Millipore SigMa

Lack of consistency in cell culture media can create significant variation in your upstream process. Our supply chain experts are committed to providing you with the highest quality and most consistent cell culture media regardless of manufacturing site location.

MANUFACTURING LOCATIONS

Liquid Centers

St.Louis, MO USA Irvine, Scotland, UK Nantong, China

Dry Powder Media Centers

Lenexa, KS USA Irvine, Scotland, UK Darmstadt, Germany

imMEDIAte ADVANTAGE® Centers

Lenexa, KS USA St.Louis, MO USA Nantong, China Songdo, South Korea



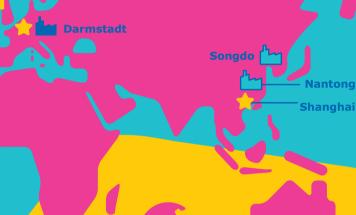
Global Raw Materials Vendor Management Program



confidence you need for consistent, quality product.







MANUFACTURING CAPABILITIES

Custom Capabilities Large Scale

Custom Capabilities Small Scale

imMEDIAte ADVANTAGE® Services

Clinical to commercial supply

Liquid; 1-200L batch sizes

• Liquid: 50 - 10,000 L batch sizes • Dry powder: 25-6000 kg batch sizes

Powder: 0.5 - 20kgs batch sizes

Our global network of manufacture sites are specifically designed and operate

to exceed industry standards for cell culture media intended for bioprocesses.

Understanding Trace Element Variability

The role of trace elements and the impact on protein and product quality is well documented. We offer the right data to begin understanding this variability.

GLOBAL QUALITY MANAGEMENT

- Quantitative testing by ICP-MS
- Cu, Mn, Zn, Mo, Ni, V, Al, Se, Cr, Co
- Results reported on the CofA



Manufacturing plant



New manufacturing facility



Redundant supply facility



R&D centers for cell culture media & related products



IEW! Emprove® I Culture Media

High-quality products, comprehensive documentation, and superior customer support for qualification, risk assessment, and process optimization. Now available for a range of cell culture media.

www.EMDMillipore.com/emprove





Irvine

Raw Materials

Option to use unique, non-qualified raw materials for your experiments



Pre-GMP product intended for bioprocess development studies

Documentation to Support

Certificate of analysis and safety data sheet with each batch



Right Technology & Processes

Equivalent liquid and dry powder manufacturing methods as compared to large scale facilities



Design Support

Let one of our R&D teams or our designs specialist help you develop your custom cell culture media.



We know the challenges global biopharma companies can have with securing dual source of cell culture media. We provide the solution by offering two sister ites-same technology, single source of raw materials and global quality management to deliver dual sourcing from one supplier.









Quality Control

Standard testing with options to add customized quality testing.

Manufacturing Practices for Excipients and applicable sections of Annex 1

of the EU Guidelines to Good Manufacturing Practice for Medicinal Products Apply to Lenexa, St. Louis-Broadway, Irvine, Darmstadt, and Nantong (liquid) sites.

Global Quality Management System

Our cell culture media sites are certified as ISO 9001:2015 * Voluntarily comply to the Joint IPEC-PQG Guide on Good

Standard toothing than options to dud outstanding quanty toothing.					
	Finished Product Testing	Methodology	NA	EU	China
	Appearance	Uniformity/color	•	•	•
	pH	USP 791	•	•	•
	Osmolarity	USP 785	•	•	•
	Bioburdon (Powder)	USP 61	•	•	•
	Sterility (Liquid)	USP 71	•	•	•
	Endotoxin	USP 85	•	•	•
		(Kinetic Chromogenic Gel clot LAL)	1		



Quality Services: Customer Inquiries



Front Line Contact

Product documentation, Q&A

Technical & Quality

Workflows

Appropriate team support

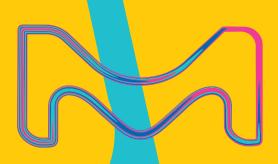




Expert Support Scientific or site expert support

The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.

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Pharma & Biopharma **Raw Material Solutions**