# SAFC<sub>®</sub>

Pharma & Biopharma Raw Material Solutions

# imMEDIAte ADVANTAGE®

# Small Volume Custom Media

Our imMEDIAte ADVANTAGE<sup>®</sup> service for pre-GMP, small scale custom media, feeds, supplements and buffers is one 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.

Aillipore

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.



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 <sup>®</sup> Ultrapure Water System	<ul> <li>✓</li> </ul>	N/A
Weigh Requirements	Procedure defined weigh tolerances	<ul> <li>✓</li> </ul>	~
Formulation	Defined raw material group rules and order of addition to the process vessel	<b>v</b>	<b>v</b>
Milling and blending controls	Designed to ensure homogeneous product. Flowability and bulk density measurements recorded.	N/A	<b>v</b>
Mixing, Solubility and Filtration	Calibrated mixing tanks with procedure requirements for mixer placement.	<b>v</b>	N/A
	Formalized check to ensure solubility prior to filtration.		
	Millipore <sup>®</sup> 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	<ul> <li>✓</li> </ul>
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 two liners, desiccant pouch and tamper evident seal
		Sterilized bags with standard connections (1-20 L)	

### 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<sup>®</sup> 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 assistance in the U.S. and Canada, call toll-free 1-800-645-5476 For other countries across Europe and the world, please visit: **EMDMillipore.com/offices** For Technical Service, please visit: **EMDMillipore.com/techservice**  MilliporeSigma 400 Summit Drive Burlington, MA 01803

EMDMillipore.com



© 2020 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rights Reserved. MilliporeSigma, the vibrant M, SAFC, Millipore, Milli-Q and imMEDIAte ADVANTAGE are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources. MS\_FL6575EN Ver. 1.0 32197 08/2020