ThermoFisher SCIENTIFIC

# mRNA MANUFACTURING SERVICES

patheon

## Flexibility. Experience. Capacity.

The emergence of mRNA therapeutics, including the development of new vaccines and gene therapies, has created a market constraint on access to critical raw materials and scientific and technical expertise. Thermo Fisher Scientific has responded quickly by ramping up a flexible solutions model for mRNA vaccine and therapeutic development. Our end-to-end services include process and analytical development, cGMP manufacturing for mRNA synthesis and liquid nanoparticle (LNP), sterile fill and finish, and logistics and supply chain networks. We are well suited to support your complex and unique cGMP mRNA manufacturing needs, with scale options ranging from 1 to 100 g. Start your mRNA project today with a flexible service offering backed by decades of therapeutic manufacturing expertise.

### À la carte options within an integrated service offering

Flexibility brings speed. From process development to cGMP, you can choose from within our core mRNA therapeutic service options and add upstream and downstream services where needed. Regulatory support and analytical development are always included to help ensure confidence in your path to the clinic.


**Flexibility means choice.**

1. **End-to-end integrated mRNA service offering:** We take care of everything from plasmid production to mRNA manufacturing to cold chain logistics
2. **Core mRNA service offering:** Have us do all your mRNA work—including synthesis, encapsulation, and fill-finish—while you do the upstream and downstream work
3. **Mix and match to fill gaps:** Choose from among our core mRNA service options, and add any upstream and/or downstream services where needed

## Decades of experience provide a solid foundation for mRNA manufacturing

Over 30 years of experience manufacturing sterile injectables, biologics, and advanced therapy products such as viral vectors have provided us the expertise to understand that producing clinical product doesn't stop at the manufacturing floor. Analytics and process development are critical factors for ensuring robust manufacturing processes and consistent clinical product. That's why we take a methodical approach to clinical and commercial readiness and work rigorously to identify critical process parameters to inform development decisions, all of which can save time and reduce overall costs.

### mRNA process development and analytical services

1. Conduct verification runs and perform a risk assessment and gap analysis exercise
2. Formulate scope of PD and/or optimization
3. Assess gaps and formulate solutions, close open steps, and automate manual steps
4. Conduct confirmation runs and gain QA approval for tech transfer
5. Transfer manufacturing workflow to GMP suites

- Scale-up and optimization (microliters to liters scale)
- Define, optimize, and industrialize mRNA synthesis workflow (*in vitro* transcription, DNAse and phosphate treatment, capping, other mRNA modifications, and purification)
- Lipid formulation and solvent removal development (RNA/lipid ratio, excipient evaluation, T-mixing, microfluidics, and TFF)
- Fill-finish services such as formulation and lyophilization recipe development and process characterization studies
- Analytical method development and qualification (mRNA and lipid ID, concentration, integrity and purity, residual molecular and chemical components, and encapsulation parameters including particle size, distribution, and zeta potential)
- Plasmid linearization available

## Our Monza, Italy, mRNA development and manufacturing site is ready to start your mRNA project today

| Non GMP development | cGMP manufacturing Coming in 2023 | QC and analytical | End-to-end approach |
|---|---|---|---|
| • 1,420 sq. ft. process and analytical development laboratory<br>• Process characterization studies<br>• Lab batches (<1g)<br>• Scale-up studies | • 10,800 sq. ft. dedicated cGMP platform<br>• 3 process trains, 1g to 100g mRNA/batch scale<br>• 2 lipid nano particle formulation areas<br>• In-house storage and buffer area<br>• Clinical to commercial | • 1,500 sq. ft. of QC labs<br>• Standard analytical, in-process testing and release<br>• cGMP method transfers, validations, and stability analytical capabilities in continuous expansion, with wide range of possibilities to adapt to customer needs | • Integrated supply chain for raw materials, single-use system, equipment<br>• Global network of expertise<br>• From starting material to fill-finish (11 filling lines)<br>• Storage in temperature-controlled GMP warehousing |

***Learn how Thermo Fisher Scientific can help you fill mRNA gaps quickly to get to clinic and to market with speed.***

+1 919 226 3200 ● thermofisher.com/patheon ● pharmaservices@thermofisher.com



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