

## Confidence<sup>®</sup> Virus Clearance Services

The Confidence You Need to Proceed

Virus Clearance Process Optimization, Design & Validation

With Confidence<sup>®</sup> Virus Clearance Services, Sartorius can provide ready access to virus clearance study slots in our laboratories for the performance of your spiking study.

### Features and Benefits:

- Evaluation of all typical downstream unit operations for virus clearance
- GLP Studies
- Non-GLP feasibility studies
- Highly purified virus stocks to ensure robust and reliable results
- Time and cost savings by consolidating virus clearance products and services under one supplier
- On-site flexibility | no sponsor participation required

### Use Cases:

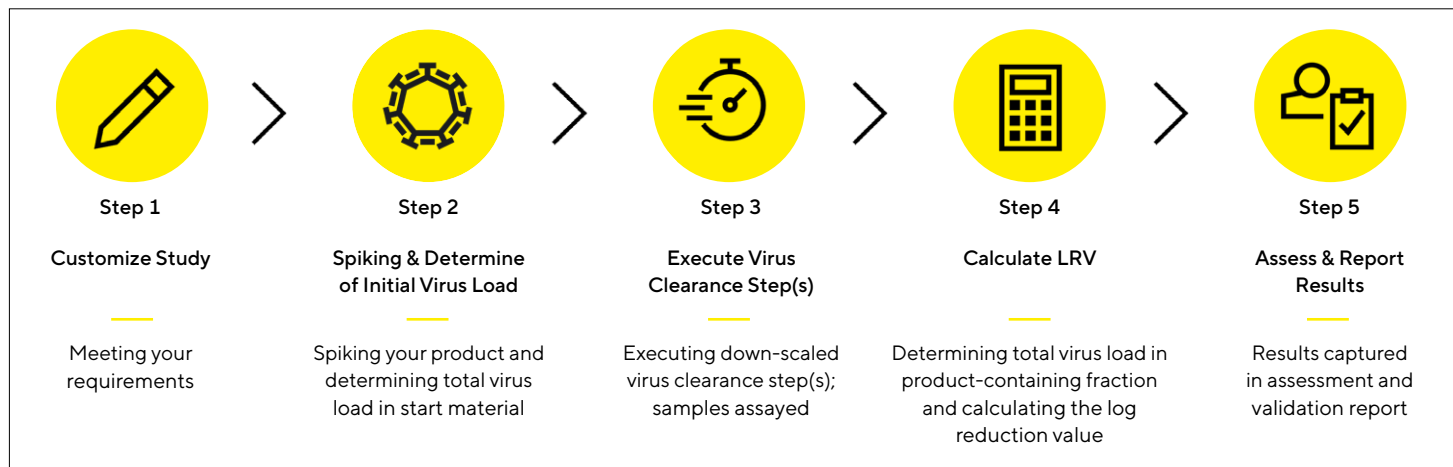
- Clinical phase I/III studies
- Feasibility or design of experiments (DoE) studies
- Virus clearance process optimization
- Process changes during development
- Troubleshooting low LRV results
- Planned technology transfer (e.g. to CDMOs)
- Commercial revalidation studies



# Virus Clearance Process Optimization, Design & Validation

As concerns over viral contamination rise, biopharmaceutical manufacturers must validate the efficacy of their processes for viral clearance. Sartorius Confidence® Virus Clearance Services provide virus spiking studies for purification technologies in compliance with regulatory guidelines, as well as expert consultation on process design and optimization. We use highly purified virus stocks to ensure robust and reliable results, and we offer readily available study slot access. It's a comprehensive virus clearance solution that gives you the confidence you need to proceed.

## The Five Basic Steps of a Virus Clearance Study




## Confidence® Virus Clearance Service Packages

Confidence® Virus Clearance Services are unique to the industry. Sartorius expertise now spans both specific clearance technologies and their required virus clearance, making it possible to provide a holistic solution to the customer. Our services are commonly combined with Sartorius' virus removal filters, membrane adsorbers, chromatographic resins, and monoliths, though products from other suppliers or other technologies can also be evaluated.

### Detailed Overview of Available Virus Panel. Additional Viruses Can Be Supported in Our BSL2 Facility.

Virus	Family	Genome	Envelope	Size [nm]	Resistance
MVM	<i>Parvoviridae</i>	ssDNA	No	18 - 24	Very high
MuLV	<i>Retroviridae</i>	ssRNA	Yes	80 - 110	Low
Reo-3	<i>Reoviridae</i>	dsRNA	No	60 - 80	High
HSV-1	<i>Herpesviridae</i>	dsDNA	Yes	150 - 200	Medium
PRV	<i>Herpesviridae</i>	dsDNA	Yes	150 - 200	Medium
BVDV	<i>Flavirviridae</i>	ssRNA	Yes	40 - 60	Low
PPV	<i>Parvoviridae</i>	ssDNA	No	18 - 24	High
HAV	<i>Picornaviridae</i>	ssRNA	No	28 - 30	High
EMCV	<i>Picornaviridae</i>	ssRNA	No	28 - 30	High
PI3	<i>Paramyxoviridae</i>	ssRNA	Yes	100 - 200	Low

 For more information, visit  
[www.sartorius.com/virus-clearance-validation](http://www.sartorius.com/virus-clearance-validation)

Do you have more questions about virus clearance and how our services can help you succeed?  
Reach out to our experts for more information: [confidence.validation-services@sartorius.com](mailto:confidence.validation-services@sartorius.com)

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