Genedata Selector for NGS-Based Biosafety Testing

INDUSTRY
Biopharmaceutical R&D

APPLICATION
Adventitious Agent Detection
Cell-line Stability

KEY CHALLENGE
NGS data analysis

SUMMARY
Genedata Selector automates NGS-based biosafety data processing, analysis and report generation.

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Next-generation sequencing (NGS) is becoming increasingly important for the rapid identification of adventitious agents (e.g., viruses and mycoplasma) introduced during biopharmaceutical development and manufacturing. Key advantages of NGS compared to traditional assays are faster, more accurate, and more sensitive results (Figure ❶). The biopharmaceutical industry recognizes that it is crucial to screen for adventitious agents regularly, as failure to detect them early can have devastating financial consequences. Particularly for evolving cell and gene therapy approaches with only short timelines between manufacturing and delivery to patients, efficient and rapid biosafety testing with NGS is crucial.

Assessing the presence of adventitious agents using NGS provides scientists with an unbiased approach, which is suitable for testing starting materials, unprocessed bulk harvest, as well as the final product. NGS-based biosafety assessment requires sequence data of the samples to be assessed, genomic data of the production host, and a reference sequence database of adventitious agents (e.g., rVDB, etc.). These data need to be analyzed efficiently using sophisticated algorithms to make data-driven decisions on biosafety (Figure ❷).

Genedata Selector® is an end-to-end software solution that enables biopharmaceutical organizations to make data-driven GO/NO-GO decisions regarding product safety, quality, and integrity with significant time savings. By providing out-of-the-box pipelines for automated NGS data analysis, Genedata Selector empowers scientists to implement biosafety testing in house without the need for extensive bioinformatics training.

Challenges

Developing a Robust Assay

To develop a robust adventitious agent detection assay, sample preparation and experimental design need to be optimized as they influence the sensitivity of the assay, limit of detection (LoD) as well as false positive and false negative rates. Biopharma R&D organizations require in-depth data analysis expertise to support their NGS assay development.

Establishing Efficient Data Analysis Pipelines

NGS-based biosafety testing is often outsourced, leading to delays in obtaining results and losses in productivity. As Biopharmaceutical organizations establish NGS-based biosafety testing internally, a scalable software solution is required to process and analyze the large quantities of complex data yielded by NGS-based assays.

Standardizing Reporting for Collaboration and Compliance

It is often laborious and time-consuming for quality control teams to compile reports from results generated using a wide variety of assays, including NGS-based assays, and to find all the relevant information for a particular sample. To eliminate any delays in the delivery of documentation to partner organizations or regulatory authorities, a data integration platform with easy to configure reports is required that can also be validated in a GxP environment.

Keeping Reference Databases and Analysis Pipelines Up to Date

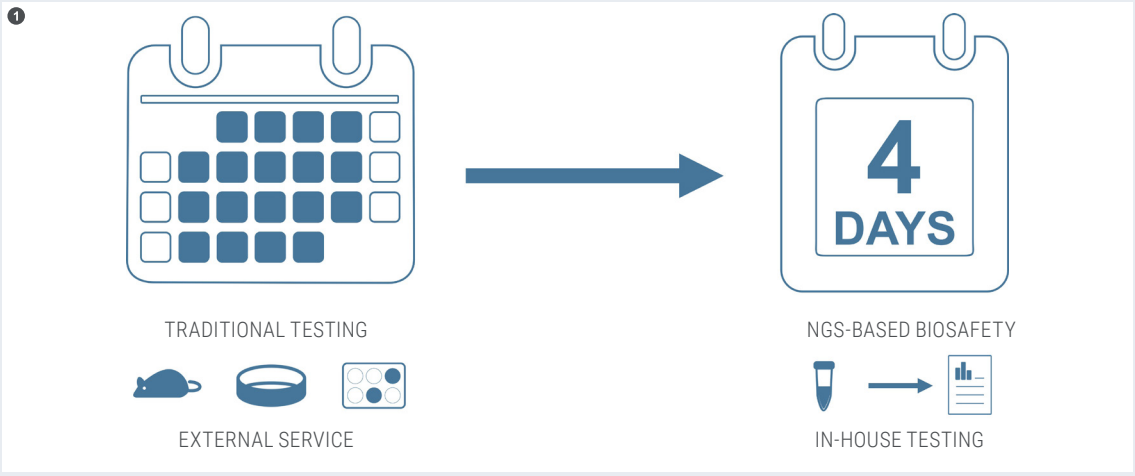
An up-to-date reference database of adventitious agents, as well as a high-quality genome sequence of the production host, is key for obtaining accurate and reliable biosafety test results. Also, data analysis pipelines need to be scientifically proven, transparent, and generate reproducible results.

1. *Traditional viral safety tests methods require approximately 4–5 weeks. NGS based Adventitious Agent Detection is faster and more versatile than traditional tests.*

2. *Adventitious Agent Detection involves 3 stages:*
   1. Sample registration
   2. Automated data analysis
   3. Report generation.

3. *The sample status card in Genedata Selector displays an overview over the processing status.*

1



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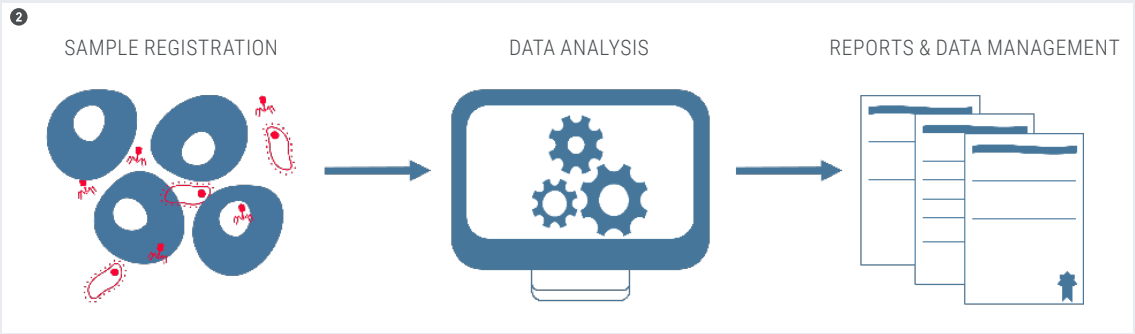

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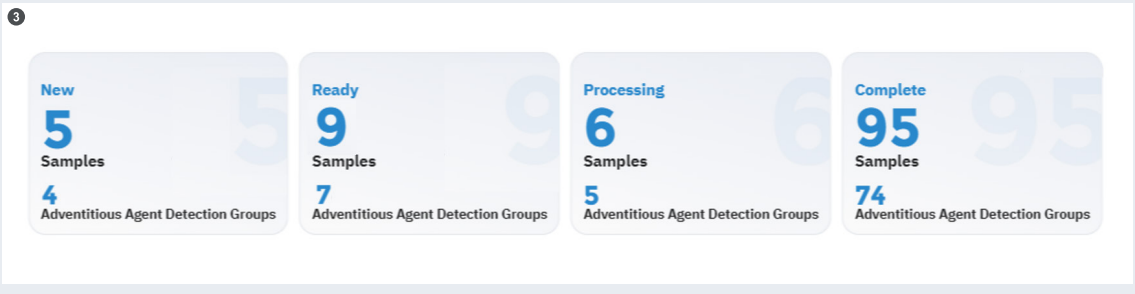

To fulfill regulatory requirements, biopharmaceutical R&D organizations require a professional software solution that maintains reference databases and analysis pipelines up-to-date and includes a reproducible curation process for viral sequences, variants of interest, new mycoplasma strains, etc.

Solution

Full Assay Development Support throughout Implementation

Besides its first-in-class Genedata Selector software platform for biosafety assessment, Genedata provides data science services to guide assay development as well as a technology transfer service enabling customers to operate independently and efficiently. Scientific consultants from Genedata with unique domain expertise are available to also assist in transitioning from a start-up into a GMP environment.

End-to-End Pipelines for Automated Data Analysis

Within Genedata Selector, the analysis of large, complex NGS datasets is standardized and automated using “Playbooks”, i.e., step-by-step guides for sample registration to data analysis and reporting (Figure ❹). After a Playbook is established, it can be locked down for usage in a regulated environment. Genedata Selector enables every scientist- independent of their bioinformatics knowledge - to efficiently analyze data from NGS-based biosafety testing and draw conclusions to quickly advance production processes.

Integrative and Compliant Data Platform for NGS-Based Biosafety

Genedata Selector is a modular enterprise software solution

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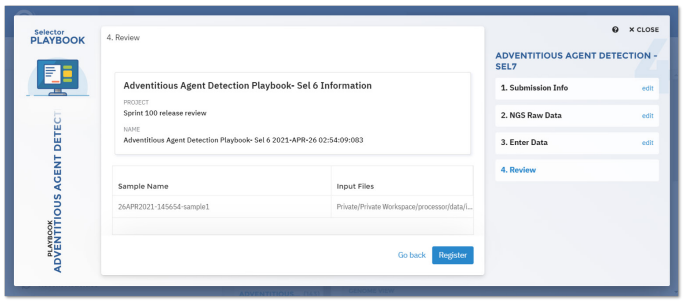

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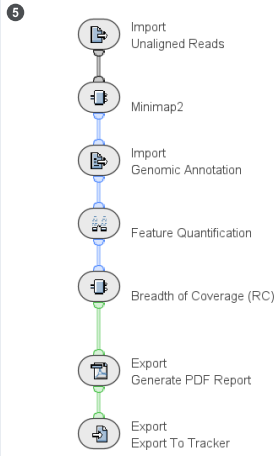

❹ *Playbooks within Genedata Selector are simple user interfaces designed to automate complex workflows and guide lab personnel through sample registration.*

❺ *An example of a data analysis workflow.*

❻ *Genedata Selector produces time-stamped reports and can follow a 21 CFR part 11 compliant operation, required to integrate the workflow into a GMP environment.*

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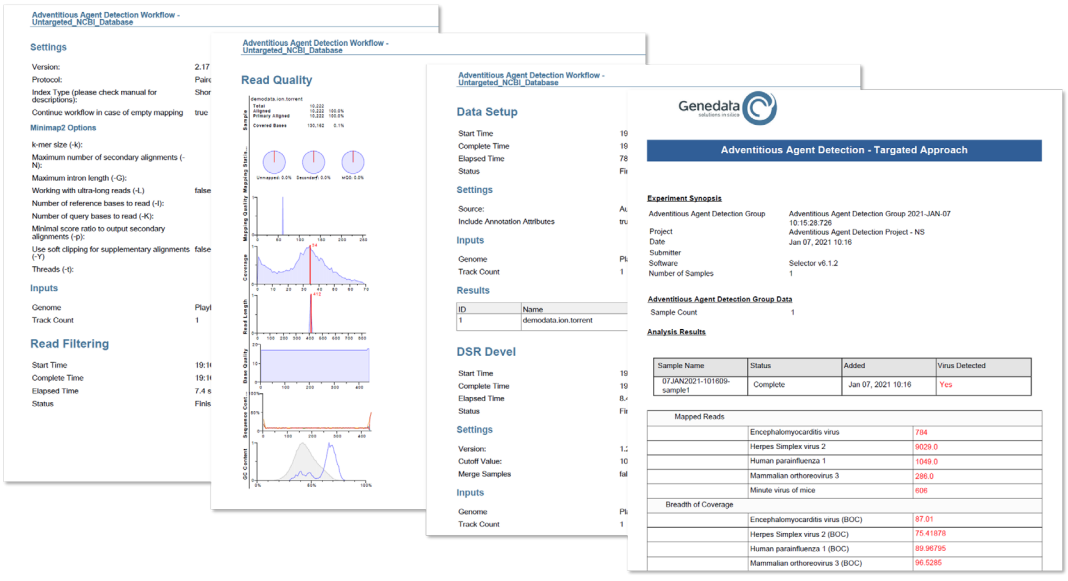

PDA®
Parenteral Drug Association

As a member ot the FDA-driven Advanced Virus Detection Technologies Interest Group (AVDTIG), Genedata participates in regular discussions with stakeholders in the field, remaining up to date on changing regulations and the needs of the biopharmaceutical industry.

that enables researchers to integrate and easily share scientific data with collaborators. It includes the modules:

- Tracker, for efficient sample registration, tracking, workflow automation, and report generation
- Processor, for automated NGS data processing and analysis (Figure ❺)
- Explorer, for integrative data management, results visualization, and knowledge sharing

Genedata Selector supports deployment in 21 CFR part 11 compliant environments, with key features such as time-stamped reports, audit logs, and complete user access control.

Automated Update of Reference Databases

Genedata Selector provides simple tools for automatic database maintenance and high-quality genome annotation as well as state-of-the-art sequence data analysis algorithms that guarantee the highest result quality. Genedata's scientific experts are also readily available to provide consultancy support e.g., curating reference databases and analysis workflows ensuring the results generated during NGS-based biosafety testing fulfill the highest standards in terms of science and technology.

Benefits

A Fast, High-Performing Assay at a Reduced Cost per Sample

In comparison to outsourcing the entire process to third-party service providers, in house NGS-based biosafety testing is cost-efficient, fully traceable, and scalable. Genedata Selector enables efficient GO/NO GO decisions on biosafety, including verification of gene inserts, as well as assessment of cell line stability and product integrity. This highly efficient biosafety testing approach leads not only to faster in-house decisions, but also to reduced costs per sample, shortened development timelines, and an increased return-on-investment (ROI) for biopharmaceutical companies.

Automated Data Processing and Accelerated Decision-Making

Genedata Selector automates data integration and analysis workflows for efficient, scientific data-driven decision-making. A process that would otherwise require several months, can be accomplished in only a couple of days, and thus accelerates the development and manufacturing of biotherapeutics.

Full Transparency and Reporting

Genedata Selector provides comprehensive data traceability and transparency for all biosafety analyses performed. The underlying data processing and scientific data analysis workflows can be configured as needed. Throughout the experimental process, sample history is completely tracked in the database (Figure ❸) and enables detailed report generation for internal assessment or submission to regulatory authorities as needed (Figure ❻).

Protected Intellectual Property

Using in-house curated host cell genome sequence data rather than publicly available sequence data has been shown to increase the accuracy of results. Genedata Selector equips scientists to undertake the complete experimental process in-house, so there is no need to share confidential data such as proprietary host cell genome information with third parties such as external service providers. When using Genedata Selector for biosafety assessment, IP related proprietary data never needs to be sent away to outside vendors.

Summary

Genedata Selector empowers biopharmaceutical organizations to assess the safety and integrity of their biopharmaceutical products without involving external service providers. While maintaining full control of the whole analysis process, and gaining full visibility, scientists receive comprehensive information regarding the safety of their processes. The standardization and automation of the complete analytical process using Genedata Selector results in improvements in efficiency and productivity. Genedata Selector enables a cost-efficient NGS-based biosafety process and accelerates the delivery of life-changing treatment to patients.

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