



TheraPure services

Access to customized materials for
producing nucleic acid therapeutics

TheraPure services

Developing and manufacturing a nucleic acid therapeutic is a complicated endeavor. At some point in the process, many drug developers find they need material that isn't readily available off the shelf.

To help drug developers navigate this issue, Thermo Fisher Scientific offers world-class capabilities to develop and manufacture raw materials for producing nucleic acid therapeutics (i.e., nucleotides, enzymes, phosphoramidites, and custom molecules). To provide the best and broadest options, we offer three types of services involving these raw materials:

- **TheraPure customization**

Customize the pack size of any Thermo Scientific™ TheraPure™ GMP* or TheraPure™ phosphoramidite product

- **TheraPure development**

A wide range of options including custom concentrations, formulations, or buffers for raw materials; development of a new molecule or extensive characterization to make it suitable for use in manufacturing therapeutics

- **TheraPure specialty manufacturing**

Access our world-class, high-quality production facilities and quality systems to manufacture your therapeutic nucleic acid raw material, phosphoramidite, or other small molecule according to your specifications and needs

These services are readily available and can be accessed through either your nucleic acid therapeutics business development manager or on the web at thermofisher.com/therapure.



A new class of therapeutics brings new challenges

Nucleic acid therapeutics have the potential to help treat some of the most serious or intractable diseases and conditions that afflict people around the world. With the breathtaking success of nucleic acid-based therapeutics such as mRNA-based COVID-19 vaccines, the race to utilize nucleic acids as therapeutics has accelerated.

TheraPure customization services: enabling process development

Developing a process to manufacture a nucleic acid therapeutic requires that the process not only be capable of producing enough material to support clinical and commercial manufacturing, but also be tailored to the equipment and facilities available to produce the therapeutic.

To address this common need, Thermo Fisher Scientific has developed TheraPure customization services for customizing the volume at which any TheraPure GMP or TheraPure phosphoramidite product is provided. From microliters to liters, TheraPure customization services are designed to quickly deliver a wide range of volumes of these key raw materials.

TheraPure customization services

These services enable users to request raw materials in a wide range of volumes. Products capable of being customized through these services include:

- Thermo Scientific™ TheraPure™ GMP nucleotides
- Thermo Scientific™ TheraPure™ GMP modified nucleotides
- Thermo Scientific™ TheraPure™ GMP IVT enzymes and accessories
- Thermo Scientific™ TheraPure™ phosphoramidites

Through these services, these products can be made available in volumes ranging from microliters to liters.





TheraPure development services: enabling innovation

Process development for a nucleic acid therapeutic requires that some characteristics of the raw materials utilized are varied and tested to find the most suitable composition. While the TheraPure GMP and TheraPure phosphoramidite portfolios are extensive and offer a number of choices for a drug developer, in some cases, the available products may not be suitable.

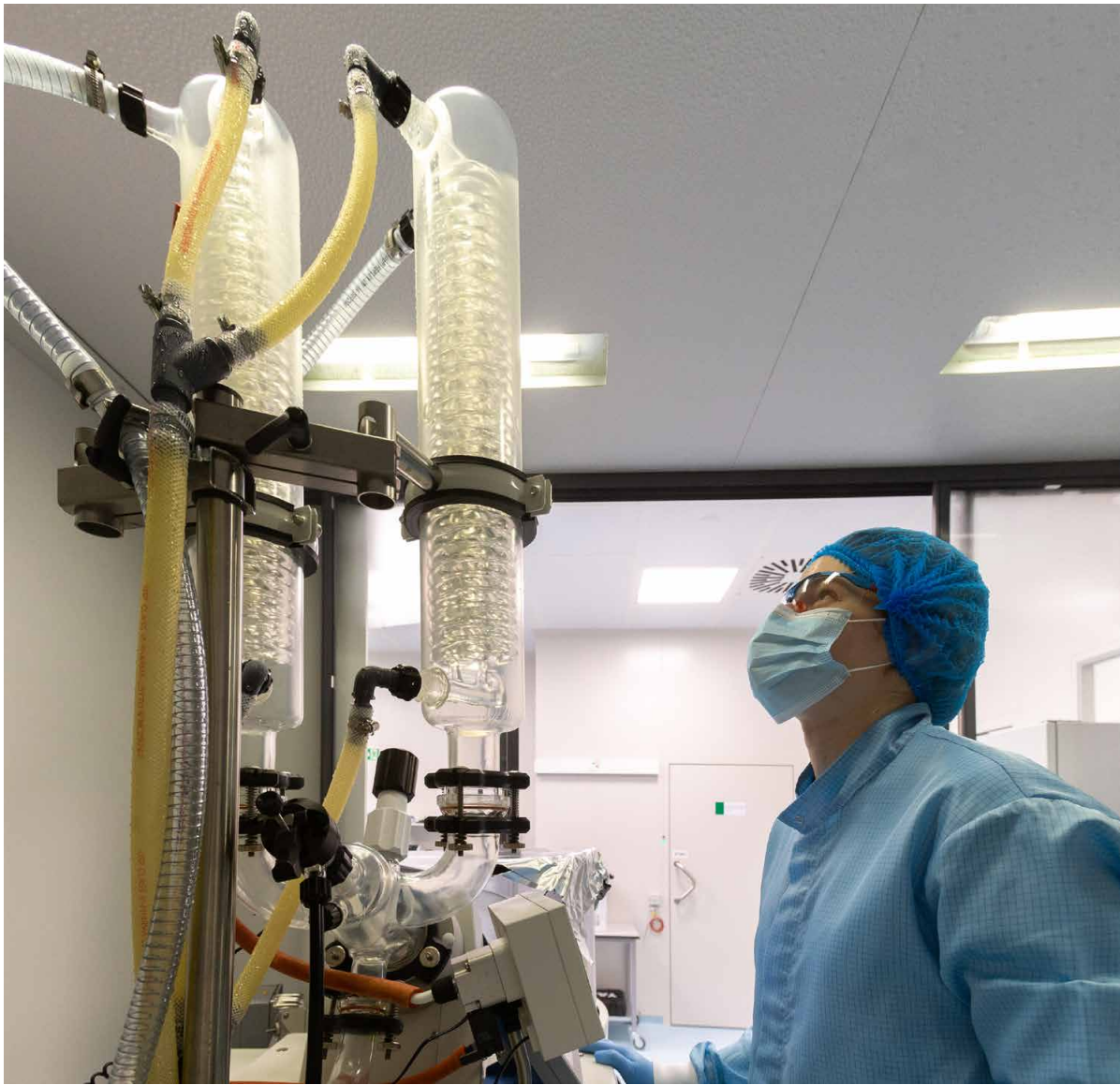
To accommodate this eventuality, TheraPure development services were created. With TheraPure development services, it is possible to access variations of TheraPure GMP, TheraPure, or even RUO raw materials.

TheraPure development services

These services enable clients to have broad flexibility in the specifications of the raw materials they are using to develop and manufacture their nucleic acid therapeutic. The following raw material attributes can be customized through these services:

- Concentration
- Formulation
- Buffer
- Product quality attributes

TheraPure development services also extend to the development of new raw materials not currently available in the Thermo Fisher portfolio or the manufacture of an existing product at a quality level suitable for use in the development and manufacture of nucleic acid therapeutics.



TheraPure specialty manufacturing services: enabling efficiency

Sometimes in the course of researching a nucleic acid therapeutic, drug developers utilize a raw material developed in-house. Using this material through process development, scale-up, and commercial manufacture of a therapeutic can require consistent production of this new material at scale and at a quality level suitable for cGMP manufacturing.

We have used our extensive manufacturing capabilities to provide raw materials at the scale, quality level, and in the time frame needed to help meet the demands of pharmaceutical companies. Now, clients have the opportunity to access the powerful, world-class manufacturing capabilities of Thermo Fisher to produce their own raw materials for nucleic acid therapeutics.

TheraPure specialty manufacturing services

These services enable clients to have Thermo Fisher produce a raw material for a nucleic acid therapeutic manufactured to their specification. Materials produced by this service are designed to deliver:

- Comprehensive quality systems and documentation
- Secure supply
- Quantities up to global scale



* "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 operating in accordance with relevant good manufacturing practice (GMP) principles as outlined in ICH Q7 or equivalent guidance documents or standards.

Contact us at thermofisher.com/therapure

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