

SAFC

Pharma & Biopharma Raw
Material Solutions

**Millipore
Sigma**

Custom Cell Culture Media Development Services

The right cell culture medium is essential for a successful upstream process. A high performing platform medium can accelerate development timelines and a tailored feed solution can enhance the titer and quality attributes of your target molecule.

Maximize Results. Minimize Risks.

We partner with you to develop custom media solutions to meet your specific performance and quality criteria, reduce time to market, and minimize risks and uncertainty. Backed by extensive experience with a variety of cell lines including CHO, HEK, and insect cells, we provide flexibility in project design, whether in-house or at your facility.



MilliporeSigma is the U.S.
and Canada Life Science
business of Merck KGaA,
Darmstadt, Germany.

Our Differentiated Workflow

Custom Services For Custom Media

Choose your project design and actively engage in the development process.

Technical Transfer to lay the groundwork for seamless process implementation in the future:

- Equipment validation and process verification to replicate your process
- Flexibility on process requirements and ability to incorporate customer-specific assays

Specialized Library Screening to identify candidate formulations using a statistical approach:

- Screening of extensive, chemically defined libraries for fed-batch, perfusion, or viral production
- Design of Experiment (DOE) studies in high-throughput format to test up to 800 conditions
- Multivariate Analysis (MVA) to identify the most important variables, evaluate positive-negative effects, and define the optimum concentration of components

Media Optimization to meet your process-specific criteria:

- Fed-batch medium optimized for robustness to ensure risk free manufacturing
- Perfusion medium optimized for low CSPR while maintaining high specific productivity
- Viral production medium optimized for rapid cell growth and high virus titers in a single formulation

Feed Optimization to improve and maintain viable cell density and viability, while maximizing productivity and targeting a specific protein quality profile:

- In-house analytical expertise with fast turnaround times
- Option to implement customer-specific assays

Process Optimization to maximize cell culture performance with scalability in mind:

- Ability to scale-up into benchtop bioreactors for process transfer
- Perfusion development in small-scale automated Mobius® Breez Microbioreactors to enable seamless transfer into production systems



Technical Transfer

Specialized Library Screening

Media Optimization (optional)

Feed Optimization (optional)

Process Optimization (optional)

imMEDIATE ADVANTAGE®
Pre-GMP Manufacturing

imMEDIATE ADVANTAGE® Services

Pre-GMP Small Scale Custom Solutions

Your custom medium solution needs to work for the long term and for large-scale production. We provide prototypes that are aligned with key elements of our GMP process and quality systems:

- Ready-to-use samples with hydration instructions
- Comprehensive product documentation, including Certificate of Analysis and Safety Data Sheet
- Scalable systems for reproducible product quality and performance

Fit-for-Purpose Raw Materials

Modulate Performance and Ensure Product Reproducibility

As trusted experts in raw materials, we apply our knowledge and innovative solutions to advance your cell culture media to the highest standards:

- Extensive knowledge of impurities and our Trace Element Program ensure consistent media performance
- Precise characterization of each medium component and stringent material selection for cell culture processes, with identical materials across R&D, pre-GMP and GMP processes
- Option to use unique raw materials, such as low-impurity iron salts for controlling and adjusting process specifics, or modified amino acids for enhanced solubility of concentrated feeds



SAFC®Pharma & Biopharma Raw
Material Solutions

Large-Scale Manufacturing

Benefit from a global network of redundant manufacturing sites, enhancing supply robustness and regional availability:

- GMP batch sizes ranging from 25 to 10,000 L (liquid) and 10 to 6,000 kg (dry powder)
- Six manufacturing sites in US, Europe, China, and South Korea* (*opening in 2026)
- Global quality management system and EXCiPACT® PAMs GMP certification across all manufacturing sites

Services and Support

We support your journey from development to commercialization with a full range of services facilitated by our local Customer Application teams including:

- Extensive analytical testing capabilities and stability studies
- Technical consultation by our MSAT experts with access to our process development M Lab™ Collaboration Centers with scales up to 50 L
- Global regulatory support, including preparation and submission of Drug Master Files

Let's Drive Progress and Innovation Together!

For over 50 years, biopharmaceutical companies around the world have trusted us to provide customized, high-performing, high-quality medium solutions for a diverse range of biologics, including formulations for blockbuster drugs currently on the market.

If you have a challenging cell line, molecule, or process, you can rely on our proven expertise and experience to find the right solution for your specific needs.

**Contact us: [SigmaAldrich.com/
custom-media-development-services](https://www.sigmaaldrich.com/custom-media-development-services)**

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

