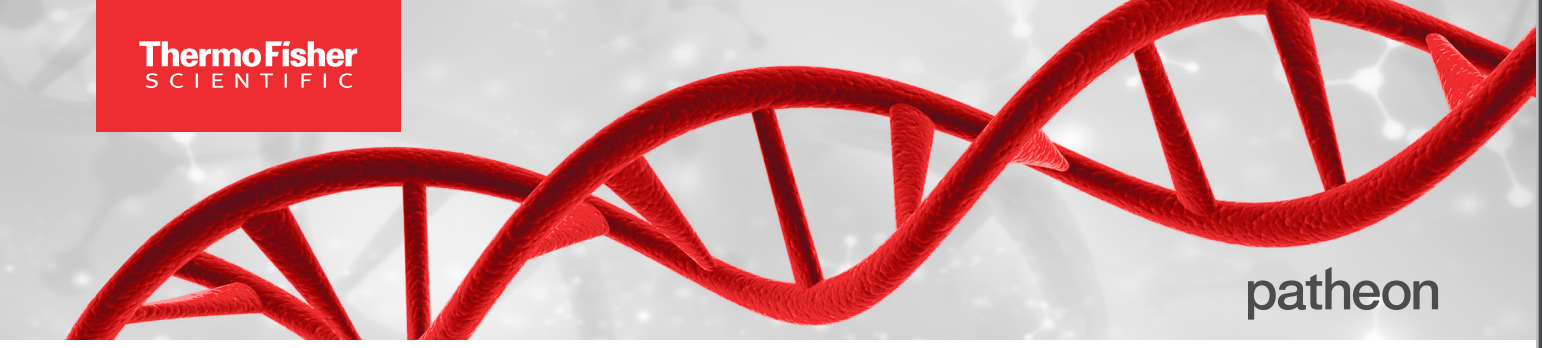


SUMMARY OF CAPABILITIES FACT SHEET

cGMP plasmid DNA manufacturing services

De-risk your path to commercialization with flexible plasmid solutions backed by proven quality systems

Plasmid DNA forms the genetic foundation for many therapeutic strategies, and the growth of cell and gene therapies as well as the rapid emergence of the mRNA vaccine market has created intense pressure on manufacturing of this critical material. Thermo Fisher Scientific has responded by expanding cGMP plasmid DNA manufacturing capacity and solutions so you can get to market faster.

Our flexible phase-appropriate plasmid service offering provides access to full cGMP quality plasmid material regardless of clinical phase of use, with the option to enhance service with additional traceability and/or customized documentation as needed. With full cGMP quality from the start, you can mitigate risk to budget and timelines by preventing changes downstream and ensure compliance with evolving regulatory guidelines.

Offerings	• Starting material for viral vector manufacturing • Nanoplasmid manufacturing • Plasmid as a drug substance • Linearized plasmid DNA for mRNA synthesis
Scale options	• 30L • 300L • 1000L
Process/analytical development	• Research cell banking • Process development or optimization • Analytical method development
QC and analytical	• Analytical method qualification and validation • Standard analytical offering for MCB, in-process testing, and plasmid release • GMP standard for clinical and commercial • Stability studies
cGMP manufacturing	• Clinical to commercial • Single-use process train at 1000L, 300L, 30L • Master and working cell banking • Storage in temperature-controlled GMP warehouse • Significant expansion potential

Why Thermo Fisher for plasmid DNA services?

Flexibility
Plasmid offerings for a variety of applications, phase-appropriate service, scalability up to 1000L, expanded capacity to accommodate growth

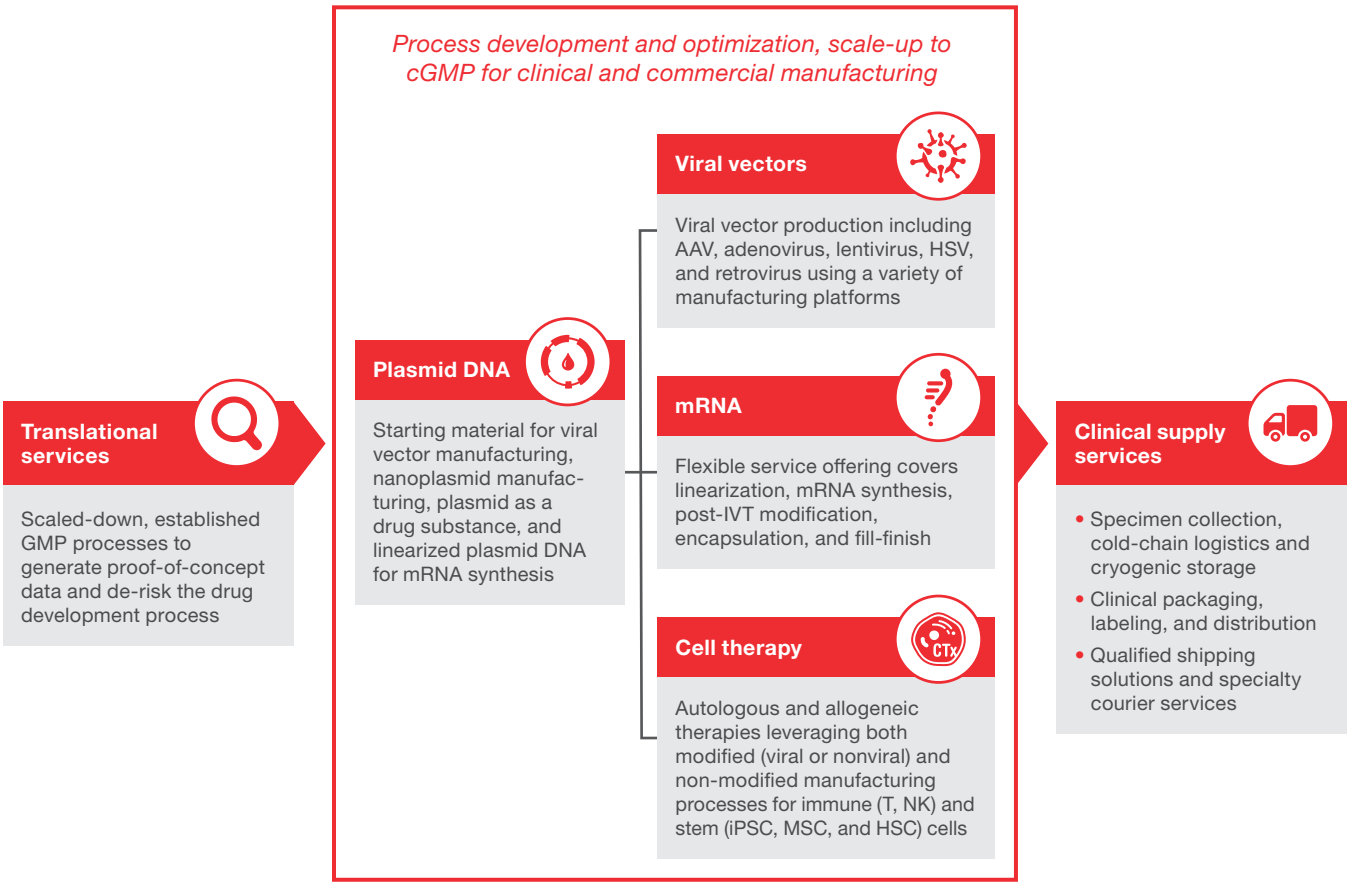
Speed
Proven plasmid platform process saves development effort and accelerates time to market, while in-stock materials mitigate risk of process delays

Quality
Plasmid treated with full application of GMP practices regardless of clinical phase of use and produced under robust global quality system

Integrated services
Combine early translational services, plasmid and viral vector manufacturing, regulatory, and cold chain logistics

Integrated solutions save time and effort on your path to commercialization

Our end-to-end solutions span early translational services all the way to storage and cold chain logistics, helping to reduce complexity and risk in your value chain. In addition to our comprehensive CDMO services, we offer the unique opportunity to leverage resources and expertise across the broader Thermo Fisher network, from industry-leading laboratory products and analytical instrumentation to large-scale bioprocessing equipment.



Contact your local Thermo Fisher Scientific representative to learn more.

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