Confidence® Validation Services

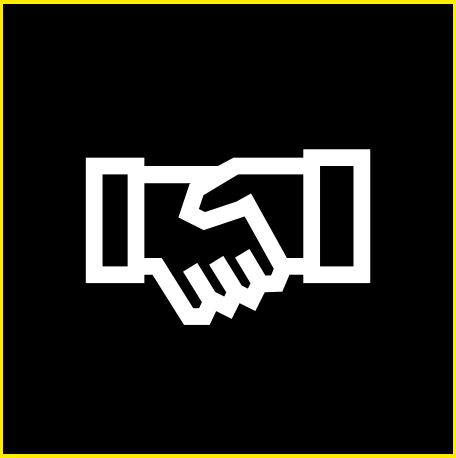
Simplifying Progress

SARTORIUS

Compliance With Regulatory Requirements

Sartorius has provided validation services to the biopharmaceutical industry for more than 30 years. We have a deep understanding of the regulatory landscape, and we take a tailored and consultative approach with every customer.
This makes us the perfect partner to address your validation-related challenges.

Your Competent Partner for Validation



Quality

All validation studies follow and are compliant with regulatory requirements. Our deep understanding of the regulatory landscape allows us to identify the right approach for each customer, resulting in over 98% first-time acceptance.

Expertise

Sartorius has provided validation services to the biopharmaceutical industry since the early 1990s and has been a pioneer in the field of E | L.

Experience

Confidence® successfully completed over 8,000 validation studies and satisfied more than 800 global customers in over 60 different countries.

Cost Efficiency

We deliver the most cost-effective testing strategy to each validation project by taking a risk-based approach.

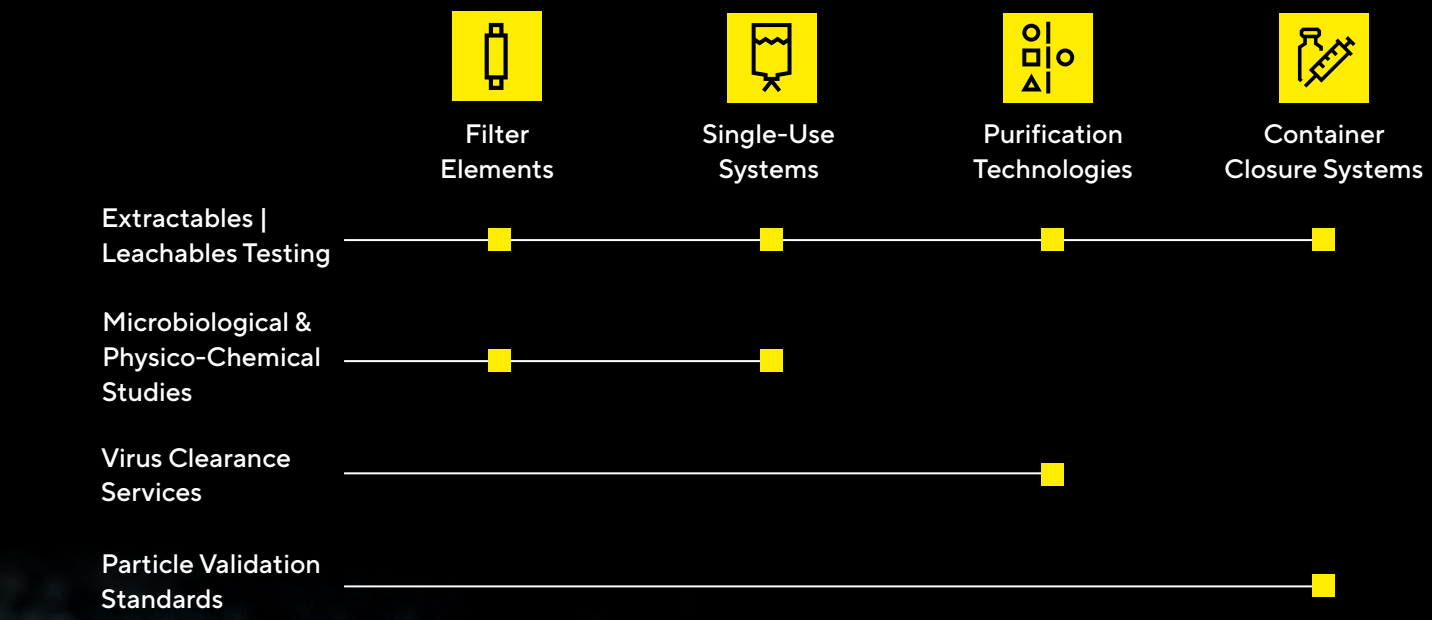
Fast Turnaround

Minimal clarification effort, agile lab scheduling, and a proactive work attitude enable study times as fast as six weeks.

Ensuring the Safe Adoption of Single-Use Systems in Biopharmaceutical Production

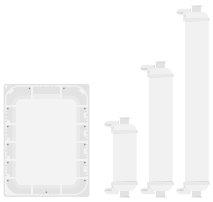
Confidence® Validation Services offers you the necessary validation services to implement single-use systems or conventional equipment. Our wide range of tests extends across all process components to provide you with a holistic solution. Let our experts support you to identify validation needs and the appropriate testing scope.

Our Portfolio Includes but Is Not Limited To:



Our services complement single-use systems perfectly, regardless of the respective process step or modality.

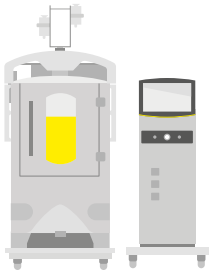
1 Buffer | Media Preparation



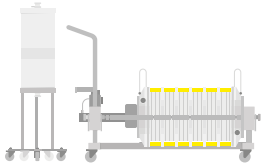
- Product-specific integrity test
- Chemical compatibility
- Validation studies for specific process applications
- Particle release test
- Adsorption studies
- Extractables assessment
- E | L testing

2 Fermentation

- Extractables assessment
- E | L testing
- Pharmacopeia testing



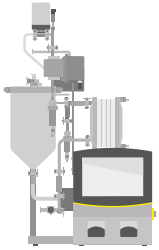
3 Purification



- Extractables assessment
- E | L testing
- Virus clearance studies
- Pharmacopeia testing

4 Concentration | Buffer Exchange

- Chemical compatibility
- Extractables assessment
- E | L testing
- Pharmacopeia testing

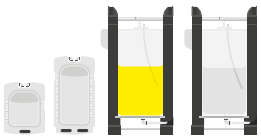


5 Sterile Filtration

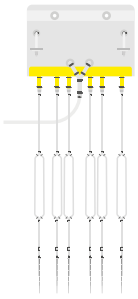
- Bacterial challenge test
- Chemical compatibility
- Product-specific integrity test
- Extractables assessment
- E | L testing
- Pharmacopeia testing

6 Storage

- Integrity & ingress testing
- Chemical compatibility
- Shipping & storage studies
- Pharmacopeia testing
- Extractables assessment
- E | L testing
- Validation studies for specific process applications



7 Final Filling



- Extractables assessment
- E | L testing
- Validation studies for specific process applications
- E | L safety evaluation
- Pharmacopeia testing
- Particle Validation Standards

Confidence® Validation Services in Detail

Extractables | Leachables Testing

Our E | L testing portfolio includes well-known solutions such as extractables and leachables tests. We also offer innovative solutions such as Extractables Assessments, facilitated by our proprietary software, the Extractables Simulator (ExSim).

As specified in USP <1663> and USP<1664>, we use state-of-the-art analytical methods, such as GC-MS, HPLC-UV, LC-MS, HS/GC-MS, NVR, FTIR, ICP-MS/OES, and IEC to detect and identify compounds released from polymer-based materials in even the most complex product formulations.

We combine extractables, material, plastics, and toxicological data with intelligent algorithms to perform process-specific extractables scaling, even for assemblies consisting of multiple components.

Microbiological and Physicochemical Studies

We carry out product-specific viability studies with industry-standard test organisms or your indigenous bioburden to determine the most appropriate test methodology for bacterial challenge testing.

In addition to microbiological studies, we offer chemical compatibility, integrity testing, and particle release testing – these are just a few of the topics that are evaluated for test relevance with your specific processes for your filters.

For single-use systems, we provide – among others - shipping tests, pharmacopeia tests, or chemical compatibility testing and validation studies on specific process applications such as connections | disconnections steps.

Virus Clearance Services

We provide virus spiking studies for all purification technologies, including virus filters, membrane adsorbers, resins, or low pH inactivation steps.

In addition, we support you with consulting and optimization of process designs by performing feasibility studies, design of experiments (DoE), or loading studies to prevent delayed time to market.

Particle Validation Standards

Our Particle Validation Standards comprise a broad range of custom-manufactured standards designed to validate the visual inspection process.

Visible particulates in injectable products can jeopardize patient safety. Therefore, reliable control of particulate contamination in fill and finish process steps is essential. Control measures include visual inspection of the final drug product to ensure it is "essentially free" or "practically free" of particles.

Portfolio Highlight

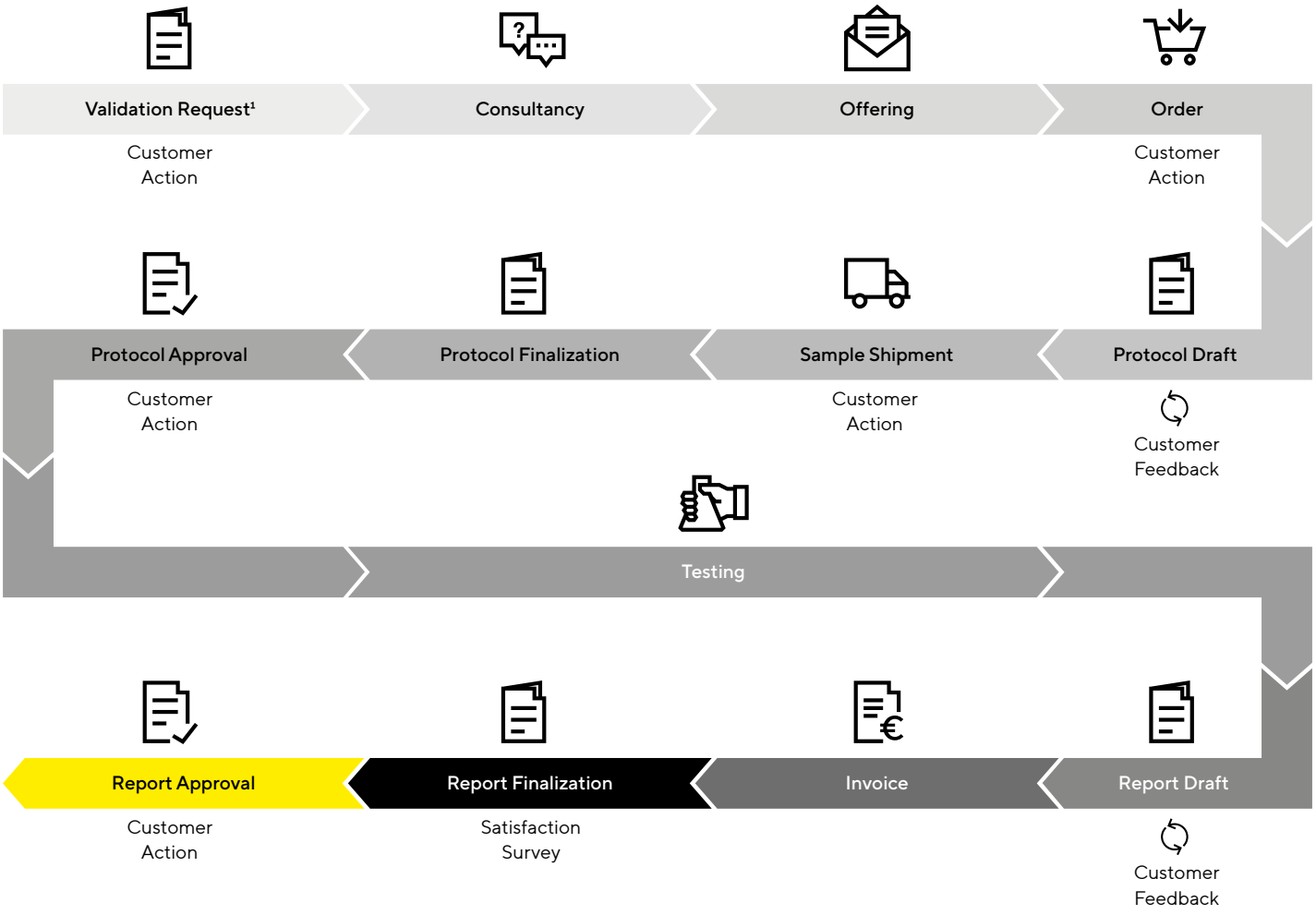
ExSim

Flexible Scaling	Precise scaling of extractables data even for complex assemblies
Comprehensive Extractables Profiles	We identify all relevant chemical entities
All Compiled in Our Extractables Assessment	Customer-specific risk assessment

Virus Clearance Services

Fast Turnaround	Sartorius has readily available slots and optimizes project management to complete studies rapidly, with 9-week testing times for a typical GLP phase I study.
Highly Purified Viruses	We use highly purified viruses for all purification and inactivation steps to achieve the highest possible log reduction values
Consolidated Solutions	With Sartorius, biopharma customers get everything under one roof, including virus clearance consumables and validation services.

Validation Project Workflow

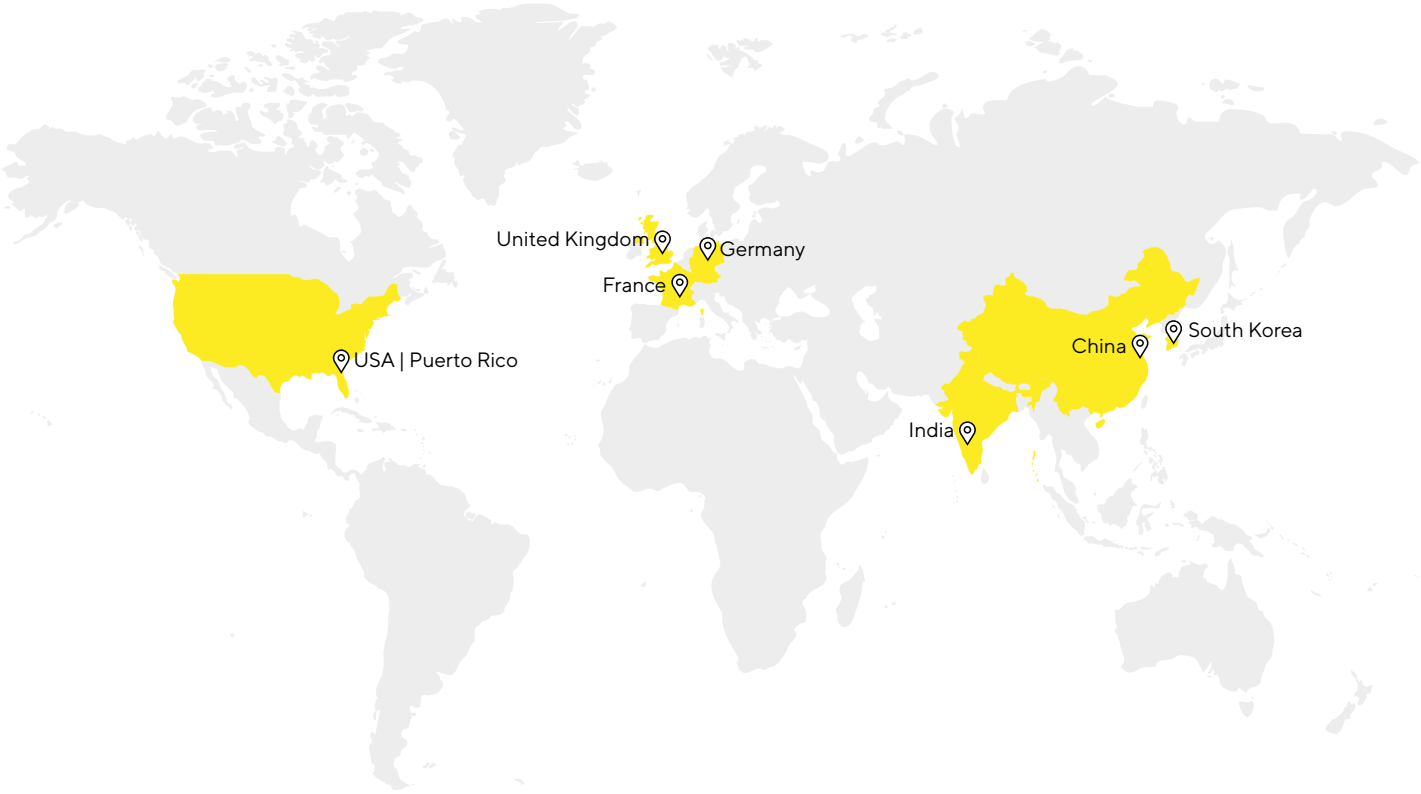


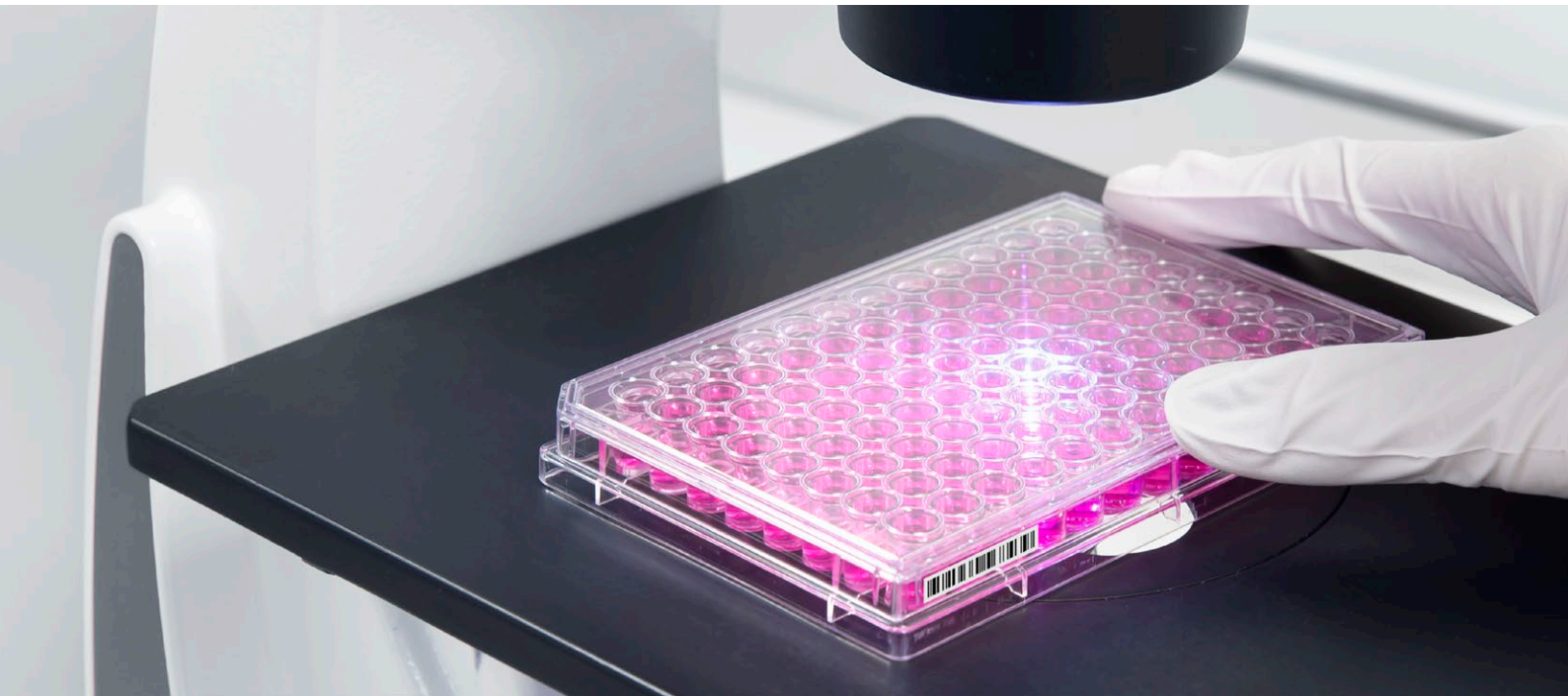
Thanks to our scalability, we guarantee full process relevance by using identical materials and formats adapted to a test product volume convenient for you.

In addition to reliable validation testing, we believe that our success is achieved through transparent project management and our commitment to support you at every stage, even after a project has concluded.

Global Presence

Confidence® Validation Services has various project management and laboratory sites around the globe to best serve local needs. Thus, our teams are close to you and familiar with local on top of global regulatory requirements.





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Explore your possibilities
We continue to lead and innovate in the field of validation studies to add value to the biopharmaceutical industry. For more information, scan the QR code.

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