

Media
by Design
Services

Cell culture

Gibco Media by Design Services

Tailored process development services,
designed for your success

Unique goals. Customized solutions. Success by design.

From stable clone development to cell culture media development and optimization, Gibco™ Media by Design™ Services offers customizable process development solutions to help you achieve your bioproduction goals.

Collaborate with a trusted pioneer of bioprocessing innovation and our dedicated, global team of bioproduction professionals. Using our in-depth technical knowledge, we can provide trusted insights to help develop tailored solutions that meet your unique project requirements. Once your process has been established, utilize our Gibco™ Rapid Prototyping Services to help streamline your transition to commercial production.

With our extensive bioprocessing experience and broad portfolio of Gibco™ products and services, you can depend on us to design and deliver solutions to help empower your success.

Helping you keep your timelines on track

We understand that meeting your planned process development timeline is essential for successful project delivery. As a result, we offer a range of solutions to help you meet your timeline requirements, from rapid prototyping services to longer-term development projects.

Find out which of our solutions are most suitable for your project needs with our guide.



Short-term project



Medium-term project



Long-term project



- Licensing simplicity
- Workflow scalability
- Superior technical support

Cell line development

Successful and efficient cell line development is essential to enable you to meet both your process goals and development timelines. However, developing a suitable stable clone can be a complex process, often requiring expertise from a specialist. To help you simplify your workflow and accelerate this process, we offer a range of Gibco™ stable clone development solutions.

Gibco Freedom stable clone development kits

Our Gibco™ Freedom™ kits are easy-to-use stable clone development solutions, containing all necessary components for cell cloning and protein expression. Included in the kit are the regulatory-friendly, cGMP-banked cell lines to help further simplify development.

The Gibco Freedom kit range includes

- Freedom™ ExpiCHO-S™ Kit*
- Freedom™ CHO-S™ Kit*
- Freedom™ CHO-DG44 Kit

Each kit comes with a complete protocol and includes access to our experienced field application scientists who can provide guidance and step-by-step support. During the development process, you also have the flexibility to work in collaboration with a contracted vendor of your choice.

Freedom kits offer flexible licensing options. Research-use rights are included with the initial purchase of the kit and, when you are ready to move to commercial manufacturing, a simplified, royalty-free licensing structure is available.












Gibco Freedom ExpiCHO-S Kit

Our Freedom ExpiCHO-S Kit can deliver high IgG titers of up to 3–5 g/L in fed-batch cultures and maintain consistent, high cell densities—all within a short development time of fewer than 6 months from transfection to stable clone.

When used with the new Gibco™ Efficient-Pro™ Feed 2 supplement (sold separately), the kit offers high-performing titers and consistent protein quality demonstrated across multiple clones.

Learn more at thermofisher.com/freedom

Flexible commercial-use licensing with Gibco Freedom kits

- | | |
|--|---|
|  Freedom from royalties |  Freedom to modify the purchased vector |
|  Freedom from annual maintenance fees |  Freedom to conduct process optimization |
|  Freedom to use multiple contract manufacturers |  Freedom to request support when desired |
|  Freedom to use host cell line for multiple projects** |  Freedom to work with others within field of use** |
|  Freedom to modify the host cell line | |

* Developed in collaboration with ProBioGen AG.

** Some sale and distribution restrictions may apply.



- Diverse formulations
- Simplified screenings
- Accelerated optimization

Media and feed panel evaluations

Identifying the optimal formulation for your cell line is a crucial step in process development. To help you accelerate this process, we provide a nutritionally-diverse library of ready-to-use formulations through our Gibco™ media and feed panels.

Each panel is composed of a selection of formulations with distinct nutrient levels, providing a greater diversity compared to testing catalog products individually. This range can help you identify components that are driving increases in product titers and quality.

All our panels are provided with a protocol to help simplify your experimental design. You can also rely on our support throughout the evaluation process. Upon completion of the panel screening, our field application scientists will provide you with a data analysis and a summary report with recommendations on next steps.

Once you have completed your evaluation and identified an optimal formulation, our team can help you move seamlessly to manufacturing

in our non-cGMP rapid prototyping or our cGMP facilities based on your needs.

Should you wish to further optimize the formulation, you can take advantage of our Bioproduction Analytics services to gain a better understanding of the nutritional utilization of your clone and identify potential modifications.



Read our media and feed panels Q&A article or register for an on-demand webinar at thermofisher.com/mediapanel

Gibco CHO Media and Feed Panel

Our Gibco™ CHO Media and Feed Panels have been designed to maximize formulation diversity. The CHO Media Panel consists of nine chemically defined, animal origin-free (AOF) formulations and the CHO Feed Panel consists of five. By utilizing these panels and their associated protocols, you can efficiently identify formulations driving productivity for your specific CHO cell line.



Gibco Viral Vector HEK Media and Feed Panel

The Gibco™ Viral Vector HEK Media and Feed Panels have been developed to help accelerate gene therapy and vaccine process development. The HEK Media Panel consists of five formulations and the HEK Feed Panel consists of three. Both panels cover a broad variety of suspension HEK293 cells and provide full flexibility to incorporate into your process regardless of the transfection techniques used.





- Optimized media
- Maximized performance
- Long-term success

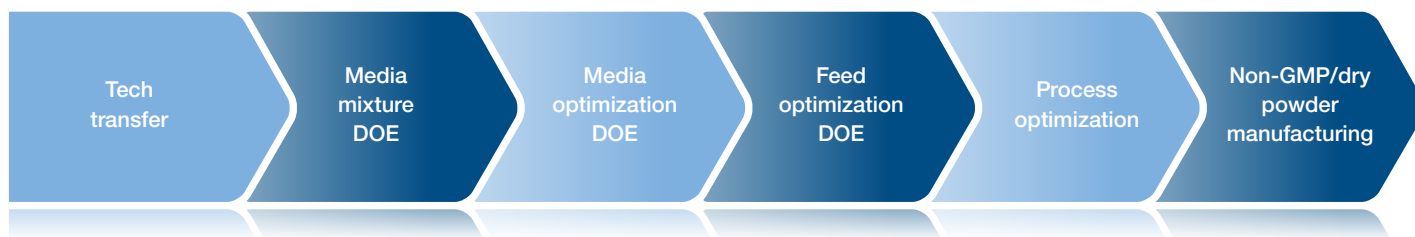
Media development solutions

Using a cell culture medium and feed formulation optimized for your process is often essential to achieve bioprocessing success. Our custom media and feed development service offers the potential to elevate process productivity and consistency and help improve product quality.

We offer a flexible range of media and feed development and optimization services to deliver solutions that can help you achieve your goals. We initiate all projects with manufacturing in mind, helping give you confidence that your solution will be scalable, suitable for conversion into multiple formats, and aligned with your

cost expectations. We have previously completed over 150 media development projects for various mammalian, microbial, and insect cell lines. Our expertise also includes supporting the development of media for novel therapeutics, biosimilars, vaccines, and cell-based therapies.

Traditional development workflow



Our traditional development workflow uses insights from spent media analyses of up to 50 key components, including select water-soluble vitamins and amino acids, in an iterative design of experiments (DOE) process to develop optimized formulations.

We offer the flexibility to work with us for a full-service project at any of our facilities or on a consultation basis at your site should you choose to keep your cell lines in-house.

The multi-omics difference



Combining proteomics and metabolomics, our multi-omics media development workflow can support the creation of a medium formulation that can unlock the true potential of your cell line. Using high-resolution UPLC-MS instrumentation, this workflow employs cellular component analyses of thousands of proteins

and metabolites to fully understand the nutritional requirements of your cell line. This results in a final formulation that can improve process productivity and enhance product quality—helping you meet your process goals.

Potential outcomes of a custom media development collaboration



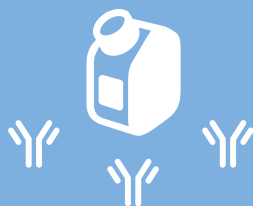
Enhanced process performance

From improving titers to optimizing product quality attributes, our team has the experience to develop a solution that can help you achieve your process targets. We can also help support the production of complex molecules, such as fusion proteins, enzymes, and viral vectors.



Improved medium manufacturability

We can work with you to help optimize your medium and feed formulation for commercial manufacturing. This includes support with removing challenging raw materials and format conversion from liquid to dry powder or our proprietary Gibco™ Advanced Granulation Technology (AGT™) format.



Platform medium development

Establishing a medium and feed platform can help manufacturers who are producing multiple molecules to streamline their processes. We can support the design of platform solutions that meet your project requirements.

Case Study

Improving antibody production in CHO cells

Situation: Antibody manufacturers using CHO cell lines sought to improve productivity to support scale-up for clinical trials or commercial production. Titer improvements of at least 1.5- to 2-fold were required to help gain manufacturing cost reductions.

Solution: Each project design was based on the client's productivity improvement goals, budget, and timeline requirements. Projects were executed by experienced Gibco Media by Design Services bioproduction scientists in a phased approach that used either a traditional or multi-omics workflow. Service options utilized included basal, feed, or clone selection media optimization; platform medium development; feeding strategy or process optimization; and liquid to dry powder format conversion. Dedicated Gibco cell culture project managers ensured all projects were executed on time and within budget.

Results: The selected media development projects met or exceeded clients' productivity goals. In CHO-K1 cell lines, an average 1.8-fold titer improvement was achieved. In CHO-S cell lines, an average 4.4-fold titer improvement was achieved, and in a DG44 cell line, a 3.0-fold titer improvement was achieved. Project outputs provided manufacturers with the ability to achieve their desired scale-up goals, including enhancing productivity, maintaining product quality, and potentially improving return on investment (ROI).

Read the full case study at thermofisher.com/mediabydesign



Read an application note, listen to our podcast, or register for an on-demand webinar at thermofisher.com/mediadevelopment



- Analytical expertise
- Data-driven insights
- Actionable results

We offer a comprehensive suite of analytical services, ranging from media and protein analytics to investigative projects, to help you make informed decisions to improve performance. In-depth consultation is available to help you interpret the analytical data and implement process improvements.

Media analytics

Spent media analysis is a valuable media development tool—enabling you to understand the utilization profiles of key components at different times throughout your process. We offer short turnaround times for analysis of a wide range of components, including amino acids, water-soluble vitamins, metabolites, and trace elements.

Our service allows you to choose only the testing you need, carried out by our experienced team of analytical scientists. Following analysis, you can engage our media development R&D scientists who can provide support with implementing the results and optimizing your formulation.

Protein analytics

Consistently meeting the required critical quality attributes (CQAs) of your protein is vital to provide a safe and effective therapeutic.

One key attribute is the glycosylation profile. Our analytics team can provide support to enable you to determine the glycan profile of your protein. Through our media development services, we can also help with modulating this profile to meet your specific targeted protein of interest. In addition to accelerating process development, this can help you improve the overall pharmacokinetics of your molecule.

Maintaining the optimal balance of positive and negative charges within your molecule is also central to its structure, stability, and biological function. We can provide charge variant analysis to help you understand changes to the charge variants for your antibody at different time points. This understanding can help you optimize process consistency, simplify downstream processing, and improve downstream product yields.

Manufacturing support analytics

In addition to supporting media development and optimization, we provide a range of analytical services to help you achieve long-term manufacturing success.

This includes our Gibco™ trace element testing service which can enable you to understand which trace elements your process or cell line is most sensitive to. Using this insight, you can proactively develop a risk mitigation strategy.

To help give you confidence in your formulation, we also offer real-time stability testing of your cGMP-manufactured product in your desired packaging configuration. These customizable studies are conducted under conditions and time points determined by you. Our capabilities include a wide variety of quality assays dependent

on your specified stability-indicating factors to help you meet your regulatory requirements.

Investigative analytics

We are also able to provide investigative analytics to help you troubleshoot batch-to-batch variability in your process related to the media. Depending on your specific needs, we can work with you to develop a customized project that helps you quickly identify the cause of the variability and propose appropriate solutions.

Case Study

Achieving consistency: understanding key drivers in cell culture media

Situation: Obtaining consistent protein production and quality attributes is critical in today's bioproduction industry. In order to meet these goals, nutrients such as amino acids, vitamins, and trace metals must be kept within a very specific range for achieving an ideal cell culture medium performance.

Solution: The Gibco Media by Design Services team has utilized a key driver identification (KDI) approach with many customers to help better control variability and achieve consistency in a specific process. To accurately assess which components in a complex medium are driving a process, multiple lots (e.g., from 5 to 10) of a medium or supplement of interest are analyzed for components showing a statistical correlation with performance. Optimal ranges are then defined for the key drivers.

Results: The use of predictive mathematical modeling through a staged KDI methodology has been shown to help customers achieve their goals. While modifications to a cell line and process can require extensive time and effort, optimization and supplementation of a cell culture medium offers a more rapid option for achieving a consistent and desired bioproduction outcome.

Read the full case study at thermofisher.com/mediabydesign



Service at a glance

- Fast delivery
- In-depth knowledge
- Streamlined scale-up

Gibco Rapid Prototyping Service

In addition to being optimized for your process, your formulation also needs to be scalable. By providing small-batch custom media manufacturing, the Gibco Rapid Prototyping Service can enable you to test the scalability and manufacturability of your medium, feeds, supplements, and buffers.

Utilizing our dedicated non-cGMP labs and cGMP-quality raw materials and processes, you can be confident that your formulation is both scalable and consistent, streamlining the transition to cGMP manufacturing. To help you maximize efficiency, we provide fast lead times, with standard orders typically shipping within 10–20 working days.*

The service can also provide you with the opportunity to modify your existing formulation—allowing you to either add novel components or reduce or remove components to improve cell culture performance. You can also test the conversion of your medium into a new format that best suits your scale-up needs, including the Gibco AGT format.

Our experienced and responsive customer service and technical sales and manufacturing teams can work closely with you to provide a solution that meets your needs. We can also provide the details required to validate Thermo Fisher Scientific as an approved primary or secondary supply source, further reducing the risk of delays during commercial production.

* Complex formulations, novel raw materials, and custom packaging may increase manufacturing times.

Case Study

Helping to sustain quality and streamline manufacturing

Situation: Bioprocessing risks exist in maintaining quality and equivalency in custom cell culture media manufacturing between the production of non-GMP prototype material and its scale-up/formulation transfer to current good manufacturing practice (cGMP) production. The success of three customer projects was evaluated to demonstrate equivalency between the prototype and cGMP material and ensure both met customers' specifications and manufacturing timelines.

Solution: A two-phase, multiple lot scale-up strategy was employed in each case. During the first phase, potential manufacturability issues were evaluated. Then, using the Gibco Rapid Prototyping Service, multiple non-cGMP pilot-scale lots were manufactured and tested. The second phase involved the internal technology transfer and scale-up with the production and testing of several larger-scale lots by the Gibco™ cGMP media manufacturing team.

Results: Comparative test analyses showed acceptable component group-level comparability from small-scale non-GMP prototype productions to larger-scale cGMP productions. Project success was supported by detailed formulation batch records; well-established technology transfer processes; common sourcing of GRP and cGMP-qualified raw materials; the use of identical or equivalent equipment design; and with robust process control systems.

Read the full case study at
thermofisher.com/mediabydesign



Taking the next step

Following the development and optimization of your custom formulation, the next step is scaling up the process for commercial manufacturing. During this transition, it is essential to work with a media manufacturer that can meet your needs—in terms of both production volumes and lead times.



Gibco cGMP media manufacturing

Our Gibco™ cGMP media manufacturing services can enable you to seamlessly scale up with consistent media quality and supply, while maintaining confidentiality and protection of your formulation. Our team has experience supporting a broad range of platforms, scales, packaging options, and media formats, enabling us to help meet your project requirements.

All sites within our world-class global media manufacturing network are ISO 13485-, CFR 820-, and/or ISO 9001-certified and FDA-registered.

Maximizing global supply assurance

All of our facilities are harmonized across four key areas: raw materials sourcing, equipment, manufacturing processes, and finished product testing. This enables us to achieve full equivalency and give you confidence that the same high product quality standards will be met, no matter the manufacturing site.

We also employ in-depth risk mitigation practices and constantly evaluate our capabilities to maximize supply assurance and reduce the risk of delays. Together with our equivalency approach, this allows us to offer dependable, global manufacturing redundancy.



Find out more about our manufacturing services at [thermofisher.com/media-manufacturing](https://www.thermofisher.com/media-manufacturing)

Our site-to-site equivalency harmonization areas



Raw materials sourcing



Equipment



Manufacturing processes



Finished product testing

To learn more about our facility harmonization and take a virtual tour of our manufacturing facilities, visit www.thermofisher.com/gibcotours



Service at a glance

- Broad portfolio
- Maximum flexibility
- Rapid results



Catalog media evaluations

Developed using over 60 years of cell culture experience, we offer an extensive catalog of trusted Gibco products. From innovative cell culture media to high-performance supplements and functional additives, our off-the-shelf solutions can help you enhance your workflow. To help you find your optimal solution, we offer a range of evaluation and customization services.

Catalog product consultation and evaluations

Our catalog products have been developed for a broad range of cell types, modalities, and bioprocessing workflows. This breadth allows us to work with you to understand your needs and find an off-the-shelf solution that is right for your process. Because our catalog products are ready to ship, choosing an off-the-shelf option can help you increase speed-to-market, while reducing costs.

Catalog media customization

Following the selection of an appropriate Gibco catalog product, we offer customization services to help you fine-tune the formulation to meet your specifications. Our knowledgeable custom media specialists and R&D scientists can help you to:

- Add or remove components
- Change a concentration
- Scale up from non-cGMP to cGMP manufacturing
- Choose QC tests

The majority of our Gibco basal media products are customizable, as are many other non-media Gibco products, such as buffers and growth factors.





Our team

The Gibco Media by Design team has decades of experience within biopharmaceutical manufacturing, providing insights and delivering results around the world. Leveraging this extensive experience, our team can work closely and collaboratively with you throughout your project and support you in achieving your unique goals.

Field Application Scientists

Our global team of field application scientists has deep knowledge of the bioprocessing industry. Specializing in the use and application of Gibco products and services, they are available for on-site or remote consultation.

Their capabilities include:

- Cell culture development
- Process characterization and scale-up
- Process troubleshooting
- Product development
- Process optimizations and technology transfer

Gibco Bioproduction R&D Scientists

Utilizing a broad base of bioprocessing knowledge, our R&D scientists can provide solutions that meet your development needs today, while also building a framework for future manufacturing success.

They are equipped to provide support for a wide variety of biological platforms—including recombinant proteins, vaccines, and cell and gene therapies. They also have experience working with many cell lines and modalities.

Business Development Managers

Our business development managers are committed to working with you to develop a project and/or supply agreement that meets your needs.

Through their detailed understanding of biotechnology business modeling and life science investment evaluation, they strive to deliver agreements that are both efficient and mutually beneficial.

Project Managers

As the dedicated point of contact throughout your project, our project management team members have a range of responsibilities, including:

- Overseeing project scope
- Mitigating project risk
- Managing timelines and meetings
- Capturing key decisions and action items
- Confirming project closure

All team members adhere to the standards established by the Project Management Institute (PMI).



Discover how we can support you

We understand that process development is a unique and important stage for all biopharmaceutical developers. From product quality and titer targets to timeline and resource requirements, every project has its own aims that must be met to deliver bioprocessing success.

Whether you are developing an antibody or an advanced therapy, no matter your organization's size or location, we can work with you to understand your goals and develop unique process development solutions. Through our portfolio of flexible solutions—ranging from

in-depth consultancy to full-service projects—we can support you to confidently meet or exceed your process targets and achieve long-term success.



Unsure where to start? Try our Media by Design Services selection tool at thermofisher.com/mediabydesign

Learn more at thermofisher.com/mediabydesign

For Research Use or Further Manufacturing. Not for diagnostic use or direct administration into humans or animals. © 2023 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **EXT5257 0623**

gibco