

# 7 Reasons to Rethink How to Do In-House Validation of NGS-Based Assays

Next-generation sequencing (NGS) has transformed biopharma workflows, enabling faster, more accurate decision-making in a Good Manufacturing Practice (GMP)-compliant environment. However, in-house validation of NGS assays comes with challenges such as variability in methods, instruments, and protocols, consistent data handling and analysis, and maintaining regulatory compliance.

Here are 7 key considerations to address before starting in-house validation of NGS-based assays:



## 1. In-House Expertise

In-house teams require specialized expertise for complex NGS assay validation to avoid potential errors and minimize inefficiencies.

*Do you have the right team?*



## 2. Regulatory Compliance

Data integrity, traceability, and GMP-compliant reporting are crucial for passing regulatory audits with ease.

*Are you confident your reports meet FDA and EMA-compliance requirements?*



## 3. Resource Allocation

In-house validation requires significant time, personnel, and financial resources.

*Are you optimizing your resources for cost-effective validation?*



## 4. Scalability & Analytics

Scaling up validation processes is challenging without an end-to-end platform.

*Are you equipped to manage advanced NGS analytics at scale?*



## 5. Data Security

In-house developed processes often lack 21 CFR Part 11 compliant features.

*Can your validation processes ensure data safety?*



## 6. Maximized ROI

Exponential ROI is expected when multiple assays, sites, and modalities are supported.

*Are you leveraging all opportunities to maximize your returns?*



## 7. FAIR Data Principles

Digital tools must grow with teams and infrastructure, ensuring data is FAIR.

*Are your digital solutions equipped to support future growth and data integration?*

Genedata Selector provides the comprehensive solutions to overcome these hurdles in NGS assay validation:



### IN-HOUSE EXPERTISE

Leverage extensive experience to develop validation-ready solutions tailored to your needs.



### REGULATORY COMPLIANCE

Generate automated submission reports, ensure record traceability, and manage users effectively.



### RESOURCE ALLOCATION

Streamline validation with Genedata Selector's automated workflows, reducing manual effort and optimizing resource allocation.



### SCALABILITY & ANALYTICS

Seamlessly integrate and process large data sets with scalable workflows.



### DATA SECURITY

Protect processes with advanced security features, user access controls, record traceability, and 21 CFR Part 11 compliance.



### MAXIMIZED ROI

Increase returns with comprehensive support for multiple assays, sites, and modalities, ensuring exponential ROI.



### FAIR DATA PRINCIPLES

Enable growth by making data Findable, Accessible, Interoperable, and Reusable.