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## Gibco Rapid Prototyping Service Small-scale non-cGMP media manufacturing

Gibco<sup>™</sup> Rapid Prototyping Service offers small-batch, custom media manufacturing solutions for research and process development. Utilizing our dedicated non-cGMP labs and cGMP-quality raw materials and processes, the Gibco Rapid Prototyping Service team provides media manufacturing expertise in liquids, dry powder media (DPM), and Gibco<sup>™</sup> Advanced Granulation Technology (AGT<sup>™</sup>) media format.



Figure 1. One of two dedicated facilities for small-scale media production.

Dedicated non-cGMP facilities provide the opportunity to:

- Test manufacturability and scalability of a formulation prior to cGMP scale-up
- Modify existing formulations by adding novel components or reducing and removing components not driving cell culture performance
- Source and test unique raw materials
- Convert media to a new format such as AGT media
- Identify a secondary source for assurance of supply

Our experienced production team will help to ensure your formulation is consistent and scalable, leading to a streamlined transfer to our cGMP manufacturing facility when you are ready. And, with the support of our responsive customer service and technical sales teams, your custom media can be shipped in as little as 10 days after ordering.\*

### Table 1. Processes and materials mirror cGMP production, helping to accelerate technology transfer during customer scale-up.

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Gibco Rapid Prototyping Service: test and				
finalize formulation				
Feasibility	Team conducts review of product feasibility and design for manufacturing			
Raw materials	cGMP-qualified raw materials; novel raw materials by request			
Batch records	Full batch record created			
Equipment	Lab-scale FitzMill <sup>™</sup> equipment, pin mill, V-blenders, tumble blenders; lab-scale AGT granulator			
Capacity	Liquid media (1x) and liquid concentrate: 1–200 L DPM: 1–10 kg (FitzMill) DPM: 1–20 kg (pin mill) AGT: 1–8 kg			
QC, analytical	pH, osmolality, sterility, endotoxin			
Packaging	Standard bottles, Thermo Scientific <sup>™</sup> BioProcess Containers (BPCs), buckets; custom packaging by request			
Delivery	For standard orders: Liquid media, liquid concentrate, DPM: 2 weeks AGT format: 4 weeks			

### cGMP: Clinical- to commercial-scale production

Team conducts full cGMP feasibility review on custom orders

cGMP-qualified raw materials; novel raw materials by request Full batch record created POMS manufacturing execution system (MES) dispensing; cGMP FitzMill and pin mill equipment, tumble and ribbon blenders; V-blenders, bin blenders, commercial-scale AGT granulator

Liquid: 10–10,000 L DPM: 20–7,500 kg AGT: 50–1,500 kg

Standard and custom testing available

Standard bottles, BPCs, buckets; custom packaging by request

Liquid, DPM, AGT format: 8 weeks New Cat. No.: 10 weeks



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

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### Standard capacity and packaging

We can rapidly deliver your media in a variety of formats. Please work with your account manager for custom inquiries.

#### Table 2. Liquid media batch sizes

Container	Maximum batch size
100 mL bottle	20 L
500 mL bottle	100 L
1,000 mL bottle	200 L
1 L BPC, Thermo Scientific <sup>™</sup> Aegis <sup>™</sup> 5-14 film	200 L
5 L BPC, Aegis5-14 film	100 L
10 L BPC, Aegis5-14 film	200 L
20 L BPC, Aegis5-14 film	200 L
50 L BPC, Aegis5-14 film	200 L
100 L BPC, Aegis5-14 film	200 L
200 L BPC, Aegis5-14 film	200 L
1 L BPC, CX5-14 film	200 L
5 L BPC, CX5-14 film	100 L
10 L BPC, CX5-14 film	200 L
20 L BPC, CX5-14 film	200 L
50 L BPC, CX5-14 film	200 L
100 L BPC, CX5-14 film	200 L
200 L BPC, CX5-14 film	200 L

#### Table 3. Dry media formats.

Batch sizes and containers	Dry powder	AGT media
Minimum batch size	1 kg	1 kg
Maximum batch size	20 kg	8 kg
Container	Ropak <sup>™</sup> bucket	Ropak bucket
Container sizes	1, 2, 5, or 10 kg	2, 4, 6, or 8 kg
Equipment options	Pin mill or FitzMill	AGT granulator

Please contact your cell culture account manager to find out how to place your order today.

### Find out more at thermofisher.com/pdexpress

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