

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**
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 - 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**
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 - 4.2 Definition of general procedures
 - 4.3 Project planning and organization
 - 4.4 Audits
 - 4.5 Type approvals
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 - 4.7 Improvement programs
 - 4.8 Use of sub-contractors
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 - 4.10 Reviews and corrective actions
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 - 4.12 Data security
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 - 5.2 Software change procedure
 - 5.3 Administration of software masters
 - 5.4 Administration of related documents
- 6 LabX Development Process**
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 - 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**
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 - 7.2 License
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 - 7.4 Software maintenance, upgrades and after sales support
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- 8 Appendix**
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Contents of LabX validation manual II:

(titration version as example, balance version differs slightly)

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- 2. Validation Procedure**
 - 2.1 Validation Phases LabX
 - 2.2 Validation Procedure LabX
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 - 3.1 LabX System layout example
 - 3.2 LabX titration software brochure
 - 3.3 LabX network installation instruction
- 4. Installation Qualification Phase (IQ)**
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 - 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



Quality certificate ISO 9001
 Environmental management system ISO 14001
 Internet: <http://www.mt.com>
 Worldwide service

Subject to technical changes
 © 09/2004 Mettler-Toledo GmbH
 Printed in Switzerland 51724385
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