

Process Development & Drug Manufacturing

support services



Millipore_®

Preparation, Separation, Filtration & Monitoring Solutions

SAFC®

Pharma & Biopharma Raw Material Solutions

The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.

Comprehensive Support Services

We aim to support all your processes and applications. Our expertise in technical and regulatory matters ensures robust and reliable aid. We assist you at every stage of drug development and manufacturing, aligned with risk management approaches in current regulatory guidance.

Our digital platforms and international team of engineers and scientists are at your disposal. We help you overcome challenges in process development and manufacturing, allowing you to meet your process objectives.

We offer a comprehensive suite of services. These services are designed to help you either implement established proven technologies, approved by regulatory agencies, or adapt to the latest Pharma and Biopharma technologies and processes. We ensure you're always ahead, helping you stay at the forefront of your field.

How we can help you: Our offerings include equipment and software services, process development support, along with quality and regulatory support.



Learn more about: **System Service Reliance Plans**

Equipment and Software Services

Our services guide you at every stage of your equipment and software life cycle. From installation and gualification to training and maintenance, we ensure smooth, efficient equipment operation.

Our services are always up-to-date with the latest technologies. They're flexible, letting you choose the service level that suits you. We've also digitalized our services for greater accessibility and faster response times.





Support

Learn more about:

M Lab™ Collaboration Center **Training Viscosity Reduction Platform**

Application Services for Solid Dose Formulation

Process Support

Our engineers, scientists, and process development experts are here to help. They solve your process development and manufacturing problems and train your operators. They analyze and explore new solutions for your site. Our tech experts support you, no matter the molecule or process scale. And they're available wherever you are in the world.

Training and application support can be provided at your facility, on-site at our M Lab™ Collaboration Centers or virtually. We also offer a variety of theoretical and hands-on Biopharmaceutical courses across the entire process train, from upstream to downstream and through final fill.

Process and Formulation Development Selection of the Best Devices & Systems

Process Optimization, Troubleshooting & Consultancy

PHASE 2

PHASE 3 MANUFACTURING SCALE

- Viscosity Reduction Platform Services Application Services for Solid
- Selection of the Best Process • Scale-up & Tech transfer
- M Lab™ Collaboration Center
- Training
- PAT Rental Service
- Chemometry Service

Quality & Regulatory Support

Transparency is our priority. We deliver comprehensive documentation to optimize your processes, qualify products, and conduct risk assessments and audits. Our team can handle various types of validation, E&L testing and patient safety evaluation. We use proven methods to ensure regulatory compliance. Our regulatory experts are ready to guide you. They can address both current and anticipated regulatory needs.

COLLECT	INTERPRET	EVALUATE & MITIGATE
USP <665> Extractables Data Self-service Digital Portal for Quality & Regulatory Content	Product Specific Extractables Reports Consultancy	 Patient Safety Evaluation Leachables Testing Microbial & Physical Validation Testing Consultancy
• Emprove® Program	VALIDATION SERVICES	

Quality &

Regulatory **Support**

Learn more about: **Emprove® Program Validation Services Quality and Regulatory** Management



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