SAFC_®

Pharma & Biopharma Raw Material Solutions

immediate and an example of our support. This expedited service provides you the competitive advantage to complete your development work quicker and accelerate your molecule to market sooner.

We understand quick never replaces quality. Our centers are uniquely designed and equipped with manufacturing technology equivalent to our large scale GMP facilities. This ensures the reliable use and quality of our small volume products.

Key Features of Our IA Program

• Raw Materials

Qualified, same source as our larger facilities with the option to use unique, non-qualified raw materials for your experiments.

Operational Management Systems

Master formulation management, batch management, controlled process procedures and trained team members.

Product Documentation

Certificates of Analysis and Safety Data Sheets for all products.



Merck

We also understand how valuable every experiment you do equates to time in the race to market. Our service has been developed with the right attributes to ensure the data you generate is trusted first time.

Attribute	Feature	Liquid	Dry Powder
Product	Batch size	1 to 200 L	0.5 to 20 Kg
Water quality	Milli-Q [®] Ultrapure Water System	 ✓ 	N/A
Weigh Requirements	Procedure defined weigh tolerances	 ✓ 	 ✓
Formulation	Defined raw material group rules and order of addition to the process vessel	v	v
Milling and blending controls	Designed to ensure homogeneous product. Flowability and bulk density measurements recorded.	N/A	~
Mixing, Solubility and Filtration	Calibrated mixing tanks with procedure requirements for mixer placement.	v	N/A
	Formalized check to ensure solubility prior to filtration.		
	Millipore [®] PES and PVDF membranes (0.2 micron for sterile filtration, 0.1 micron used as needed).		
Product use information	Hydration instructions developed in-house or with customer collaboration.	N/A	~
Performance	Certificate of Analysis	Appearance, pH, osmolality, solubility, contamination clearance and conductivity (buffers only).	Appearance, pH, osmolality, and solubility.
Packaging	Standard Product Packaging	Sterilized PET bottles with tamper evident	Bottles with tamper evident seal
		seals (100-2000 mL)	Protective buckets with
		Sterilized bags with standard connections (1-20 L)	two liners, desiccant pouch and tamper evident seal

Site to Site Comparability

As your process development may require global involvement, we know the importance of ensuring all of our Centers operate to the same standards. All sites are managed locally with global program oversight and autonomy to ensure the global consistency you expect.

- Similar or same equipment design and execution
- Same procedures for operation and process boundaries
- Proven performance of product comparability

Our imMEDIAte ADVANTAGE[®] Centers are strategically located to support global process developers with needed access to small volume, expedited service, custom cell culture products.

- Lenexa, Kansas USA
- St. Louis, Missouri USA
- NEWLY OPENED Nantong, China
- NEWLY OPENED Songdo, South Korea

The work you do today defines the products of tomorrow. Our ability to support your bioprocess development activities is strengthened by more than 40 years of cell culture media formulation and manufacturing expertise. Let us be your trusted partner. Contact your sales representative or sales development personnel for how to order and a personalized quote.

To place an order or receive technical assists	ance in Europe, please call Customer Service:
France: 0825 045 645	Spain: 901 516 645 Option 1
Germany: 069 86798021	Switzerland: 0848 645 645
Italy: 848 845 645	United Kingdom: 0870 900 4645
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For other countries across Europe, please call: +44 (0) 115 943 0840 Or visit: MerckMillipore.com/offices For Technical Service visit: MerckMillipore.com/techservice Merck KGaA Frankfurter Strasse 250 64293 Darmstadt, Germany

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