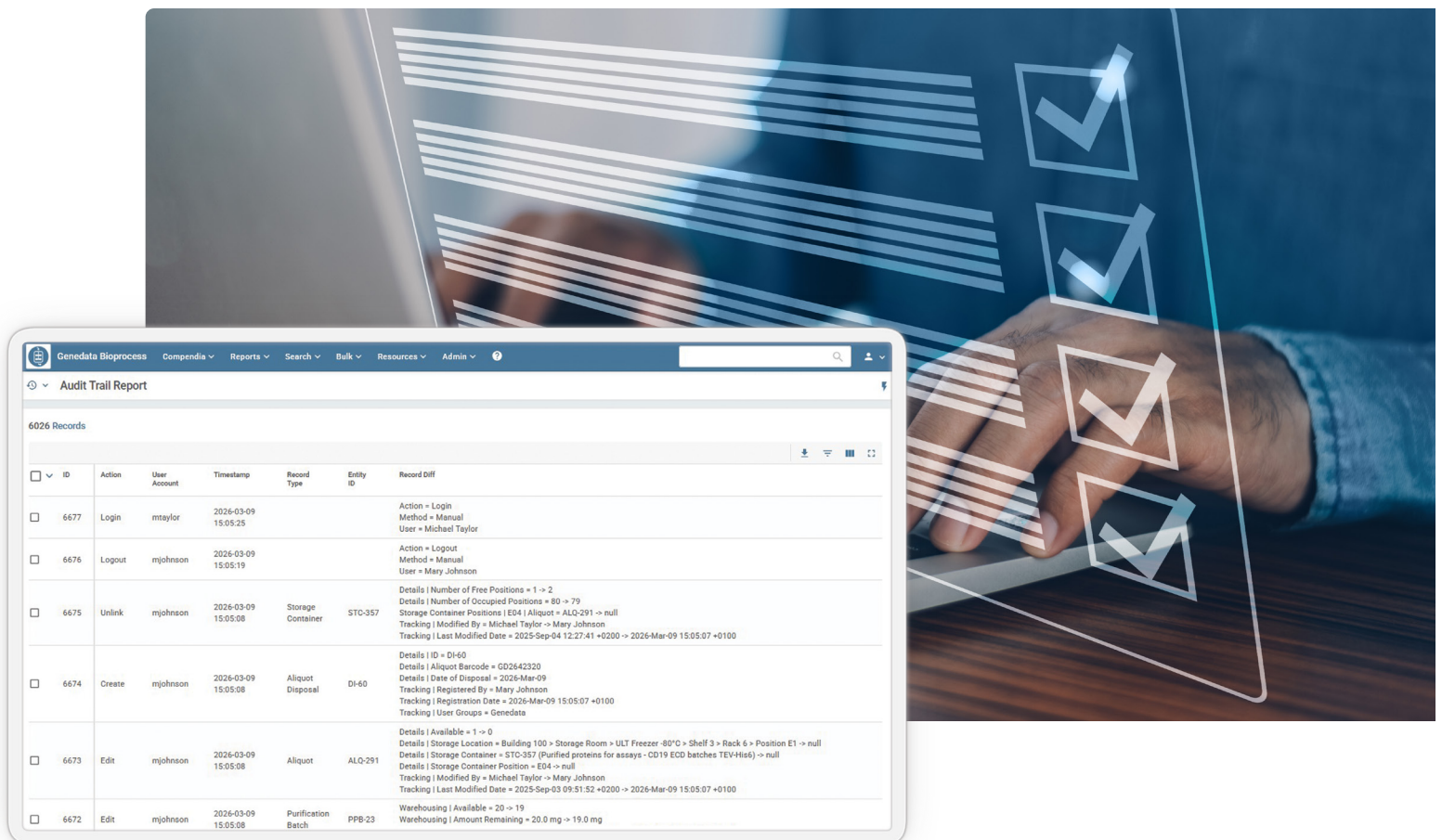


# Genedata Biopharma Platform: Compliance-Ready

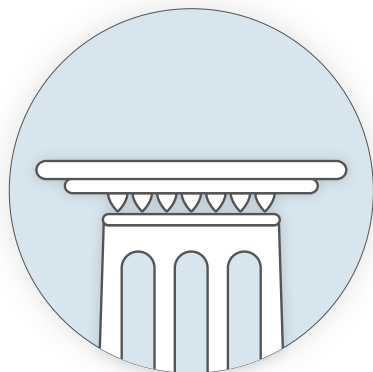


**Audit Trail Report**

6026 Records

<input type="checkbox"/>	ID	Action	User Account	Timestamp	Record Type	Entity ID	Record Diff
<input type="checkbox"/>	6677	Login	mtaylor	2026-03-09 15:05:25			Action = Login Method = Manual User = Michael Taylor
<input type="checkbox"/>	6676	Logout	mjohnson	2026-03-09 15:05:19			Action = Logout Method = Manual User = Mary Johnson
<input type="checkbox"/>	6675	Unlink	mjohnson	2026-03-09 15:05:08	Storage Container	STC-357	Details   Number of Free Positions = 1 -> 2 Details   Number of Occupied Positions = 80 -> 79 Storage Container Positions   ED4   Aliquot = ALQ-291 -> null Tracking   Modified By = Michael Taylor -> Mary Johnson Tracking   Last Modified Date = 2025-Sep-04 12:27:41 +0200 -> 2026-Mar-09 15:05:07 +0100
<input type="checkbox"/>	6674	Create	mjohnson	2026-03-09 15:05:08	Aliquot Disposal	DI-60	Details   ID = DI-60 Details   Aliquot Barcode = GD2642320 Details   Date of Disposal = 2026-Mar-09 Tracking   Registered By = Mary Johnson Tracking   Registration Date = 2026-Mar-09 15:05:07 +0100 Tracking   User Groups = Genedata
<input type="checkbox"/>	6673	Edit	mjohnson	2026-03-09 15:05:08	Aliquot	ALQ-291	Details   Available = 1 -> 0 Details   Storage Location = Building 100 > Storage Room > ULT Freezer -80°C > Shelf 3 > Rack 6 > Position E1 -> null Details   Storage Container = STC-357 (Purified proteins for assays - CD19 ECD batches TEV-His6) -> null Details   Storage Container Position = ED4 -> null Tracking   Modified By = Michael Taylor -> Mary Johnson Tracking   Last Modified Date = 2025-Sep-03 09:51:52 +0200 -> 2026-Mar-09 15:05:07 +0100
<input type="checkbox"/>	6672	Edit	mjohnson	2026-03-09 15:05:08	Purification Batch	PPB-23	Warehousing   Available = 20 -> 19 Warehousing   Amount Remaining = 20.0 mg -> 19.0 mg

# Three Pillars



**Genedata Quality Management System (QMS)**



**Genedata Software with Compliance Functionalities**



**Customer-Specific Validation Support**

✓ FDA 21 CFR Part 11 Ready

✓ EudraLex Vol 4 Annex 11 Ready

✓ FAIR Data & ALCOA++ Function

✓ Open & Scalable Data Infrastructure

✓ Ensured Data Integrity & Security

**A market leader in biopharma R&D digitalization for nearly three decades, Genedata brings deep domain expertise across discovery, process development, and precision medicine.**

The Genedata Biopharma Platform automates scientific workflows for any biotherapeutic modality and provides a central, structured database that captures, stores, processes, integrates, analyzes, and visualizes data across the organization.

By reducing documentation burdens and simplifying processes, the platform enables greater efficiency, accuracy, and agility, while supporting compliant operations.

Designed with an open and scalable architecture, the Genedata Biopharma Platform is future-ready and continuously evolves to meet customer scientific and technical requirements. The platform is developed in alignment with GAMP5 guidelines and enables FAIR (findable, accessible, interoperable, and reusable) data to support efficient, informed decision-making.

The Genedata Biopharma Platform GxP Edition addresses stringent regulatory requirements off the shelf and can be readily deployed in validated GxP environments. It meets the requirements for computerized systems, including FDA 21 CFR Part 11 and EudraLex Vol 4, Annex 11. The platform's underlying data architecture scales to accommodate rapidly growing data volumes while preserving data integrity and minimizing risk.

Comprehensive validation support services are available from our in-house quality assurance experts to help customers rapidly deploy and operate the platform in GxP environments. Our foundation for the compliant use of the Genedata Biopharma Platform is built on three pillars: built-in compliance functionalities, the Genedata QMS governing software development and operational processes, and dedicated validation support services.

**Capitalize on the power of the Genedata Biopharma Platform and start compliantly digitalizing your processes today.**

Ready for Rapid Deployment

# Built-In Compliance Functionalities



## FAIR Data. Ensured.

For over 25 years, Genedata has pioneered FAIR data usage across complex global organizations. The Genedata Biopharma Platform is instrument- and technology-agnostic and can directly integrate with existing systems via web services and APIs. By enabling FAIR data, the Genedata Biopharma Platform provides the necessary foundation for data science, computational modeling, and AI/ML approaches.



## ALCOA++. Built-In.

The Genedata Biopharma Platform follows ALCOA++ principles to ensure product quality, regulatory compliance, and patient safety. Following these principles safeguards data throughout the drug development lifecycle and ensures seamless data transfer with maximum traceability.



## Data Quality & Integrity. Improved.

The Genedata Biopharma Platform enables fully defined, customizable, and configurable workflows, which reduce errors and increase process efficiency. Unique built-in scientific-domain data quality checks (for example sequence integrity, feasibility flags, automatic uniqueness checks, go/no-go signals for batch quality) and detailed analysis reports provide a basis for fast and reliable decision-making.



## Biopharmaceutical Quality Control. Next-Gen.

Rapidly developing technologies such as mass spectrometry and next-generation sequencing have enormous potential to enhance quality control processes for biopharmaceuticals. The Genedata Biopharma Platform facilitates the adoption of these powerful technologies and eliminates data processing bottlenecks to streamline the development of safe and efficacious therapeutics.



## Security. Compliance. Delivered.

Genedata regularly engages in external audits to verify we meet current best practices. This includes business process and cybersecurity audits. Genedata maintains a current SOC 2 Type II report covering the Trust Services Criteria for security, availability, confidentiality, and privacy to ensure that Genedata Managed Cloud installations meet the highest professional standards.

The Genedata Biopharma Platform GxP edition addresses stringent regulatory requirements off the shelf and can be easily deployed in validation GxP environments.



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Genedata transforms biopharma data into intelligence by combining deep science, technology, and AI domain knowledge. From early discovery through development to the clinic, the Genedata Biopharma Platform digitalizes and automates complex data workflows, fueling innovation and data-driven decisions to maximize ROI.  
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