Efficient system validation
LabX validation services

Whether you have to validate your system to comply with regulatory needs or you want to improve internal quality standards, the METTLER TOLEDO Validation Services is where you get professional support and additional information to make your life easier. System Validation is the last step of a whole series of qualification steps for your system. An analytical instrument first has to pass the:

- IQ (installation qualification)
- OQ (operational qualification)
- PQ (process qualification)

After these tests are successfully completed (i.e. the instrument itself is qualified), you may want to validate the LabX instrument control software in order to prove that the complete system performs as specified.

METTLER TOLEDO can help you to efficiently go through the LabX system validation by offering the following tools and services:

- **Validation Service**: Full on-site support of the LabX validation.
- **Validation Manual I**: Folder containing all information necessary for the qualification of METTLER TOLEDO as software supplier.
- **Validation Manual II**: Folder containing guidelines and all the necessary forms for the LabX system validation.
- **Revalidation Service**: Information package including new forms for the revalidation after a LabX upgrade/update.

An overview of the content of the validation manuals and the revalidation package is given on the back page. For further information please contact your METTLER TOLEDO representative.
### Contents of LabX validation manual I:
*(titration version as example, balance version differs slightly)*

1. **Non-disclosure Agreement**
2. **Overview**
   2.1 Purpose and amendments
   2.2 LabX validation services
   2.3 LabX validation phase plan
3. **Company Information and Structure**
   3.1 Contact address
   3.2 Parent company address
   3.3 Company information
   3.4 Company structure
   3.5 Employees
   3.6 Company history
   3.7 Customers
   3.8 Product portfolio
4. **Quality Management System: Infrastructure**
   4.1 Responsibilities
   4.2 Definition of general procedures
   4.3 Project planning and organization
   4.4 Audits
   4.5 Type approvals
   4.6 Qualification and suitability of staff
   4.7 Improvement programs
   4.8 Use of sub-contractors
   4.9 Validation experience and healthcare regulations
   4.10 Reviews and corrective actions
   4.11 Documentation
   4.12 Data security
5. **Quality Management System: Software Development**
   5.1 Software development procedure
   5.2 Software change procedure
   5.3 Administration of software masters
   5.4 Administration of related documents
6. **LabX Development Process**
   6.1 LabX user requirements
   6.2 LabX project planning
   6.3 LabX functional specification
   6.4 LabX software design and modules specification
   6.5 LabX code production
   6.6 LabX testing
   6.7 Market introduction
7. **LabX Sales, Support and Training**
   7.1 Software master and reproduction
   7.2 License
   7.3 Software distribution
   7.4 Software maintenance, upgrades and after sales support
   7.5 Training of the sales force
   7.6 Customer training
8. **Appendix**
   8.1 Documentation of software changes
   8.2 Sample system assessment report relating
   8.3 High level postal audits
   8.4 Table of exhibits

### Contents of LabX validation manual II:
*(titration version as example, balance version differs slightly)*

1. **Purpose and Administration**
2. **Validation Procedure**
   2.1 Validation Phases LabX
   2.2 Validation Procedure LabX
   2.3 Validation Responsibilities LabX
   2.4 Validation Team
3. **System Overview**
   3.1 LabX System layout example
   3.2 LabX titration software brochure
   3.3 LabX network installation instruction
4. **Installation Qualification Phase (IQ)**
   4.1 Documentation Identification
   4.2 Equipment and cable Identification
   4.3 Compliance to System layout
   4.4 Cabling Inspection
   4.5 Equipment Calibration
   4.6 System start
   4.7 Software Installation
5. **Operational Qualification Phase (OQ)**
   5.1 Configure Peripherals
   5.2 Test Peripherals
   5.3 Functionality test
   5.4 Check user manager/access control
   5.5 Check audit trail
   5.6 Back up procedure (Database)
6. **System security**
   6.1 System security LabX
7. **Back up**
   7.1 Server file back up
8. **Disaster recovery**
   8.1 Disaster recovery procedure
9. **Release notes**

### Contents of the LabX Revalidation Package
- Release notes of the new version
- Revalidation guidelines
- New pages for validation manual II
- Copies of forms for parts of Validation Manual II that have to be redone during revalidation