

# Analytical Instrument Qualification

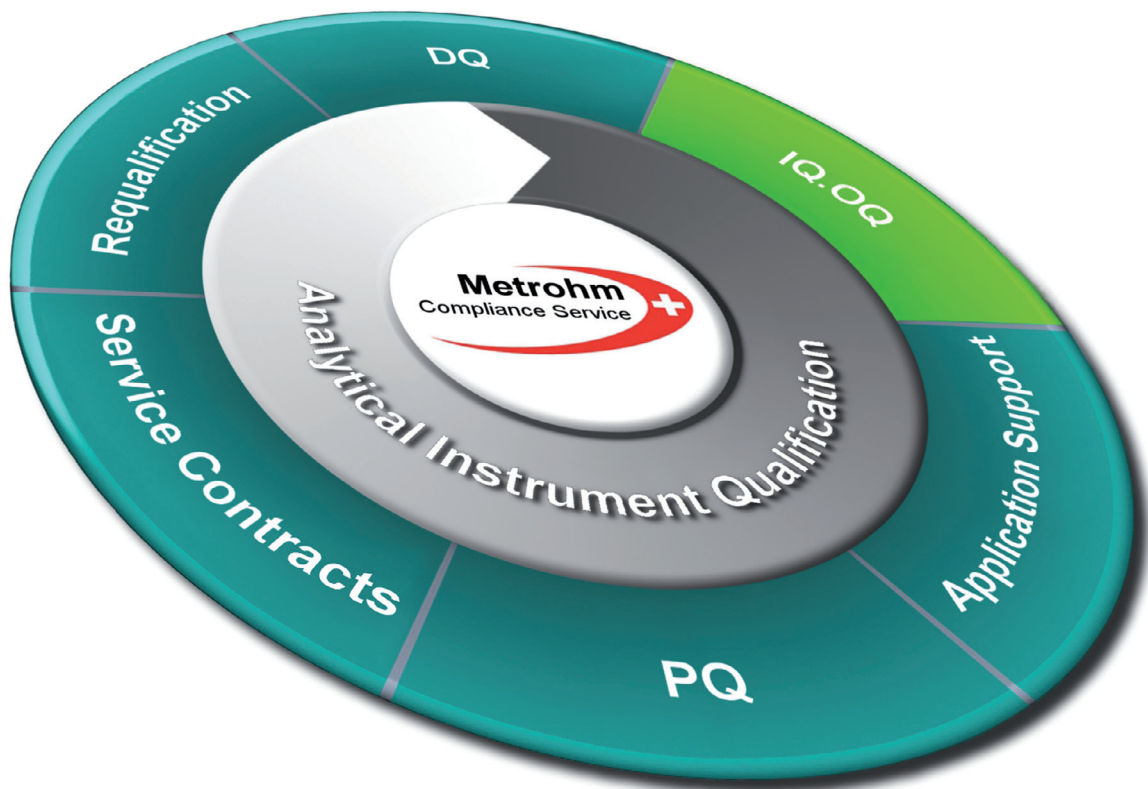


Confidence in quality with IQ/OQ

## Metrohm – because quality matters

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- certified and professional IQ/OQ
- accurate and precise results
- regulatory compliance
- complete traceability
- support when you need it





## Play it safe with professional and certified IQ/OQ

As QA manager in a regulated industry you face strict requirements regarding Analytical Instrument Qualification (AIQ). However, complying with the very latest regulations from the USP, FDA, GAMP, PIC/S, and other regulative authorities at all times is a challenge that takes time and effort.

With this in mind, Metrohm have developed services exactly tailored to your needs. These services do not just ensure the perfect operation of the component parts of your hardware and software but also the correct operation of your analytical system as a whole. Your benefits are clear. Rely-ing on the professional services of our trained and certified qualifying engineers, you protect yourself against liability while saving valuable time and money that you can spend on other work in your lab.

These are your key benefits of the Metrohm AIQ Services:

- Compliance with the latest regulations and standards (ISO, USP 1058, GAMP, 21 CFR pt 11, PIC/S, etc.).
- Documented proof of whole system operation functionality.
- Confidence in the quality of the data you produce, from the start.
- Traceable monitoring of the system performance through regular re-qualification and testing.
- Peace of mind that the qualifying engineers are trained and certified in all procedures.

# Flexible documentation services to qualify your instruments

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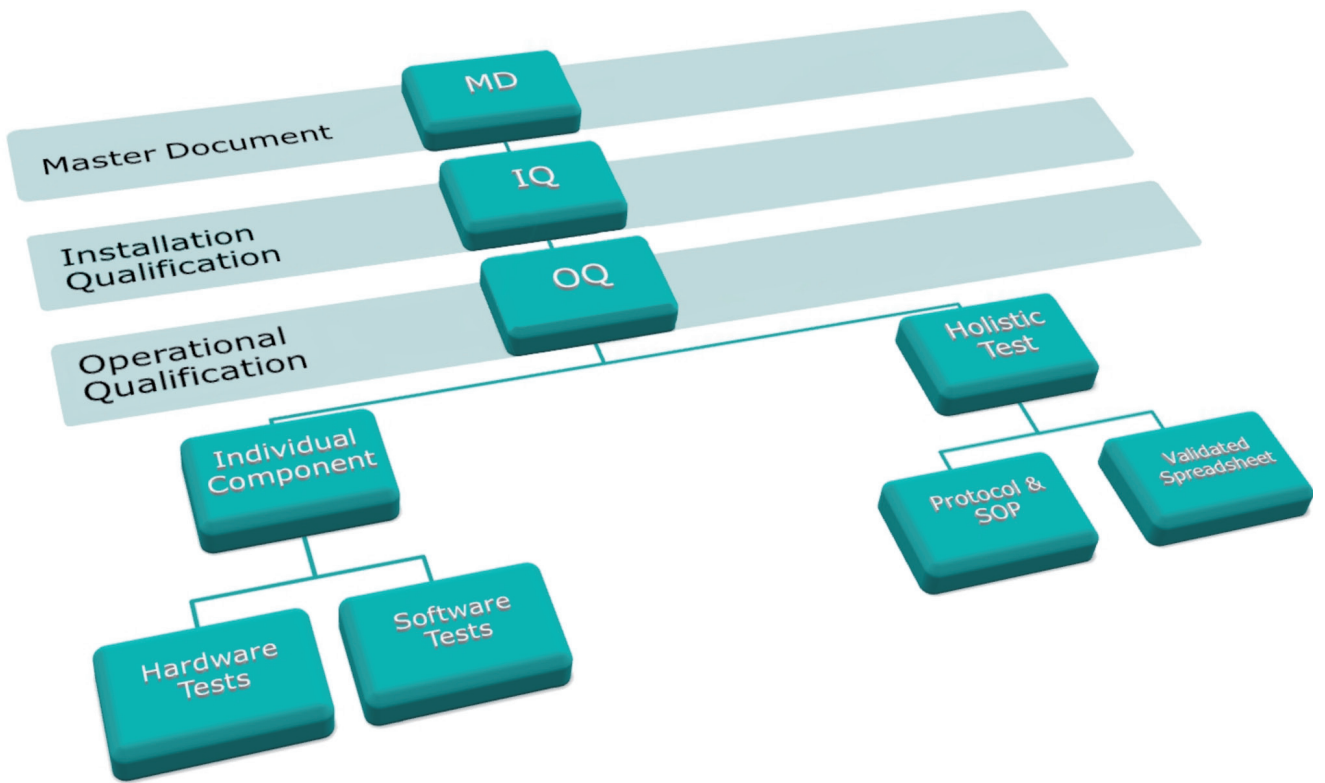
## Why choose IQ/OQ by Metrohm?

Analytical Instrument Qualification by Metrohm provides a simple, modular approach to the process of qualification. Each module documents completely and reliably:

- The identity and credentials of personnel performing and reviewing the qualification.
- The identity of each instrument, software, and document involved in the qualification.
- The holistic test procedures performed to prove the accuracy and precision of the results.
- The correct operation of the instruments with operator training as an optional part of the qualification.

## The Master Document – always see the bigger picture

The master document is the central organising document for the AIQ procedures. It describes not only the process of installing and qualifying the instruments, but also the competence and training of the qualifying engineer. The master document also identifies the other components to be added to the qualification – this gives a really flexible framework on which to build up a set of documentation. The master document is the entry-point of any Metrohm qualification process as it indexes all other documents included in the process.



- Modular document structure
- Individual component tests
- Holistic system test
- Engineer certification
- Certified reference instruments



### **Installation Qualification – the best start you can get**

The installation qualification is designed to ensure the environment is suitable for the instruments. The installation qualification outlines all the information required to assemble both the Metrohm and any non-Metrohm components. For the hardware this means documenting the hardware and the connections made, and this provides a useful record of the instrumental set-up at day one of operation. The installation qualification of the software, similarly, details exactly the configuration of each PC client and the software installed.

### **Operational Qualification – hardware test**

The individual component tests are performed according to set procedures designed to guarantee your instrument works without fault. The test procedures contain a mixture of manual and automated tests to check the safety, performance and reliability of each instrument. This provides you with vital proof that the instrument is working perfectly, as designed, and is safe to use.

### **Operational Qualification – software tests**

Just as every function and feature of the hardware must be extensively tested to prove everything works correctly, so each and every function of the software is tested to prove that it reliably functions on the computer it has been installed on.

For Client-Server installation the tests provide documented proof that the functions of the software operating over the network perform correctly.

This detailed functional test procedure is provided not just for PC software but also for the new Touch Control instruments.

### **Holistic Test – prove the accuracy and precision of your results any time**

Once each individual component has been tested in isolation, the performance of the system as a whole is proven by means of a «holistic» test. The holistic test verifies the components have been assembled and configured correctly and that the software or Touch Control is set up correctly to receive data and print reports.

The holistic test is a series of «wet-chemical» tests performed using certified reference materials to prove the system is capable of generating quality data, i.e. results that are accurate, precise and above all fit for purpose.

### **A Standard Operating Procedure (SOP) for each analytical technique**

For each ion analytical technique, Metrohm has developed a standard operating procedure (SOP) – outlining exactly how to perform the test. This SOP is included in the documentation, demonstrating clearly and openly the analysis procedure used.

Qualifying engineers also receive extensive training and certification on performing the chemical tests.

The results of the data generated must be handled correctly to generate some performance indicative statistics. For this reason, for each technique and SOP, Metrohm has developed and validated a spreadsheet, which is appended to the documentation.



## Metrohm – your trusted partner in all matters of regulatory compliance

### **Design Qualification**

Competent and professional decision making in the design process provides instruments guaranteed to fulfill the user requirements

### **IQ/OQ – Installation Qualification/ Operational Qualification**

New compliance documentation provides you with peace of mind and liability protection

### **Application Support**

You get the answers you need – with help, support and advice from our global team of application specialists

### **PQ – Performance Qualification**

Performance qualification of methods can be arranged in co-operation with our dedicated quality professionals

### **Service Contracts**

Periodic preventative maintenance prevents/reduces down time and guarantees the optimal performance each component

### **Re-Qualification**

Routinely document and prove the accuracy and precision of your system

# Standardize your documentation – worldwide

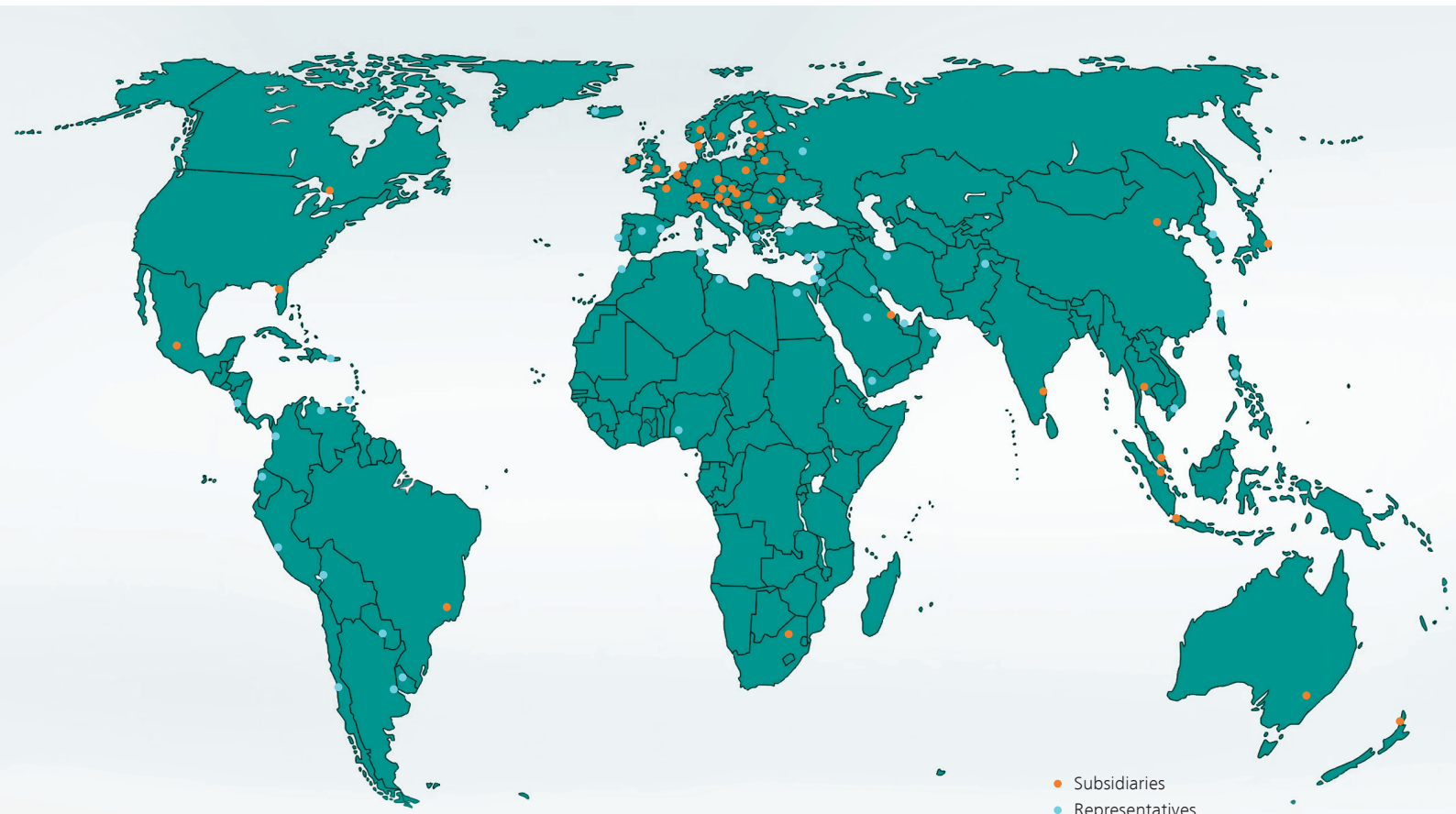
## We are where you are – everywhere

Metrohm is represented exclusively in more than 80 countries, with direct subsidiaries in more than 40.

Well-known companies from all industrial sectors rely on our instruments and applications. Our customers come from the chemical, petrochemical and pharmaceutical industries, as well as from the automotive and food industry and environmental laboratories and universities.

The Metrohm compliance services and AIQ documentation provide a globally consistent service.

This guarantees worldwide compliance to the latest regulatory requirements and a consistent set of documentation in every country.



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