

## mRNA CDMO Services to accelerate your mRNA program

### Next generation PCR-based mRNA manufacturing at your service

As part of our globally integrated CTDMO capabilities, our mRNA CDMO Service is laying the foundation for the success of your mRNA programs with a flexible, robust, and scalable process that can be adapted for each new project. This enables highest product yield and quality for every individual mRNA sequence. Our manufacturing expertise is complemented by in-house, state-of-the-art analytical method development and validation capabilities.

### Discover our mRNA Center of Excellence

**We are expanding our offering by establishing two new mRNA manufacturing sites for GMP grade mRNA manufacturing, all under the umbrella of our mRNA Center of Excellence.**

This expansion will enable us to provide mRNA at all scales and qualities, from research through all clinical stages to commercial needs – becoming the single source provider of mRNA drug substance, for all mRNA program life cycle steps.\*

\*mRNA as active substance for human use requires a GMP manufacturing authorization issued by the National Competent Authority.

### Next generation PCR-based mRNA manufacturing

Scalable & flexible manufacturing platform



Plasmid DNA



Polymerase Chain Reaction (PCR)



Tangential flow filtration (TFF)



In Vitro Transcription (IVT)



Chromatography



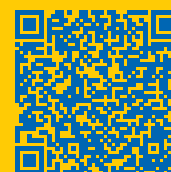
Quantification & dilution



Bioburden filtration & fill

# Key features of PCR-based mRNA manufacturing

Discover more about our mRNA CDMO



With our proven PCR-based workflow, mRNA manufacturing is highly reproducible, and the final product has excellent properties.



## Debottleneck pDNA supply chain

PCR-based manufacturing requires ~10,000 fold less pDNA compared to conventional linearization approach.



## Reproducibility

Consistent reproducible results from lengths of 200 to 9,000 nucleotides, longer upon request.



## Time and cost savings

Low quantity of pDNA required may not necessitate Master Cell Banking establishment, potentially saving months. pDNA according to GMP principles, only.



## Quality

Highly homogenous *in vitro* generated template for IVT synthesized with high fidelity polymerases, minimize trailing or truncated IVT templates.



## Flexibility

Highly adaptable synthetic mRNA template generation, poly(A)-tail introduction during PCR-step.

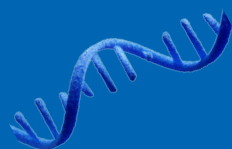


## Purity

Cell free *in vitro* process, mitigating risks of microbial DNA, microbial protein and endotoxins carryover.

## Our integrated CDMO capabilities:

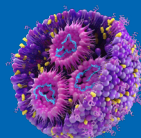
### Your experienced partner from mRNA to final drug product



mRNA



Lipids



LNP formulation & manufacturing



Fill & Finish

As part of the Millipore® CTDMO Services offering, we provide fully integrated CDMO capabilities to support all stages of your mRNA-LNP drug development and manufacturing process, from mRNA, through lipids and lipid nanoparticles (LNPs) to final Fill & Finish.

Discover more about our mRNA-LNP CTDMO services and contact us at:

[SigmaAldrich.com/mRNA-CTDMO-Contact](https://SigmaAldrich.com/mRNA-CTDMO-Contact)

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