



Media Services & Custom Manufacturing

Accelerating the Evolution
of Cell Culture Manufacturing

Simplifying Progress

SARTORIUS

Accelerating the Delivery of High Quality, Customized Media With Rapid Set-up Times, Fast Turnaround, and on-Time Delivery.

Our media and custom manufacturing services range from raw material supply, custom labeling, and flexible packaging, to manufacturing your own media formulation for commercialization.

Backed by more than 40 years of experience in custom media development, our state-of-the-art cGMP-compliant manufacturing facilities are ISO-certified, with the highest levels of quality management systems in place.

Our media is manufactured following cGMP and FDA guidelines in ISO-9001 and ISO-13485 certified clean rooms. Standard QC testing is conducted on all batches of media and custom orders are typically completed in 4 to 8

weeks. We offer versatile solutions for pilotscale and large-scale manufacturing and the capability to fill liquid into vials, bottles, or bioprocess containers (bags).

- Standard custom media orders completed in 10 to 12 weeks
- Pilot- and large-scale cGMP manufacturing
- Unparalleled scientific and regulatory support
- cGMP, FDA, ISO-9001 and ISO-13485 certified and inspected facilities
- Controlled environment clean rooms graded from ISO 8 up to ISO 5
- Supply chain management and scale-up manufacturing
- Continuity of a reproducible and standardized supply

Our Standard and Custom Services Include:



Make Your Own Media

Manufacture your own proprietary formulation. Services include:

- Flexible packaging options and fill volumes
- Finishing services include OEM packaging and labeling
- Fast turn-around times from inquiry to delivery
- Powder media capability, up to 850 kg/batch

Optimizable Formulations

Add or remove ingredients from an existing product. Services include:

- Pilot- and large-scale manufacturing
- Flexible packaging options and fill volumes
- Finishing services include OEM packaging and labeling
- Fast turn-around times from inquiry to delivery

Scale-up Services

Custom large-scale production of specialty media. Services include:

- Manufacturing in bottles or bioprocess containers
- Flexible bag sizes and volumes
- Finishing options include selecting connectors, clamps, and tubing
- Global shipping and packing options include clam shells and bagging for fresh and frozen media

Standard Quality Testing

Standard quality testing is conducted on all batches of custom media, including appearance, pH, osmolality, and sterility. Additional QC parameters, such as cell growth assays and endotoxin testing, may be available upon request.

Custom Small-Scale and Large-Scale Batch Size Capabilities

Liquid Media

Standard Bottles	Batch Size Volumes	Standard Bags	Batch Size Volumes
1 mL	6 L - 1000 L	1 L	6 L - 1000 L
5 mL	6 L - 1000 L	5 L	6 L - 1000 L
10 mL	6 L - 1000 L	10 L	6 L - 1000 L
20 mL	6 L - 1000 L	20 L	6 L - 1000 L
50 mL	6 L - 1000 L	50 L	6 L - 1000 L
100 mL	6 L - 1000 L	100 L	6 L - 1000 L
500 mL	6 L - 1000 L	200 L	6 L - 1000 L

Please note sizes and volumes may be dependent on media formulation and manufacturing facility. Other custom sizes, packaging options, testing requirements, and stability studies are also available. Some projects may require larger batch minimum, depending on the complexity of the media formulation.

We provide a full range of capabilities to meet your custom media formulation, packaging, and regulatory requirements.

Manufacturing Capabilities:

- Cell culture media manufacturing
- Kitting and packaging
- Continuity of supply
- Consistent product performance
- Reproducible processes

Culture of Quality

We are founded on a culture that fundamentally believes that quality must be at the forefront of everything we do. To back up this belief, we are fully committed to the current Good Manufacturing Practices (cGMP) and adhere to international guidelines adopted by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Our quality systems comply with the international standards for Quality Management Systems as defined by the ISO, and are routinely audited by an accredited external body. Our primary manufacturing facility is ISO-9001 and ISO-13485 certified, and our controlled environment clean rooms are graded from ISO 8 up to ISO 5.



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