

21 CFR Part 11 Compliance with qPCRsoft For Secure and Traceable qPCR Workflows

**21 CFR PART 11
COMPLIANCE**





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.

Roles	Permissions
<input checked="" type="checkbox"/> Administrator <input type="checkbox"/> Supervisor <input type="checkbox"/> Operator <input type="checkbox"/> Data auditor <input type="checkbox"/> Service engineer	<input checked="" type="checkbox"/> User is allowed to manage settings <input checked="" type="checkbox"/> User is allowed to manage export configurations <input checked="" type="checkbox"/> User can configure devices <input checked="" type="checkbox"/> User is able to edit, create and delete other users <input checked="" type="checkbox"/> User can edit color modules <input type="checkbox"/> User can manage data groups <input checked="" type="checkbox"/> User can change the licence of the software <input type="checkbox"/> User can import LIMS <input type="checkbox"/> User can stop and start measurement <input type="checkbox"/> User can calculate Ct/Tm <input type="checkbox"/> User can use unreleased methods for measurement <input type="checkbox"/> User can manage templates <input type="checkbox"/> User can edit template general parameters <input type="checkbox"/> User can edit template thermal cycler parameters <input type="checkbox"/> User can edit template scan parameters <input type="checkbox"/> User can edit template sample layout <input type="checkbox"/> User can manage projects <input type="checkbox"/> User can add and edit analyses <input type="checkbox"/> User can import and export analyses

User management

Created	User	Text	Group	Category
08.08.2025 10:15:22	Administrator	Administrator recovery generated...	User Audit Trail	Login
08.08.2025 10:15:22	Administrator	Administrator recovery generated...	User Audit Trail	Login
08.08.2025 10:15:15	Phantomas (Phantom)	User Admin Administrator recovery generate...	User Audit Trail	Login
08.08.2025 10:14:12	Phantomas (Phantom)	Color module config. changed for Virtual iris...	Device Audit Trail	Operate
08.08.2025 10:12:46	Phantomas (Phantom)	Color module config. changed for Virtual iris...	Device Audit Trail	Operate
08.08.2025 10:09:02	Phantomas (Phantom)	Project PowerQuant opened	Project Audit Trail	Result
08.08.2025 10:08:48	Phantomas (Phantom)	Device parameters changed for during the d...	Device Audit Trail	Service
08.08.2025 10:01:58	Phantomas (Phantom)	Project PowerQuant opened	Project Audit Trail	Result
08.08.2025 10:01:40	Phantomas (Phantom)	Project Absolute Quantification created	Project Audit Trail	Result
08.08.2025 09:33:47	Phantomas (Phantom)	Device parameters changed for during the d...	Device Audit Trail	Service
08.08.2025 09:33:36	Phantomas (Phantom)	Device Virtual iris device of type 96 connecte...	Device Audit Trail	Operate
08.08.2025 09:24:32	Phantomas (Phantom)	Instrument 3107B-0759 initialized	Device Audit Trail	Operate
08.08.2025 09:24:32	Phantomas (Phantom)	Device 3107B-0759 connected via usb/\\171...	Device Audit Trail	Operate

Audit trail

Sign action

Please sign the action:

Please confirm your credentials to sign:

Username: Testuser Password: [input]

Version: [input] Is Current Version

Sign Status: Signatures

Here you can sign the Template

Template: [Created] [Checked] [Released] [Invalid]

Here you can sign the Project

Project: [Created] [Checked] [Released] [Invalid]

Electronic signatures

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



Order Information

Product	Item Number	Description
21 CFR Part 11 Software Module	844-00703-9	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



Learn more about our compliance module and schedule a demo.

www.analytik-jena.com/qTOWERiris-CFR



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Subjects to changes in design and scope of delivery as well as further technical development.

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