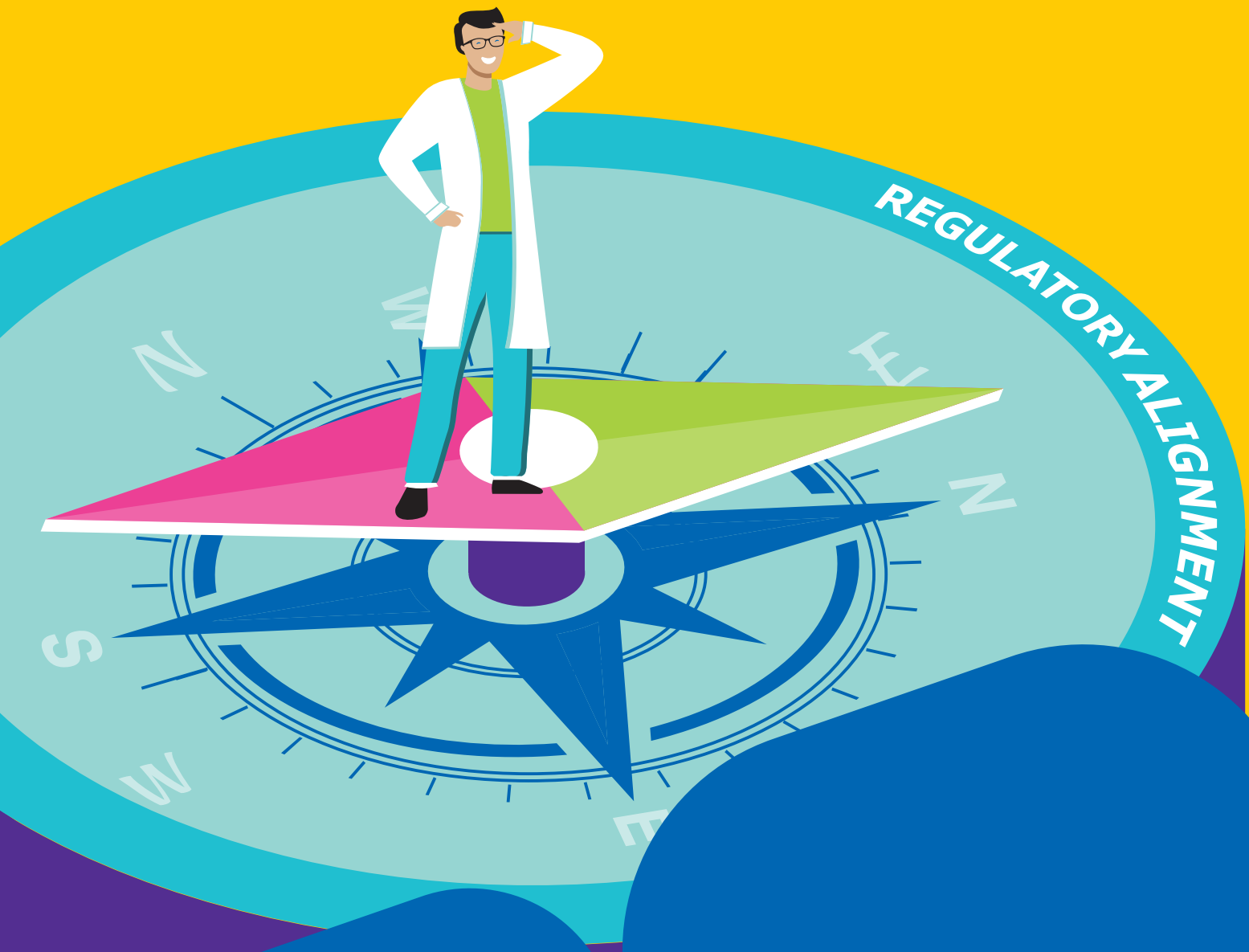
MERCK

Filter & Single-Use Validation Services: Discover an Easier Way

Align with Regulatory Guidance by Relying on our Expertise and Experience



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

Millipore®

Expert Pharm/BioPharm Products & CTDMO Services

Validation Services for You: Manage Process Risks

Regulatory guidance documents offer a framework for drug manufacturers to ensure the production of safe medications for patients. Manufacturers must demonstrate that their production equipment does not react with, add to, or adsorb substances in a way that affects the drug's safety, quality, identity, strength, or purity of the drug product. Staying up to date with global regulatory guidance and understanding testing expectations can be resource-intensive and time-consuming. That's where we can help.

Our Validation Services team provides access to industry-leading experts in pharma/biopharma filtration. Whether your focus is alignment with global guidelines or you need consultative support to implement compliant, robust, and effective validation strategies, we're here to assist you in:

- Understanding the most recent quality and regulatory standards
- Confidently designing validation strategies that will meet your needs
- Developing scale-down models that can be tested under your worst-case process conditions

Our Comprehensive Validation Offering Guarantees You an Easy Path Forward

As the validation pioneer, we have the expertise to develop your critical validation studies:

1987
First filter supplier to deliver validation service

5
labs around the globe

800+
bacterial retention tests per year

1,000+
E&L evaluations per year

Our streamlined process and simplified price structure make it easy to find the services and level of support you're looking for including:

- Extractables & Leachables Safety Evaluation
- Bacterial Retention Testing
- Filter Integrity Testing
- Chemical Compatibility Study
- Custom Services
- Consultancy

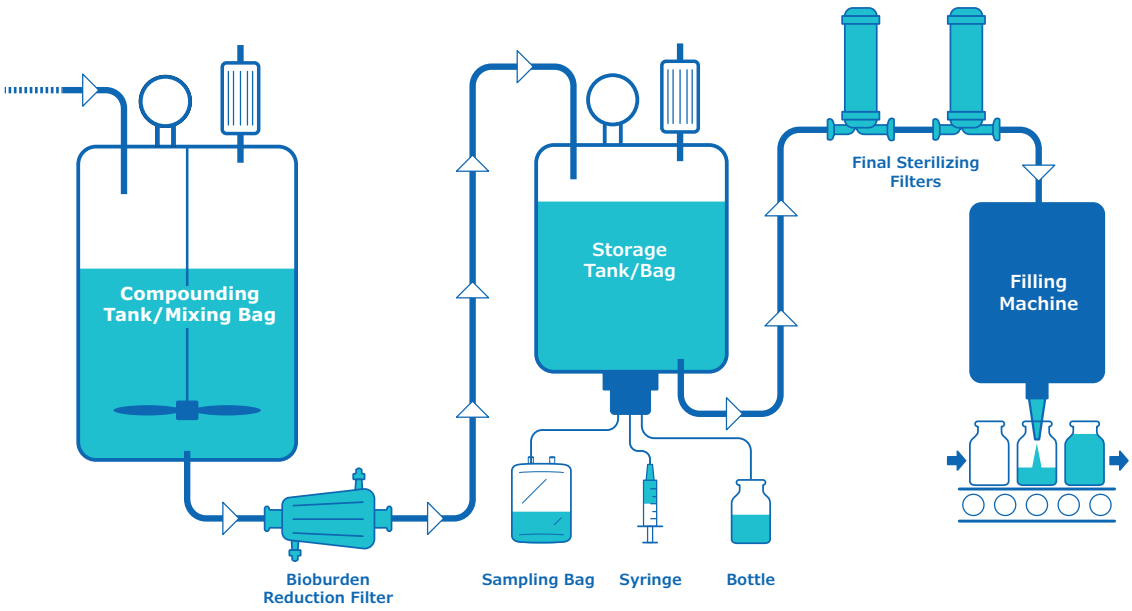
You select your path: simplicity and convenience, or flexible optionality. Either way, you'll feel confident thoughout your process validation.

Validation Services for Single-Use Sterile Filtration Systems

Upstream to the Compounding Tank/Mixing Bag
- Chemical compatibility
- Extractables/Patient Safety

Final Storage Single-Use Assembly
- Chemical compatibility
- Extractables/Patient Safety/Leachables
- Non-permeation test

Final Sterilizing Filters and/or Single-Use Assembly
- Bacterial retention validation
- Bubble point/Diffusion determination
- Chemical compatibility
- Extractables/Patient safety/Leachables
- Binding study
- Particle shedding study
- Vmax™ confirmation i.e. filter fouling evaluation



Bioburden Reduction Filter
- Chemical compatibility
- Extractables/Patient Safety
- Bubble point/Diffusion determination

Sampling System
- Chemical compatibility
- Functionality test
- Non-permeation test

We partner with you to implement a compliant, robust and effective validation strategy.

Extractables & Leachables

Discover an Easier Way to Show That Plastic-Product-Contact Materials Do Not Adversely Affect Patient Safety

As single-use technology is increasingly used in drug production, industry associations have developed standard test protocols for assessing extractable and leachable (E&L) compounds from contact surface materials in drug product manufacturing.

Aligned with these industry best practices we can help you adopt a risk-based approach to assess E&L:

1. Safety Evaluation based on standard extraction conditions:
   - We provide standard extractables data from our extensive library. Available on request or from the Emprove® Program Dossiers.
   - If necessary, we perform studies designed for your process and system (e.g., lipid formulation, high organic concentration)
2. If risks are identified, a second evaluation is performed based on actual specific leachables. This evaluation considers process conditions in tandem with worst-case extractables data.

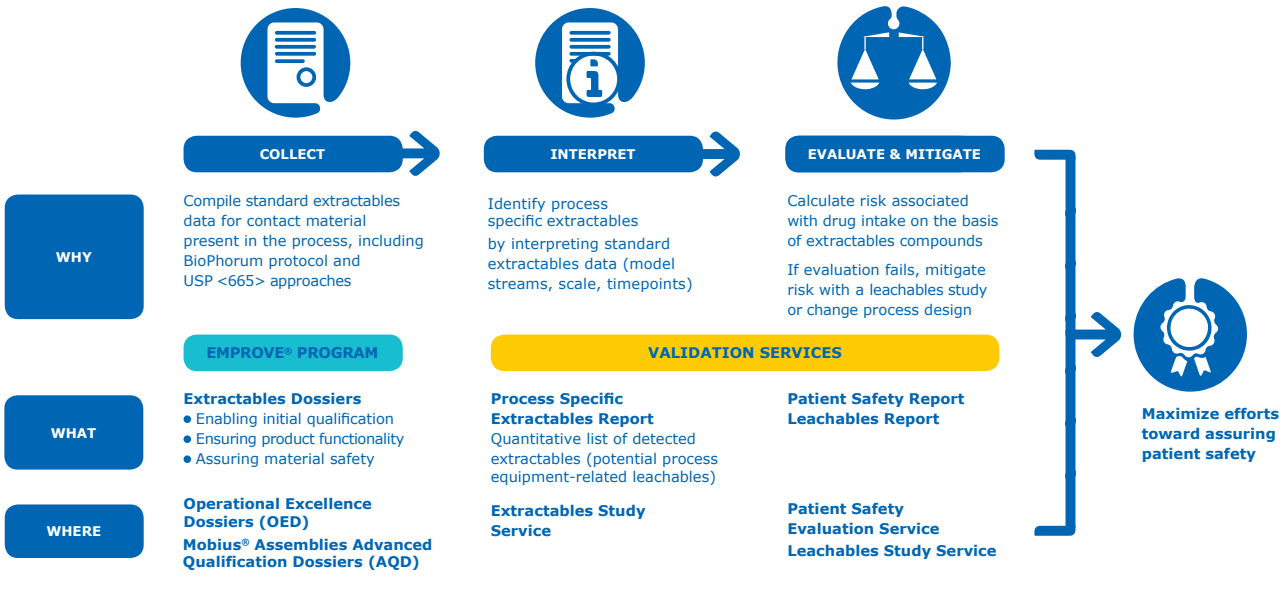
Discover an Easier Way to Access Standard Extractables Data: Emprove® Dossiers

The Emprove® Program contains over 400 raw and starting materials, and approximately 50 product families covering filters, single-use components, and chromatography resins. Each product portfolio is supported with Emprove® Dossiers which provide comprehensive, up-to-date documentation to help you navigate regulatory challenges, manage risk and improve your manufacturing processes.

The Emprove® Operational Excellence Dossiers for filters and single-use systems and Emprove® Advanced Qualifcation Dossiers for Mobius® custom assemblies provide standard extractables data that align with industry standards such as the relevant BioPhorum protocols and USP <665> general chapter.

Need help interpreting the Dossiers? Reach out to us to request a scaled & personalized report at **SigmaAldrich.com/sufiltervalidation**

An Easier Way to Achieve a Seamless and Robust E&L Assessment



Bacterial Retention Testing

Discover an Easier Way to Test Filter Performance

Confirming the bacterial retention capabilities of sterilizing-grade filters is a critical element of filter validation, and is outlined in global regulatory guidance documents for aseptic drug manufacturing.

We perform bacterial retention testing with a scale-down model under your worst-case process conditions using at least one membrane at or near the minimum integrity specification.

Brevundimonas diminuta (*B.diminuta*) is the standard test microorganism, although we can evaluate other strains on request. Complete retention of the test organism confirms sterilizing-grade performance of your filter.

Bacterial Retention Testing by our Validation Services Team Aligns with Worldwide Regulatory Guidance and Industry Standards

- FDA Guidance on Sterile Drug Products Produced by Aseptic Processing
- European Union, Japan and China Good Manufacturing Practices
- Parenteral Drug Association's (PDA) Technical Report 26
- Aseptic Processing of Health Care Products ISO 13408-2

Filter Integrity Testing

Discover an Easier Way to Establish Your Product's Filter Integrity Test Specification

The integrity of your critical sterilizing filter should be tested before and after use.

The Certificate of Quality lists minimum integrity test specifications for the filter wetted with a standard fluid such as water or alcohol. To minimize delays in production, many manufacturers use filter bubble point values specific to the product being processed. We can help determine the minimum integrity test specification for

- Filters wetted with your drug product
- Filters wetted with your drug product and rinsed with a specific fluid

Chemical Compatibility Testing

Discover an Easier Way to Evaluate the Compatibility of Product Contact Components

Selecting and qualifying a filter or single-use assembly means evaluating the compatibility of all components in contact with your drug product including filters and single-use systems. All filters and single-use systems used in your manufacturing process must be shown to be fit for use, compatible with your process and not reactive, additive or absorptive when confronted with your drug product.

To support your risk assessment, we evaluate:

- Filter and single-use assembly materials
- Process fluid composition
- Process conditions
- Regional and intended market regulations

Chemical compatibility studies can range from a compatibility report based on existing data to testing the filter devices and comparing filter performance before and after exposure to your product under your processing conditions.

Validation Services Consultancy

Take Advantage of our Global Team of Experts

With Validation Services available through an expansive, global network of laboratories and in-country/in-region experts, you can access rapid-response local assistance wherever and whenever you need it.

Our validation experts will help you develop a comprehensive validation strategy, aligned with the regulatory guidance for the countries in which you manufacture and market your drug product.

We will provide the information you need so you can feel confident you have:

- The right services for your quality risk management
- The right validation plan to optimize studies

We tailor our response to your needs and support all our filtration devices, single use components and assemblies.

Custom Services

Discover an easier way to solve your unique bioprocessing challenges

Complementing our product and filtration system portfolio, Millipore® Validation Services can support you with custom studies and tests for filters, single-use components & assemblies, under your process-specific conditions.

Designed around your application's specific requirements, these custom services enhance process reliability and efficiency while helping you navigate regulatory complexity and process-specific validation. Among other things, we can perform tailored extractables & leachables studies, single-use assemblies characterization or detection of residual detergent in samples. Because every "custom" need is unique, we're ready to listen.

Contact us to discuss your challenge and explore how we can support you.

Strategically Located, Harmonized Validation Services Labs Provide the Support You Need

Discover an Easier Way to Global Regulatory Alignment

New, Streamlined Ordering and Pricing for Better Value and a Better Experience

Our streamlined process and simplified price structure make it easy to find the services and level of support you're looking for, all with our product management support keeping you informed with lead times and report dates.

You benefit from:

- A simpler way to order the right validation services
- A partner that will ensure the validation services are aligned with the most updated quality and regulatory standards
- The right level of service for your needs, including customized solutions when desired

Choose the Classic or Advanced Package

Our two predefined service levels can help determine the level of service you need.

Classic

Rely on us for guidance. We'll do what's required to get your validation study done — with the highest quality standards.

Advanced

Let's collaborate. We'll discuss your specific requirements and customize a validation plan for more complex studies.

	Classic	Advanced
Satisfies Applicable Global Regulatory Expectations	•	•
Regulatory Query/Inquiry Assistance	•	•
Online Support	•	•
Call-in Support from Project Management Team	•	•
Test Customization[1]	—	•
Bacterial Retention and Compatibility Study Conditions	Process duration 48 h max Room temp range[2]	Maximum process duration Maximum process temperature
Extractables Study Conditions	Model solvent(s) selected based on risk level Extraction temp 40 °C & duration 24 h, 7 d, or 21 d	Customizable
Integrity Testing	1 product lot	Up to 3 product lots
Documentation	Templated	Customizable
Documentation Revision	1 on specific sections[3]	Up to 3 on full document

1 Classic testing covers predetermined range of process conditions with defined study parameters. Advanced testing provides higher level of customization, including process conditions, additional test equipment/resources, and more complex study requirements
2 as per Pharmacopoeias
3 Drug product and process information sections

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Expert Pharm/BioPharm
Products & CTDMO Services

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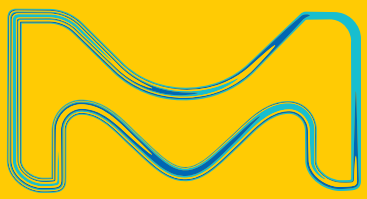
Frankfurter Strasse 250
64293 Darmstadt, Germany

Request a quote:
SigmaAldrich.com/sufiltervalidation



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