



2



Feel Free To Explore – With Compliance Built In

Secure compliant qPCR workflows with the optional 21 CFR Part 11 module for qPCRsoft. Designed to meet regulatory requirements, it ensures traceable and auditable data handling—so you can focus on your work with peace of mind.

Easily meet regulatory requirements with the 21 CFR Part 11 compliance module for the qPCRsoft software. Designed specifically for use in pharmaceutical and GxP environments, the module guarantees secure, traceable, and documented handling of electronic records and signatures — from template creation to result approval.



Why 21 CFR Part 11 Compliance Matters

- Ensured data integrity
- Increased traceability
- Meeting regulatory requirements in development, quality control, and routine testing



Supported Standards

- FDA 21 CFR Part 11
- GMP/GxP Environments

Key Features



User Management: Assign user roles and access rights to control data and template editing according to your internal quality procedures.



Audit Trail & Version Control: Benefit from automatic logging of all user activities with timestamps and details, ensuring full transparency and traceability of changes.



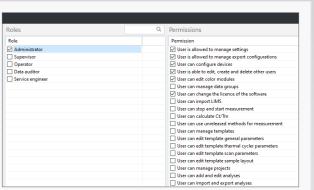
Electronic Signatures: Securely document creation, review, and approval of data following the dual control principle.



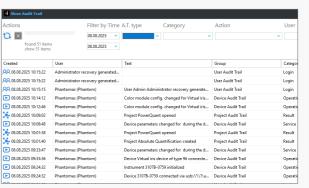
Qualification & Validation Services: Simplify your compliance implementation by using the IQ/OQ service for hardware and on-site software validation support.



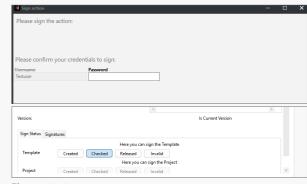
Centralized Data Handling: Securely manage and store qPCR data in a centralized database with easy access from multiple instruments.



User management



Audit trail



Electronic signatures



Order Information

Product	Item Number	Description
21 CFR Part 11 Software Module	844-00702-9	Compliance module for qPCRsoft*
IQ/OQ Hardware Qualification	846-500-900-2-N	Qualification service for qTOWERiris hardware
Software Validation Support	846-500-900-4-N	On-site software validation assistance

^{*} Requires version 6 to operate.

License & System Requirements

- License bound to instrument serial number(s)
- License can be installed on multiple PCs
- Compatible with qPCRsoft V6 on Windows 11





Headquarters

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