



Off-the-Shelf Analysis Solution for GMP-Compliant NGS Assays in CGT & Biologics Development

Next-generation sequencing (NGS) assays have revolutionized the analytical characterization and manufacturing of advanced biotherapeutics by providing an unbiased, more sensitive and faster approach than traditional methods. Genedata Selector® is your all-encompassing, off-the-shelf analysis solution for all NGS-based assays to simplify sample management and data analysis. Powered by Playbooks, wizard-based guides, Genedata Selector unlocks a powerful multi-attribute method (MAM) for assessing multiple critical quality attributes (CQAs) such as biosafety, identity, potency and integrity of biotherapeutics in a single assay. As a GMP-compliant platform, Genedata Selector automates NGS data analysis workflows to generate reports for internal evaluation and regulatory submissions.



Interactive buttons are embedded in this figure; click them to explore further and access more content

Genedata Selector Playbooks

- · GMP-compliant automated NGS data analysis
- Standardized lockable workflows for greater reproducibility & security
- Data-driven decisions with clear go/no-go signals
- Time-stamped reports for internal evaluation
- Out-of-the-box and/or customizable to the organization's needs
- · Accessible, non-editable audit trails

- · Compliance with FAIR data principles
- Integrated with Nextflow pipelines and functionalities
- · Compliance with FDA's 21 CFR Part 11