

Accelerating development and manufacturing of mRNA vaccines and therapeutics: Why raw materials matter

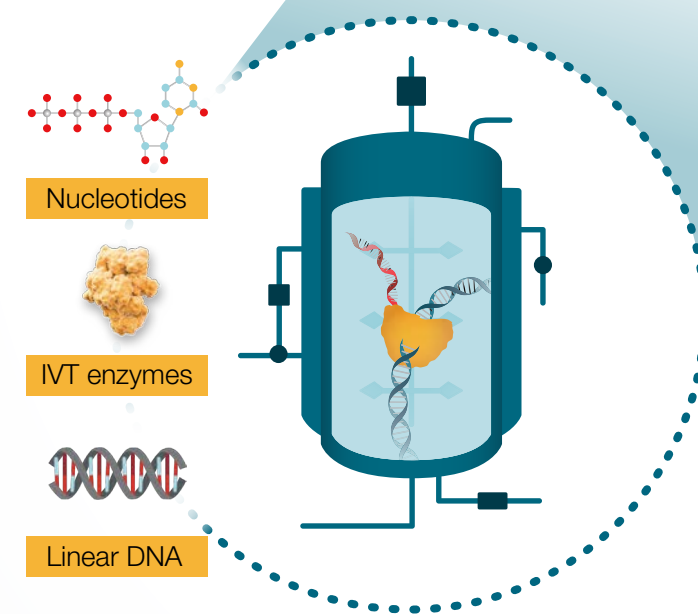
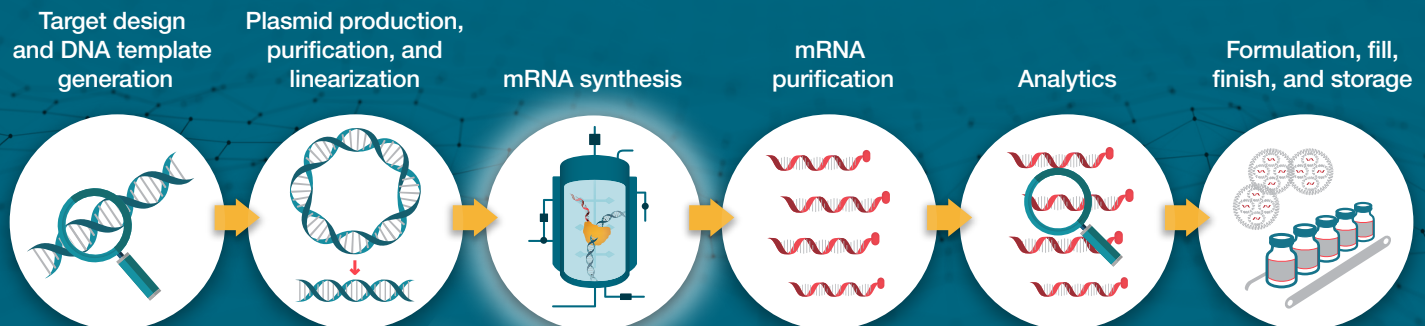
With the validation of the SARS-CoV-2 mRNA vaccines on the global stage, mRNA vaccines and therapeutics are taking the front seat of many biopharma development pipelines. There is an ever-increasing demand for **trusted raw materials and manufacturing processes** that can lead developers safely down the long and winding road to **regulatory approval**.

Yet, identifying a **raw materials supplier** who can scale from preclinical to commercial supply in a cost-effective way is a major roadblock for many drug developers. Finding a company who will be a **true development partner**, rather than just a supplier of raw materials, is a key to success.

Below we review the **mRNA production process** and some **critical considerations for choosing raw materials** to support clinical manufacturing efforts. Discover how Thermo Scientific™ TheraPure™ GMP* solutions can enable mRNA developers to succeed, with raw materials of **proven quality and consistency** supported by **dedicated technical support and partnership**.

The mRNA production process

There are several methods for synthesizing mRNA; cell-free, low-cost, simple, and large-scale production is commonly achieved by **in vitro transcription (IVT)**. IVT-based manufacturing relies on **six key steps** for IVT-based mRNA production. Successful large-scale mRNA synthesis depends on **three essential components**: an RNA polymerase, nucleotides (sometimes chemically modified), and a linear DNA template.



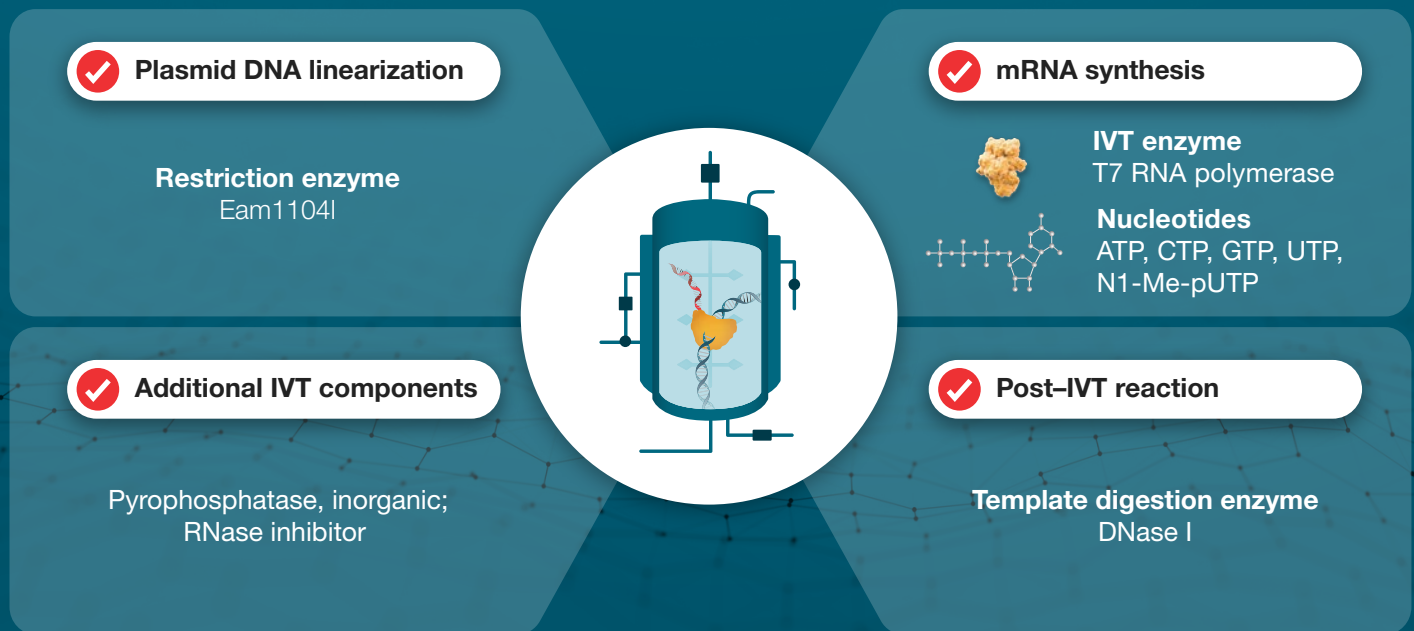
Choosing the right raw materials for mRNA production

To help ensure the quality, scalability, consistency, and regulatory support of your raw materials, **ask any potential supplier these questions:**

- Quality**
Are materials high-purity, animal origin-free (AOF), and β-lactam-free?
- Flexibility**
Can raw materials be customized for our unique formulations?
- Compliance**
Can appropriate documentation be provided for regulatory bodies?
- Low risk**
Do materials have a successful track record of use in approved therapeutics?
- Consistency**
Are the materials produced and analyzed by fully validated processes to minimize lot-to-lot variability?
- Scalability**
Are adequate quantities and quality of materials available as we move from preclinical to commercial scales?

Accelerate your mRNA production with the TheraPure GMP portfolio

Exploring an **enzyme and NTP supplier** starts before your mRNA enters clinical trials. From preclinical studies to commercial approval, the TheraPure GMP portfolio offers **high-quality materials, technical support, and proven quality management** to enable successful scale-up of mRNA production.



Choose a partner who knows the path from preclinical studies to commercialization.

* "TheraPure GMP" refers to the quality level of the raw, ancillary, or starting materials to be used for further manufacturing. TheraPure GMP products are manufactured in facilities with ISO 9001-certified quality management systems that operate in accordance with relevant good manufacturing practice (GMP) principles, as outlined in ICH Q7 or equivalent guidance documents or standards.