

# A Robust Validation Framework for In-House NGS Assays in Viral Safety Testing

In line with the global shift towards replacing animal testing, NGS has emerged as a highly sensitive method for viral safety testing adhering to the ICH Q5A(R2) guidelines. Genedata Selector® is an end-to-end enterprise software designed to simplify and streamline the analysis of NGS biosafety workflows in-house in a GMP environment. This approach ensures the reliability of your results, accelerates turnaround times, and improves ROI, ultimately contributing to safer, more efficient, and ethical biopharmaceutical development.

## The Single Software Solution for NGS-Based Viral Safety

Validating NGS biosafety assays in-house is a complex process that requires expertise, and know-how for handling, analyzing, and reporting data. Genedata Selector experts support the validation process while the software enables full automation from sample registration to report generation in a validated environment, simplifying assay development and execution.

	↻ Outsourced Testing	SELECTOR In-House Testing	🌱 Impact/ROI
Critical Quality Attributes (CQAs)	Limited	Broad	<b>Higher Sensitivity</b>
Turnaround Time	3-4 months	2-3 weeks	<b>5x Faster</b>
Material Resources	Substantial	Minimal	<b>50x Less Material</b>
Human Resources	Manual Interpretation	Automated Workflows	<b>50x Less Resources</b>
Knowledge Management	No Direct Access to Data	Direct Access to Data	<b>Faster Access to Information</b>
Multi-Attribute Method	Separated Assays, Read-Outs & Reports	Multiple Results per Assay & Reporting	<b>Effective CQA Monitoring</b>

**ICHQ5A NGS Application Areas**

- Virus seed testing
- Cell bank testing
- Unprocessed bulk

As an alternative to in vitro and in vivo tests for adventitious agents

**TABLE.** The positive impact of in-house validation for NGS-based viral safety.

## Genedata Selector’s Functionalities



### PLAYBOOKS FOR AUTOMATED WORKFLOWS

Automate routine tasks, simplify workflows, enhance collaboration, and ensure efficient sample tracking with wizard-based user guides.



### BUILT-IN COMPLIANCE FUNCTIONALITIES & REPORTING

Obtain automated reports for regulatory submissions, maintain full record traceability, and implement defined user management.



### ADHERENCE TO FAIR DATA PRINCIPLES AND GLOBAL SHARING

Overcome geographical barriers with real-time access to workflows and easy data and report sharing from any location.



### FAST DECISION MAKING

Benefit from the system’s decision-making support, with clear go/no-go signals for testing multiple critical quality attributes in one assay.



### VALIDATION SUPPORT

Benefit from Genedata’s expertise in developing validation-ready solutions tailored to your specific needs.



### NEXTFLOW INTEGRATION

Effortlessly integrate proprietary pipelines using Nextflow and ensure seamless NGS data processing.