

CONFIDENCE[®] Virus Clearance Services

The Confidence You Need to Proceed

Virus Clearance Process Optimization, Design & Validation

With CONFIDENCE[®] 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:

- Non-GLP feasibility studies
- LRV determination for all virus clearance steps possible
- Fast turnaround: 6 weeks from start to finish
- Highly purified virus stock ensuring robust and reliable results
- Save time and cut costs by consolidating virus clearance products and services under one supplier

Use Cases:

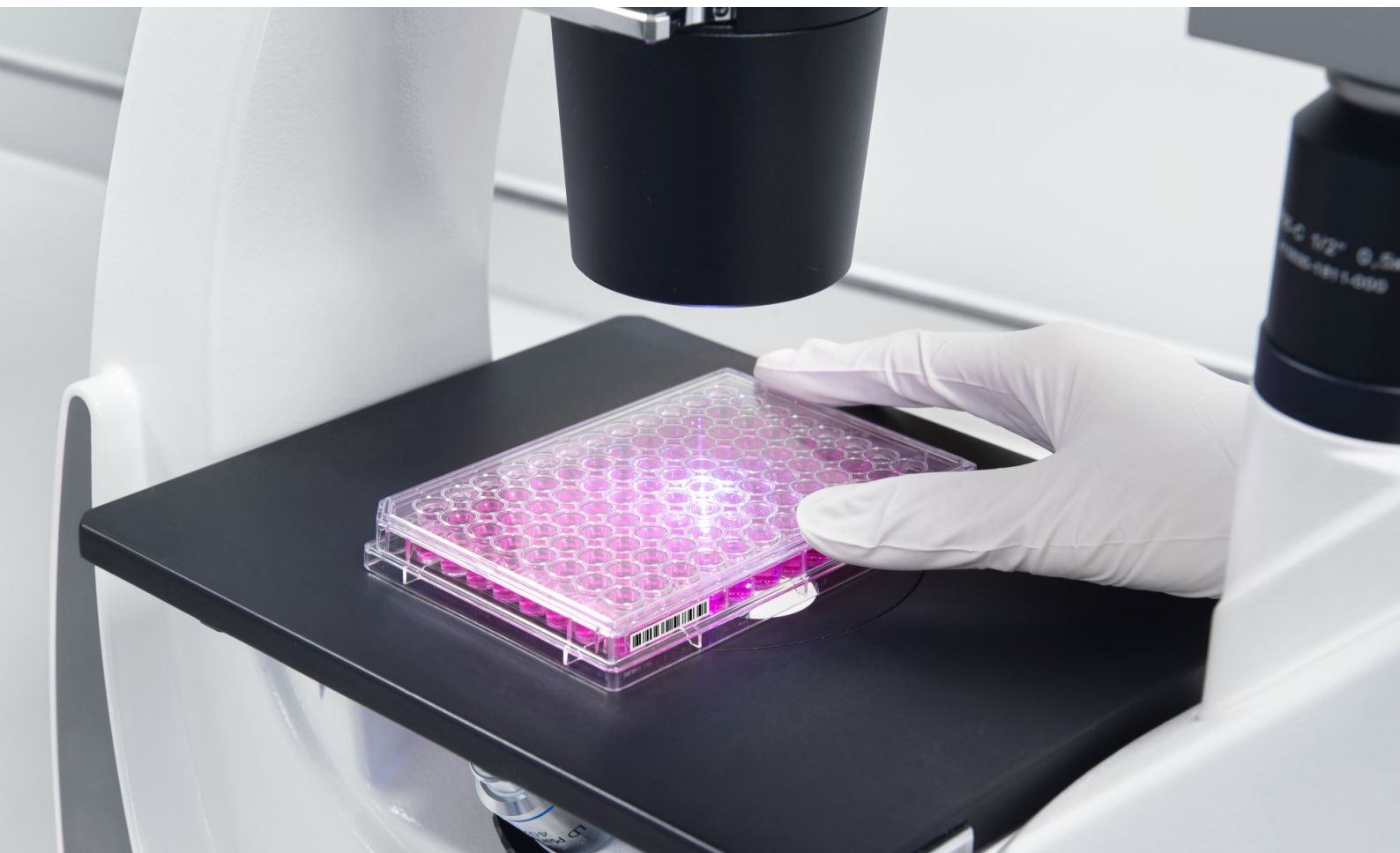
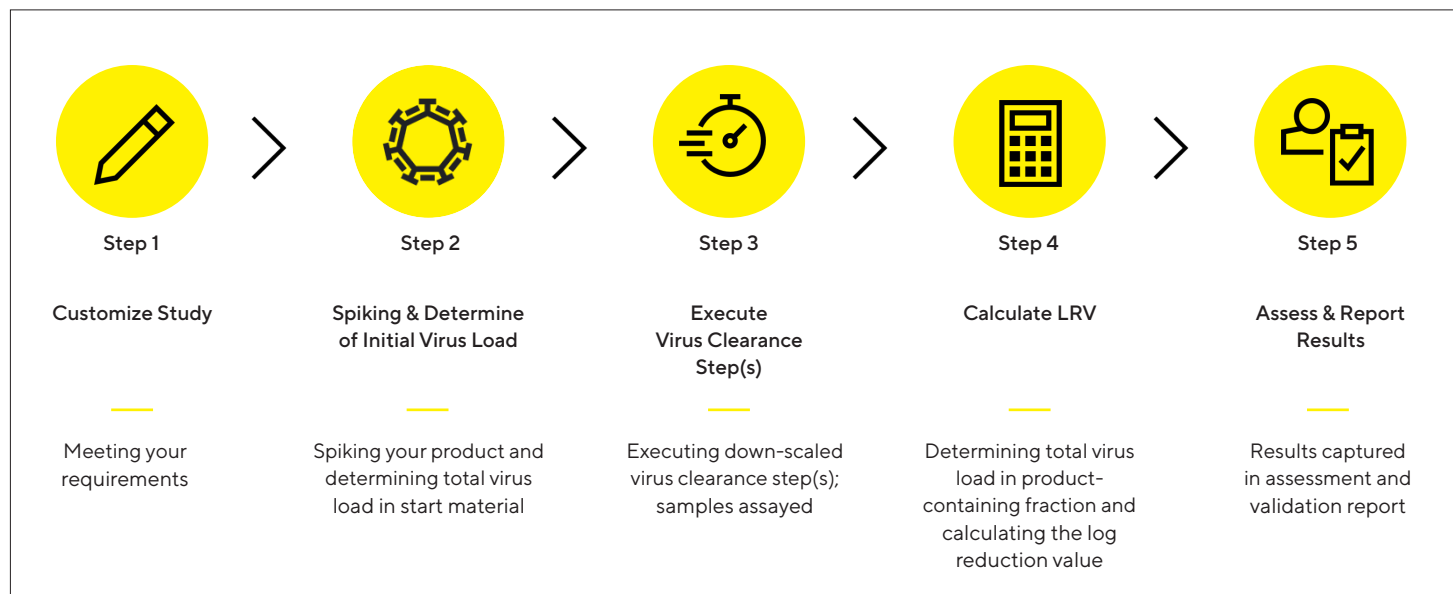
- Study slot needed for feasibility or design-of-experiment reasons
- Virus clearance process optimization
- Recently made process changes during development
- Dissatisfying LRV results
- Planned technology transfer (e.g. to CDMOs)



Virus Clearance Process Optimization, Design & Validation

As concerns over viral contamination rise, biopharmaceutical manufacturers must validate the efficacy of their virus clearance processes. Sartorius CONFIDENCE® Virus Clearance Services provide virus spiking feasibility studies for purification technologies, as well as expert consultation on process design and optimization. We use highly purified virus stocks to ensure robust and reliable results, and we provide rapid turnaround times – as fast as six weeks. 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 spans both virus clearance and our specific clearance technologies, making it possible to provide a holistic solution to the customer. Our services are commonly combined with Sartorius' virus filters and membrane adsorbers, though products from other suppliers or other technologies, such as resins and low pH, can also be available.

Virus Filters

Package	Basic	Advanced	Customized
Cytotoxicity test	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Viral interference test	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Virus titration (per run)	4x (2x load, 1x product, 1x load hold)	MVM: 8x (2x load, 1x product, 1 load hold, 3x fraction, 1x rinse) MuLV: 5x (2x load, 1x product, 1 load hold, 1x rinse)	Flexible
Large-volume plating (5x free of charge)	5x	5x	Flexible
Supply of virus	Variable*	Variable*	Variable*
Documentation and flux data	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Report	Standard (short summary)	Detailed	Detailed
Viruses available	MVM, MuLV	MVM, MuLV	MVM, MuLV, Reo-3, PRV, ...
Total Price	On Request	On Request	On Request


Membrane Adsorbers

Package	Basic	Advanced	Customized
Cytotoxicity test	3x (1x load, 1x wash buffer, 1x strip buffer)	3x (1x load, 1x wash buffer, 1x strip buffer)	3x (1x load, 1x wash buffer, 1x strip buffer)
Viral interference test	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Virus titration (per run)	4x (1x load, 1x flowthrough, 1x wash, 1x strip, 1x load hold)	8x (1x load, 5x flowthrough, 1x wash, 1x strip, 1x load hold)	Flexible
Large-volume plating (5x free of charge)	5x	5x	Flexible
Supply of virus	Variable*	Variable*	Variable*
Documentation and flux data	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Report	Standard (short summary)	Detailed	Detailed
Viruses available	MVM, MuLV	MVM, MuLV	MVM, MuLV, Reo-3, PRV, ...
Total Price	On Request	On Request	On Request

* Depending on filter | membrane size and spike ratio

Resins & Low pH

In addition to virus filters and membrane adsorbers, our services also support resins and low pH purification steps. These latter processes can be highly variable, so we recommend that you contact us for a quote.

 For more information, visit 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