

Validation in Regulated Environments

Comet System: Your partner for efficient compliance

Validation in laboratories, pharmaceutical environments, and healthcare is an essential step in meeting regulatory requirements.

Comet System provides both the technology and the documentation – you confirm compliance within your own operation.

Qualification Documentation (IQ / OQ)

For the Comet Cloud system, we provide documentation to support validation:

- **IQ – Installation Qualification**
Documentation confirming correct installation and configuration of the system.
- **OQ – Operational Qualification**
Test scenarios verifying proper functionality of all key system features.
- **Technical System Description**
Supporting documentation for internal processes, data security, and access control management (RBAC).
- **Regulatory Documentation**
Support for compliance with regulations such as 21 CFR Part 11.

These documents serve as a basis for your internal validation process.

Division of Responsibilities

Comet System	Customer
Provides technically ready system	Defines URS
Provides IQ/OQ documentation	Performs risk analysis
Provides Audit Trail	Performs PQ
Provides regulatory documentation	Approves the system for operation

New: Audit Trail – A Validation Tool

The **Audit Trail** feature supports the validation process by ensuring:

- Automatic recording of **WHO – WHAT – WHEN**
- Immutability of audit records
- Export of reports (PDF)
- Regeneration of reports

Audit Trail provides documented proof of data integrity during audits.

Why is this important?

Validation must demonstrate that the system:

- Operates according to its intended use
- Is controlled and managed
- Ensures data integrity
- Supports traceability of changes

Comet Cloud is prepared for this process.

Comet delivers a validation-ready and documented system.
You validate it according to your regulatory requirements.