

## **IQ and OQ made easy – with the practical validation documentation from Metrohm**

Metrohm Ltd. has always been highly quality-conscious and is ready to support you in the implementation of quality management measures in your laboratory. We have therefore compiled comprehensive validation documents for many of our instruments. These provide manifold information and practical help for carrying out the Installation Qualification (IQ) and Operational Qualification (OQ). Using the forms contained in the validation binder, each working step can be documented during the installation and start-up of the analytical instrument or analysis system.

The Installation Qualification begins with checking the correctness and completeness of the supply; attention should be given to any transport damage. This is followed by the description and assessment of the workplace and the existing electrical connections. The analysis system is set up and connected according to the manufacturer's instructions. A functional check of the individual components concludes the Installation Qualification.

Within the context of the Operational Qualification the supplied certificates have first to be checked. The actual start-up of the analysis system begins with electronically checking the measuring inputs of the individual instruments according to a defined procedure. The complete system is then subjected to a detailed test. This performance check is carried out by means of a standard application (e.g. titer determination) using certified reagents. The results are documented and compared with the acceptance criteria defined in the Design Qualification.



Extremely helpful in the Installation and Operational Qualification: the comprehensive validation documentation from Metrohm.

Instructing and training the operating personnel also forms part of the Operational Qualification. The completed training must be documented, each user being provided with a separate training control sheet.

Finally the intervals for carrying out the Performance Qualification are defined. Is a contract for regular certified instrument maintenance to be signed? Are additional periodic checks necessary? All these activities are entered in the instrument logbook contained in the validation binder as a matter of course.

You can obtain the practical validation documentation, for which a charge is made, from your local Metrohm agency. The general order number is 6.998.XXX.Y, with XXX standing for the number of the respective instrument (e.g. 751 for the 751 GPD Titrino) and Y for the required language version (3 for the English, 1 for the German version).

Currently the validation binders are available for all potentiometric and Karl Fischer titrators, the 756 KF Coulometer as well as our compact IC systems (see overview shown below). Additional Metrohm instruments will follow in the near future.

#### **Validation documents currently available**

	<b>English</b>	<b>German</b>
<b>Potentiometric titrators</b>		
702 SET/MET Titrino	6.998.702.3	6.998.702.1
716 DMS Titrino	6.998.716.3	6.998.716.1
718 STAT Titrino	6.998.718.3	6.998.718.1
719 SET Titrino	6.998.719.3	6.998.719.1
736 GP Titrino	6.998.736.3	6.998.736.1
751 GPD Titrino	6.998.771.3	6.998.771.1
785 DMP Titrino	6.998.785.3	6.998.785.1
<b>Karl Fischer titrators</b>		
701 KF Titrino	6.998.701.3	6.998.701.1
756 KF Coulometer	6.998.756.3	6.998.756.1
758 KFD Titrino	6.998.758.3	6.998.758.1
784 KFP Titrino	6.998.784.3	6.998.784.1
<b>Ion chromatography</b>		
761 Compact IC	6.998.761.3	6.998.761.1
790 Personal IC	6.998.790.3	6.998.790.1
792 Basic IC	6.998.792.3	6.998.792.1

*We live on an island  
surrounded by a sea  
of ignorance.  
As our island  
of knowledge grows,  
so does the shore  
of our ignorance.*

*John Archibald Wheeler*