mL	In development	Yes	Yes	Yes	Yes
Pseudo-UTP	In development	100 mL 1.0 mL	In development	Yes	Yes	Yes	Yes

[1] For details see Certificates of Origin.
[2] TSE/BSE certificate available.
[3] Orthogonal virus depletion steps included in manufacturing process (e.g. virus retentive filter). Further information on virus depletion study is available.
[4] Includes e.g. testing for bioburden, endotoxin, heavy metals, host-cell DNA, host-cell protein.

Use GMP Grade reagents to reduce process risks.
Our reagents are manufactured under ISO 13485.
GMP Grade reagents include:

Manufacturing
- Validated manufacturing process
- Validated cleaning procedures
- Adequate hygiene environment
- Continuous monitoring

Quality control
- Stability program
- Validated release methods

QM-System
- Change control system incl. notification
- Deviation management
- Periodic reviews

Regulatory disclaimer
For further processing only.

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