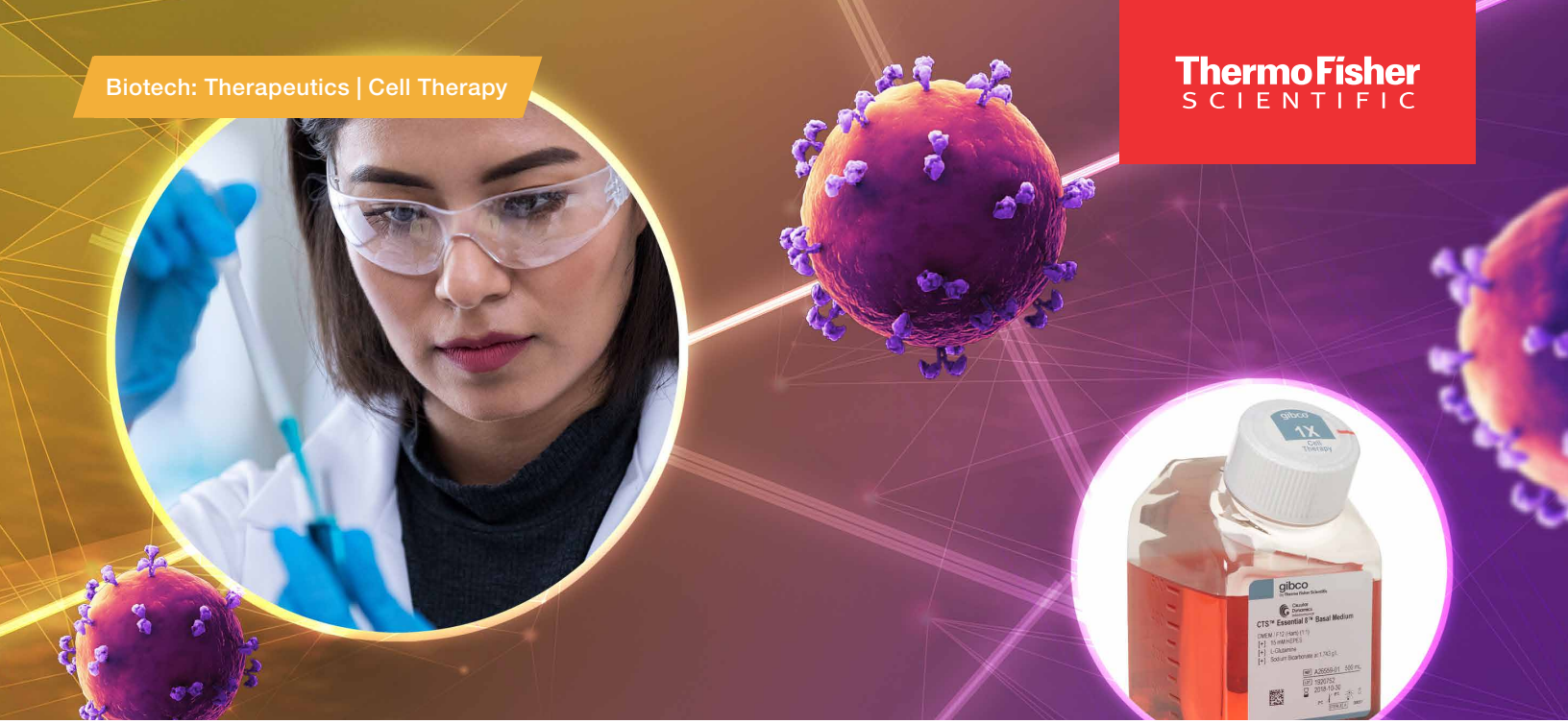

Benefits of customizable cell culture media in therapeutic development

For biotechs seeking to develop novel therapeutics for conditions like Parkinson's disease, diabetes, and cancer, the development of a relevant cell model for use in preclinical research and development phases is imperative. And regardless of whether your research calls for adherent cells or the more *in vivo*–like 3D organoids, cell culture will remain an important part of your process as you scale.

With the right cell model, early-stage discovery is streamlined. But how do you ensure that your cell model performs the way you need and expect it to during transition from research to development? The right cell culture media can certainly help, and as many researchers have experienced, there is no such thing as a one-size-fits-all medium. Every cell model has unique requirements.

What to consider when selecting a cell culture medium

The ideal cell culture medium for therapeutic research and development should:

1. Cater to the basic nutrient needs of that particular cell type
2. Foster cell growth and viability, phenotype, and function
3. Enable scale-up from small-volume research to large-scale production

Each of these metrics in turn is affected by the composition of the basal medium (i.e., the identity of the salts, buffers, and growth supplements like vitamins and amino acids), the pH (i.e., atmospheric CO_2 levels, which can be buffered using sodium bicarbonate in the medium), and any media supplements such as growth factors, cytokines, and chemokines required by the cell type, antibiotics, and proteins [1].

Click here to learn more about our small-scale media customization services

Remember to re-evaluate your media formulation as you scale

There are many parts of your therapeutic development operation that require continual evaluation as you scale, and your media formulation is no exception.

As you move your cell culture from a smaller volume (e.g., a flask) to a larger volume (e.g., rocker bag, bioreactor), the optimal cadence and timing of media exchanges can differ, which can affect the ratio of media components such as salts, proteins, and growth factors. Ratios that are ideal in a small vessel may not be so in a large bioreactor.

Then, as you approach clinical trials, you'll need to exchange undefined media additives like fetal bovine serum (FBS) for chemically defined, animal origin–free, or xeno-free alternatives in order to be compliant with the appropriate regulatory agencies. Many therapeutics manufacturers choose chemically defined media at the outset for this reason, and due to the contribution of serum to the overall cost at scale. Since therapeutics are highly regulated, it's also important to ensure that the manufacturer of the medium adheres to good manufacturing practices (GMP) and can assure supply as you scale.

Learn more about the regulatory support we provide

Custom media services can help get your novel therapeutic to market faster

In addition to ensuring that your media formulation caters to the basic needs of your cell model and contains raw materials that will enable you to scale quickly, custom media services offer the following benefits:

- **Accelerated timeline to market**—outsourcing media optimization places your project in the hands of professionals who bring expertise to your project and frees up resources that can help you get your novel therapeutic into the clinic faster
- **Flexibility**—custom media services are flexible and can be leveraged at any point in the media development process (Figure 1)
- **Regulatory support**—for custom media projects based on catalog products (e.g., a custom pack size), we can provide regulatory support in the form of Drug Master Files, Regulatory Support Files, Certificates of Origin, and Certificates of Analysis. The customer can reference the Drug Master File and relate any modifications to their regulatory agency

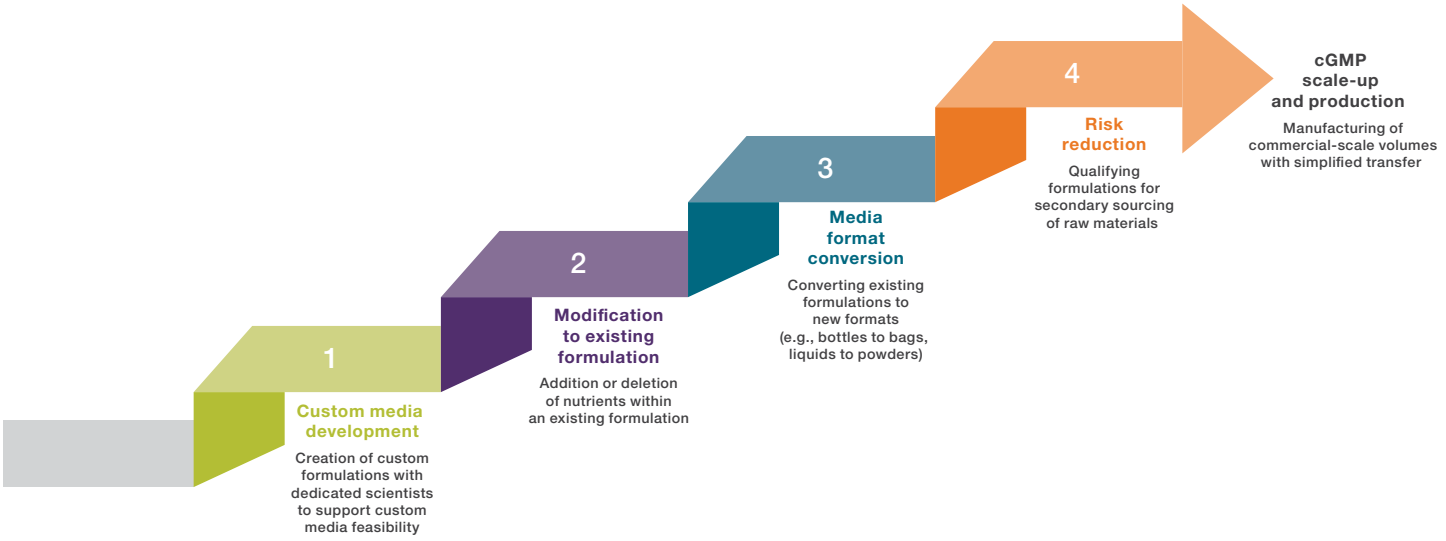

Figure 1. Custom media development allows multiple points of entry.

Count on connections for your media development

- As a GMP-compliant manufacturer of animal origin–free media, we have small- and large-scale solutions to meet your immediate needs and help you scale from discovery through commercialization. When your projects require non-standard, reliable, high-quality solutions, you can count us for one-on-one consultations and novel solutions to your life-saving research.
- With years of experience perfecting media recipes for a myriad cell types, Gibco™ custom cell culture media services can help you find the right medium to accelerate your therapeutic development workflow, regardless of stage or scale. For customers with time constraints or those seeking to develop custom solutions specific to their clone and molecule, Gibco™ Media Express™ Services (small scale) and Gibco™ PD-Express™ services (large scale) combine readily available solutions with our team of experienced professionals to quickly and cost-effectively achieve an optimal result (Figure 2).

Differences between Gibco Media Express and cGMP custom media manufacturing

Gibco Media Express services	cGMP productions
Harmonized raw materials	**cGMP-qualified raw materials**
Research Use Only (RUO)	**RUO and other Intended Use options available**
Batch volumes • 1–200 L liquid medium • 1–10 kg powdered medium • 1–8 kg AGT medium	**Batch volumes** • 10–10,000 L liquid medium • 1–3,500 kg powdered medium • 50–6,000 kg AGT medium
Packaging options Standard packaging available	**Packaging options** Standard and custom packaging options available
QC testing Limited testing available for a fee **Liquid medium** • pH • Osmolality • Sterility • Endotoxin **Powder medium** • pH • Osmolality • Solubility • Endotoxin Results provided without a CoA.	**QC testing** Price includes the following tests: **Liquid medium** • pH • Osmolality • Sterility **Powder medium** • pH • Osmolality • Solubility Additional tests available. Results provided with a CoA.
Production lead times Typically 2 to 3 weeks for liquid and powder medium	**Production lead times** Lead times vary based on request

Figure 2. Gibco custom media services use harmonized raw materials regardless of scale. Customize as little as 1 L liquid medium, or up to 10,000 L.

Case studies: CAR T cell therapy production

Situation #1

A clinical-stage biopharma company was looking to improve manufacture of their CAR T cell therapy product.

Specific goals

- Reduce use of human serum to minimize risk of viral contamination
- Utilize a fully defined medium with minimal lot-to-lot variability for more consistent manufacturing of gene-modified lymphocyte cell product

Outcomes

Thermo Fisher Scientific provided fully defined serum-free formulations manufactured according to GMP. With these solutions, the biopharma company achieved their target expansion with minimal risk. The custom media and supplements are now used in their commercial cell therapy manufacturing process.

Situation #2

A large biopharma company was scaling up for production of novel cell-based therapeutics for unmet medical needs.

Specific requirements

- Raw materials suitable for GMP manufacturing of a cell-based therapeutic to be distributed globally
- Scale that can support clinical trials and treatment of >50,000 patients per year once the therapy is commercialized

Outcomes

Thermo Fisher Scientific invested in a new, state-of-the-art aseptic manufacturing facility in Vilnius, Lithuania, to help meet quality and scale standards; partnered with the customer to manage risk and meet regulatory standards worldwide; and increased manufacturing capacity 2.5-fold at the new site to meet demand.

By partnering to develop best-in-class technologies at the new facility and manage risks, the novel therapeutic was in compliance with varied worldwide regulatory standards and security of supply was provided. The biopharma met demand for up to 50,000 patients per year and reduced their costs by limiting the number of suppliers and decreasing the number of lots per year.

Reference

1. **https://cellculturedish.com/cell-culture-basics-stem-cell-media-the-what-and-why/**

Partner with us today to develop your unique products through customization to fit your precise specification and workflow needs.

Click here to find the right customization option for your process

Learn more about our end-to-end solutions for biotech or **request more information**