

Scaling up with Gibco media

Streamlining your proprietary media production

An unbeatable collaboration—your formulation, our expertise, and economy of scale

From pioneering the use of serum, through our leadership in gene therapy and helping solve tomorrow's challenges, Gibco™ media are known for innovation and quality. That expertise is especially valued by customers who are ready to scale up, or simply outsource, production of their own media formulations.

Work with Thermo Fisher Scientific as an extension of your bioproduction suite and leverage our network of suppliers, packaging, and granulation technologies. Whether you're a small biotech company or a Fortune 500 pharmaceutical house, you will receive unparalleled support for your cell culture process. Our experts will partner with you along the development journey from piloting to commercial production—all while maintaining confidentiality and protection of your intellectual property (IP).

Gain efficiency as we work together to solve the three biggest scale-up challenges you face:

Transparent and consistent supply

Your formulation will be dependably of the highest quality, on time, and in the proper format and packaging. Global manufacturing redundancy helps assure continuous supply to reduce risk.

Quality outputs

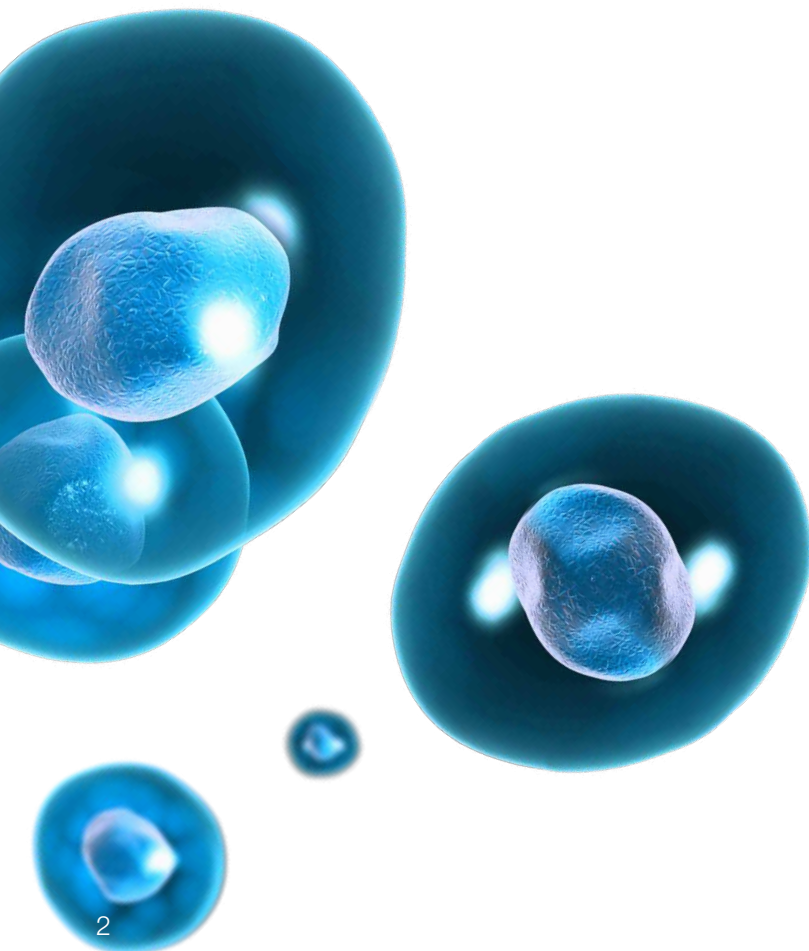
We have been helping companies scale to GMP for over 50 years and are a world leader in formulation expertise and media optimization. Our strict quality assurance systems and capabilities enable clinical-grade manufacturing excellence.

Enhanced efficiency

With lot-to-lot consistency and help from our dedicated program management team, we'll make sure product titers and yields remain consistently high throughout scale-up. It's our speed-to-scale that helps distinguish us from other media suppliers. We focus on small-scale solutions to accelerate large-scale results.

When you partner with us, your cell culture media formulation is as important to us as it is to you. Discover the many benefits of a proprietary media formulation partnership today.

Our experts will partner with you along the development journey ... while maintaining confidentiality and protection of your IP.



Transparent and uninterrupted supply

Economies of scale for both primary and secondary supply

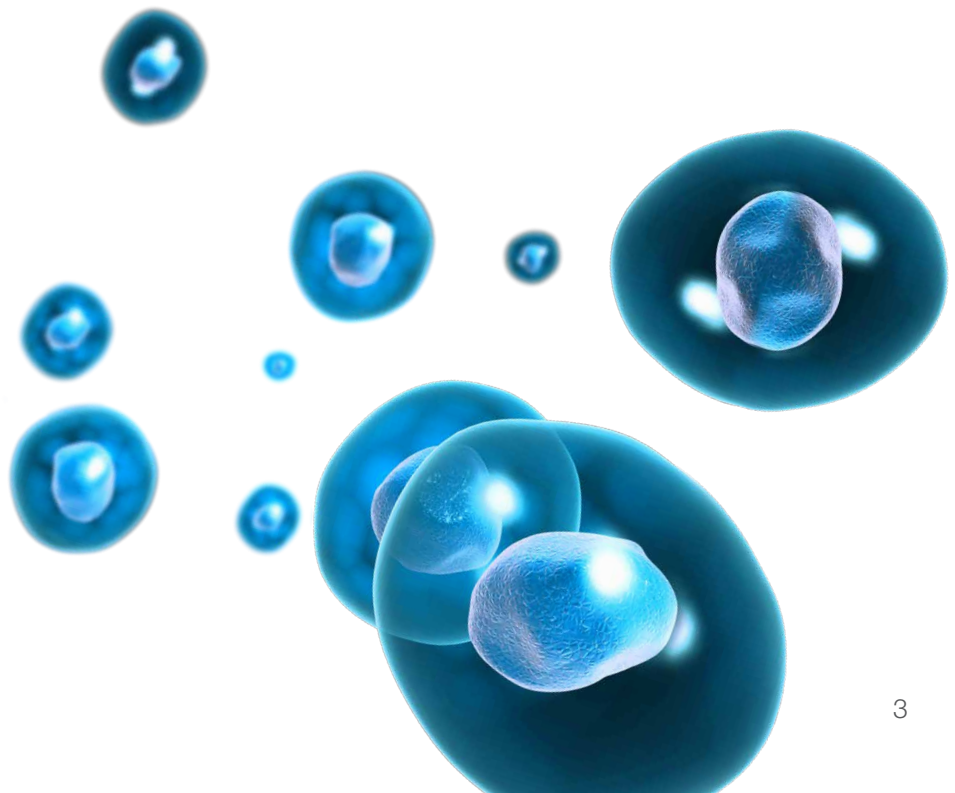
Our large-capacity, purpose-built, segmented (AO and AOF) global manufacturing facilities are strategically located to ensure ultimate redundancy, capacity, and continuity in both pin mill and FitzMill™ technologies.

This offers you a consistent and harmonized primary or secondary supply source.

We produce more than 15 million liters of liquid media and 3 million kg of dry media formats annually. We can help you reduce costs, increase your productivity, and mitigate supply risk.

Let us remove the overhead and hurdles of ordering, warehousing, stocking, and production of material. Our world-class logistics and distribution solutions offer security, transparency, and right-on-time delivery to streamline your supply chains.

Media format	Grand Island	Paisley, Scotland	Miami
AGT	290,000 kg	225,000 kg	
AOF dry powdered media	800,000 kg FitzMill	50,000 kg FitzMill	750,000 kg Pin mill
AO dry powdered media	670,000 kg	400,000 kg	
Liquids (core)	9.6 million L	4 million L	625,000 L
LVL (BPCs)	3.5 million L	3 million L	



Consistent quality: The Gibco media promise

Add our formulation experts to your extended team

Helping ensure consistent quality in media formulations starts with the raw materials. Our strict control over sourcing raw materials, enabled by deep analytical expertise, helps reduce your risk in media manufacturing.

We perform QC testing on all cGMP media products. We offer tailored testing services as well, depending on your needs. If there are specific attributes that you wish to test, such as trace elements, we can design a testing regimen into the process to meet all quality or regulatory requirements.

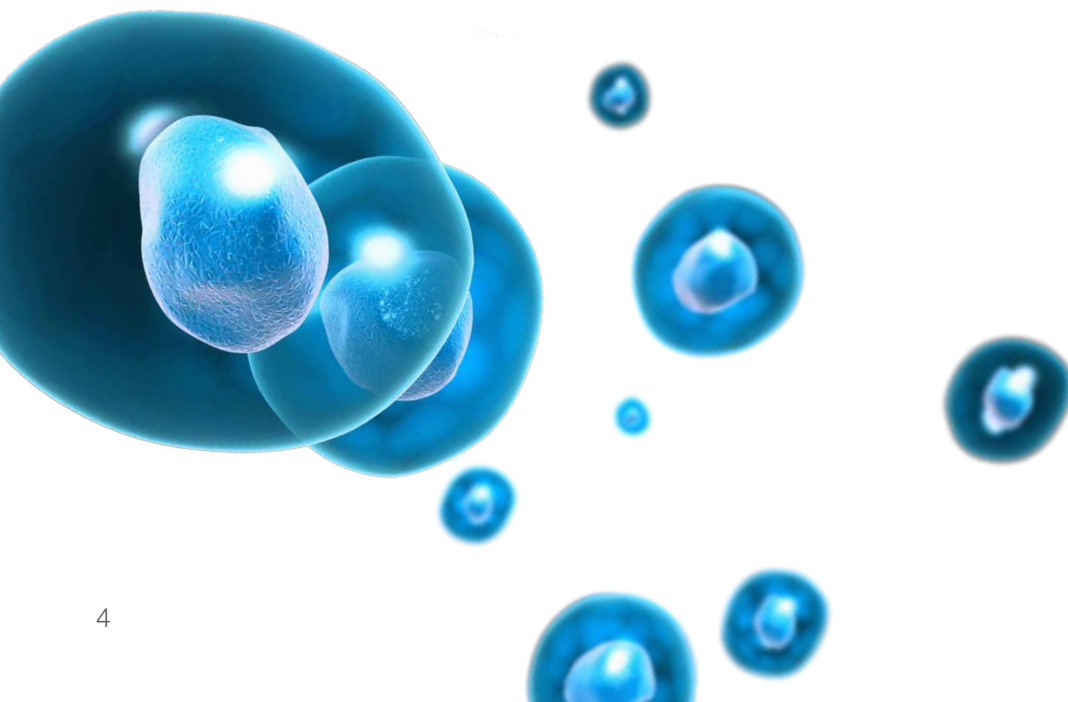
QC testing performed on all cGMP media products

- pH
- Osmolality
- Sterility
- Stability
- Mycoplasma
- Virus testing
- Amino acid analysis
- Many more

Highlights

- All major manufacturing sites are either ISO 13485 CFR 820 and/or ISO 9001–certified and registered with the FDA
- Business continuity, risk mitigation, and emergency response plans are in place to provide continuity
- Raw materials meet strict compliance regulations, with over 90% sourced from established markets
- Tiered audit and re-auditing program of all suppliers on a periodic basis

You'll be assured of rigorous site and product ISO compliance, as well as robust analytical capabilities to characterize your final formulation.



Enhanced efficiency and productivity

Scale up faster with optimized processes, titers, analytics, and format flexibility

We understand the complex technical, logistical, and capacity challenges faced when scaling up to a global commercial output. Between Gibco™ Rapid Prototyping Media Service, cGMP biomanufacturing services, and pioneering solubilization technology, your consistent and scalable productivity is our priority.

Available in both pin mill and FitzMill manufacturing, we can provide liquid media in batch sizes from 10 L to 10,000 L; dry powder media from 1 kg to 8,000 kg; and Gibco™ Advanced Granulation Technology (AGT™) format from 50 kg to 8,000 kg in less than a 10-week turnaround from purchase order to doorstep.

Process analytics, such as glycan profiling and charge variant analysis for antibodies, help to characterize product quality and optimize a consistent end product.

Our stability study offering can be customized to your needs to determine product shelf life. We can also offer trace element profiles on raw materials to help mitigate other issues. Our suite of mass spectrometry instruments is also available to facilitate the development of target clones.





Our characterization services are unparalleled across the industry and will help you scale up faster and at less cost than doing it alone.

Capabilities include:

- Custom development of both mammalian and microbial platforms
- Rapid Prototyping Services for quick turnaround on all non-GMP needs
- cGMP analytical services, including trace-element finished good testing
- Unique add-mix capability that makes use of liquid concentrates to produce up to 30,000 L batches of liquid media

Tailored format solutions

We understand that there are unique needs for every situation. From small-scale to large-scale cGMP manufacturing, we offer more formats, sizes, and packaging solutions than any other supplier.

-  Liquid media
-  Liquid concentrates
-  Standard dry powder media (DPM)
-  Advanced Granulation Technology (AGT) format

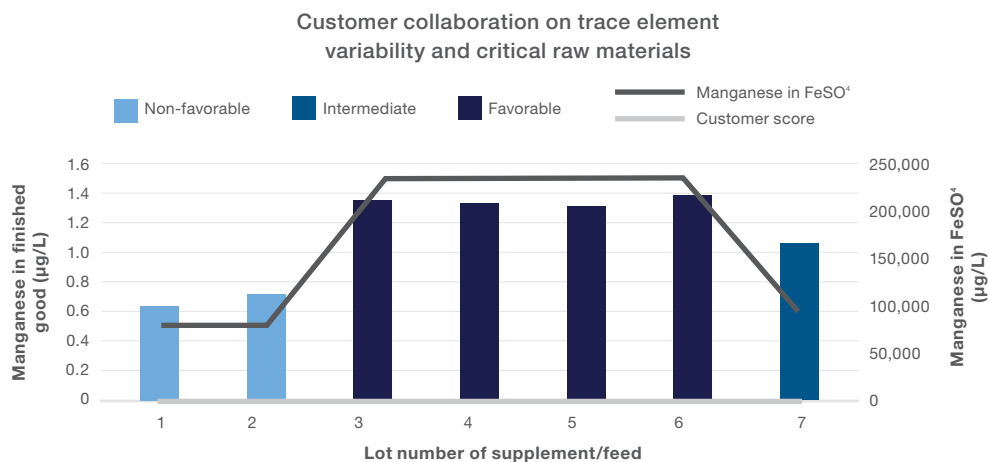


Figure 1. Data that we provided allowed a customer to identify which trace element was impacting product quality due to sensitivity of a particular cell line. Full trace element profile data for historical lots was provided. The trace element profile is now proactively reviewed for each lot to optimize the process and meet specific requirements.

Find out more at thermofisher.com/media-manufacturing

ThermoFisher
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