



Miltenyi Biotec

Regulatory compliance with MACSQuantify™ Software

21 CFR Part 11 module on MACSQuant® Analyzers and MACSQuant Tyto® Cell Sorters

Building on the robust framework of MACSQuantify Software, the 21 CFR Part 11 module supports GMP-compliant flow cytometry and cell sorting workflows with secure, traceable, and audit-ready electronic records that streamline your regulatory submissions.

► miltenyibiotec.com/flow-software



Data integrity by design with the MACSQuantify Software

Built on our proprietary, Linux®-based MBCore Operating System and developed to meet IEC 62304 requirements for medical device software, the MACSQuantify Software applies ALCOA+ principles within a Data Integrity by Design framework to keep all records accurate and traceable from acquisition through final reporting.

Streamline your regulatory submissions with the 21 CFR Part 11 module

Enable audit-ready workflows and simplify submissions to the FDA, EMA, and other regulatory agencies by moving from manual documentation to secure electronic records with the 21 CFR Part 11 module for the MACSQuantify Software.

Specifically designed to support GMP-compliant flow cytometry and cell sorting workflows, the 21 CFR Part 11 module is available for MACSQuant Analyzers running MACSQuantify Software 2.11, 2.13, 3.0.1, and 3.0.2, as well as for the MACSQuant Tyto Family of cell sorters operating MACSQuantify Tyto Software 3.1 and higher.

Core features of the 21 CFR Part 11 compliance module

Traceable data

Time-stamped audit trails for all actions

MD5 checksum verification applied to all generated files to confirm authenticity

Reports with electronic signatures

Secure and controlled access

User management system with full segregation of rights and configurable password policies

Support for external authentication services (e.g., AD, LDAP)

Customizable lock-screen functionality to prevent unauthorized access

Automated data backup and disaster recovery system*

Performance and quality control (QC) tracking tool*

* Only available for the MACSQuantify Software version 3.1 and higher

LEARN MORE



Learn more about the MACSQuantify Software solutions for flow cytometry and cell sorting.

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LEARN MORE



Explore our 21 CFR Part 11 Statement for detailed information on all the software features that simplify compliance.

► miltenyibiotec.com/21CFRPart11



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