



# Metrohm Qualification Services

Trust is earned

**PEOPLE  
YOU  
CAN  
TRUST**





# We ensure you are audit-ready!

## HAVE YOU EVER FELT UNCERTAIN ABOUT YOUR NEXT AUDIT?

### Are you struggling to ensure your analytical instruments meet regulatory standards?

The daily work in a regulated environment has no room for compromises. Analytical Instrument Qualification is essential for generating reliable and compliant data. Get peace of mind with IQ/OQ procedures backed by the knowledge only the manufacturer can provide.

### Beyond instrument qualification

We don't just qualify your system – we ensure consistent, high-quality results and full reliability throughout your system's entire lifecycle.

Every step of the qualification process is meticulously recorded in a comprehensive and easy-to-navigate documentation set. This documentation serves as a vital reference for regulatory audits and accelerates your review processes.

Metrohm IQ/OQ procedures are designed to reduce the time needed for their execution. Our automated procedures ensure your system downtime is kept to a minimum.

## YOUR BENEFITS WITH IQ/OQ FROM METROHM

### PEACE OF MIND

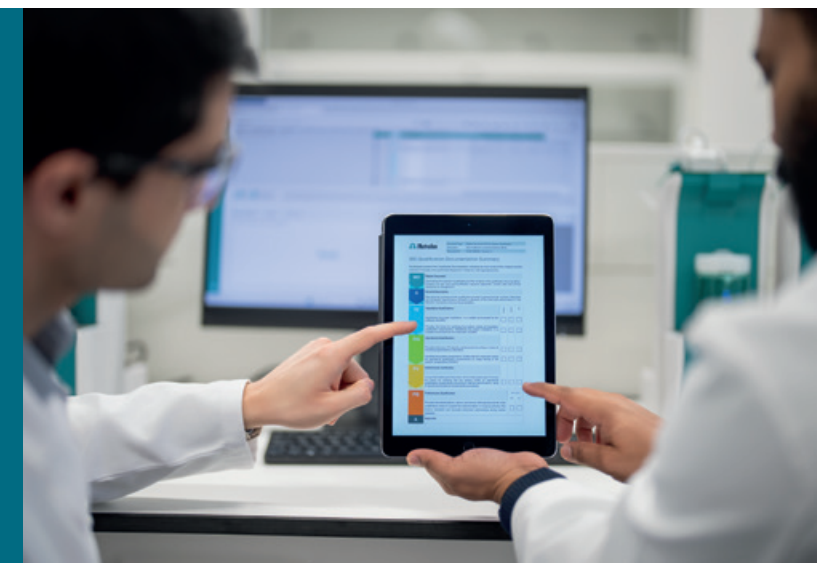
- **Confidence in our expertise:** Our engineers, trained and certified in IQ/OQ procedures, ensure your system meets regulatory standards.
- **Ensured Data Integrity:** Traceable, digital documentation from day one.

### MAXIMUM EFFICIENCY

- **Audit-ready documentation:** Clear and well-organized documentation for smooth audits and faster reviews.
- **Minimal Downtime:** Automated tests ensure faster and error-free execution.
- **Remote Software Validation:** Upon request, the OMNIS automated software validation can be performed remotely.

### COMPLETE LIFECYCLE SUPPORT

- **Tailored Services:** Consultation before the purchase and support for your system until its end of life.





# Metrohm Qualification Services – An overview

## A COST-EFFECTIVE APPROACH

Depending on the environment you work in, and your specific requirements, we offer a tailored qualification approach. We deliver exactly what your system needs over its lifecycle. The level of qualification required depends on your risk assessment. We focus on testing what needs to be qualified. This streamlined approach makes the complete qualification process as efficient as possible.

### OPERATIONAL QUALIFICATION (OQ) – SOFTWARE

We use **automated software validation procedures** to ensure that the OMNIS Software performs on your client PC as expected. These are available for OMNIS Stand-Alone and Client/Server setups. **Parallel client validation** makes sure your OMNIS Client/Server network remains operational during the validation process – safeguarding your productivity.



### INSTALLATION QUALIFICATION (IQ)

We provide you with documented proof that your Metrohm instrument and software have been installed correctly. This includes records for the instrument delivery, the hardware setup and all connections. The OMNIS Software installation and the exact configuration of each PC client are also fully traceable.



### OPERATIONAL QUALIFICATION (OQ) – PERFORMANCE VERIFICATION (PV)

We validate the performance of your complete Metrohm setup using proven, standardized procedures. By conducting a series of «wet chemical» tests with certified reference materials, we confirm that your system delivers the accuracy and precision it was designed for – right in your own laboratory environment.

### OPERATIONAL QUALIFICATION (OQ) – HARDWARE

We demonstrate that the components of your Metrohm instrument operate correctly as per their operational specifications. Each hardware component undergoes a series of predefined and traceable tests. This ensures that the Metrohm standards about safety, performance, and reliability are fulfilled.



### PERFORMANCE QUALIFICATION – (PQ)

We support you in the final qualification step proving the reliability of your system. After successful execution of the Installation Qualification and Operational Qualification, we support you in setting up a test under your real-use conditions. This ensures that your system consistently performs for your specific intended use.





# More than just IQ/OQ ...

Our Qualification Services go far beyond the qualification of your Metrohm system. Analytical Instrument Qualification ensures the generation of high-quality data with the required data integrity. Our Qualification Services are about confidence – confidence that we will support you from the moment you define the specifications for your next Metrohm system, and up until it is time to decommission it.

## DESIGN QUALIFICATION – DQ

Confidence that the specifications for your next Metrohm instrument align with your intended purpose.



## INSTALLATION QUALIFICATION – IQ

Confidence that your Metrohm instrument and software have been correctly installed.



## INSTRUMENT DECOMMISSIONING

Confidence that the retirement of your Metrohm system is properly documented based on your own assessment.



## OPERATIONAL QUALIFICATION – OQ HARDWARE

Confidence that each hardware component of your Metrohm system functions correctly from the beginning.



## PERIODIC REQUALIFICATION

Confidence that your Metrohm system remains in a qualified status over its complete lifecycle.



## OPERATIONAL QUALIFICATION – OQ SOFTWARE

Confidence that the OMNIS Software performs as expected on your client PC.



**CONFIDENCE ALONG  
THE ENTIRE  
LIFECYCLE OF YOUR  
METROHM SYSTEM**

## PERFORMANCE QUALIFICATION – PQ

Confidence that your specific operational requirements and quality standards are met consistently.



## OPERATIONAL QUALIFICATION – PERFORMANCE VERIFICATION (PV)

Confidence that your Metrohm system as a whole produces accurate and precise results.



# Metrohm – People you can trust

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## WE ARE YOUR PARTNER FOR REGULATORY COMPLIANCE!

For decades, regulated industries have relied on Metrohm for qualification services. Our certified service engineers are regularly re-trained to uphold the highest standards. Customers worldwide trust Metrohm for consistent, expert support.

«I recommend Metrohm IQ/OQ documentation. Meaningful and good quality reports are a must for us. With Metrohm documentation I do not have a 'black box' documentation, but a quality documentation.»

*QM Manager,  
leading global pharmaceutical company*

«Automated Validation is at the cutting edge in the industry. This is one of the main criteria that I look at when purchasing my next Metrohm system.»

*QC Manager,  
leading global pharmaceutical company*



[www.metrohm.com](http://www.metrohm.com)