

MassLynx Basic Security

Built-in System Integrity

MANAGE SYSTEM ACCESS

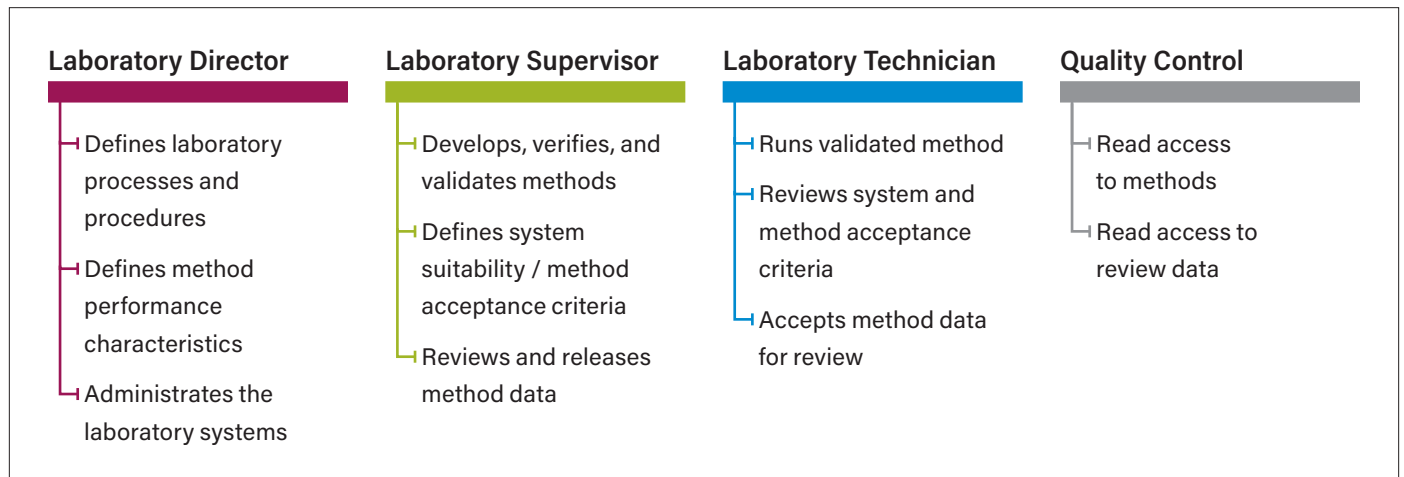
With Waters™ MassLynx™ Basic Security, you're in control. MassLynx Basic Security is ideal for clinical laboratories who need to manage or control access to an LC-MS system. With MassLynx Basic Security you can manage system access of specific users and assign access rights to different system functions, giving you more control and increasing the ease of use for the everyday user.

Need to know who did what for an audit or an accreditation? An events audit log is maintained for added traceability, which identifies the user accessing the system, performing the analysis and processing the data. MassLynx Basic Security can be used with MassLynx Instrument Control and Acquisition Software including, TargetLynx™ XS and IonLynx™ application managers.

ENSURE LABORATORY WORKFLOW MEETS REGULATORY REQUIREMENTS

Clinical laboratory quality management systems (QMS) need to comply with local (Standards and Certification: Laboratory Requirements, 42CFR493) and international guidelines (ISO 15189) in order to report results.

One important aspect of a laboratory's QMS is documenting laboratory staff qualifications and assigned responsibilities dependent on their role. Using MassLynx Basic Security Software, the Laboratory Director configures the software to ensure only trained laboratory staff can access MassLynx functionality based on their assigned role, thereby, aiding laboratory compliance.



Schematic illustrating how a laboratory can assign roles when implementing MassLynx Basic Security.

HOW IT WORKS

MassLynx user accounts are created from existing Microsoft Windows user accounts with their credentials being authenticated against the Operating System. Only an Administrator (full privileges) can access the MassLynx Security Manager and configure individual user access based on Group Rights (Laboratory Role). For example, a Method Developer and Analyst could both have access to method files but only a Method Developer would be able to create a new method.

The screenshot shows the MassLynx Security Manager interface with a 'Manage Group' dialog box for the 'Analysts' group. The dialog shows the group name, description, members, and a list of rights. The 'Group Rights' dialog is also open, showing a list of permissions with checkboxes for 'ACE Inlet Editor' and 'Acquisition'.

Group Name	Role	Responsibilities
Administrator	Laboratory Director	<ul style="list-style-type: none"> Configures MassLynx Security Manager Defines group rights (Laboratory Role) Assigns users to groups
Method Developer	Laboratory Supervisor	<ul style="list-style-type: none"> Full access to UPLC-MS/MS systems and software Resolution and calibration setup Create acquisition and processing methods Troubleshoot methods
Analyst	Laboratory Technician	<ul style="list-style-type: none"> Create sample batches, run acquisition, and processing methods Review system suitability and batch acceptance criteria Accept TargetLynx XS datasets
Reviewer	Quality Control	<ul style="list-style-type: none"> Review UPLC-MS/MS methods Review TargetLynx XS datasets Print and report results

Examples of Groups (laboratory role) and Rights (access and actions in MassLynx and TargetLynx XS) configurations in MassLynx Basic Security.

The MassLynx Security Manager incorporates a configurable Audit Policy for software interactions (such as logging on or off, security policy changes, and permission checks) which are recorded in an encrypted Audit Database. The Audit Database is not editable, cannot be deleted, and can be reviewed by an Administrator using the dedicated LogLynx™ Application Manager.

The TargetLynx XS Application Manager, for post-acquisition, automates the processing and reporting of quantitative results. Embedded in the TargetLynx XS report file are all the sample acquisition and processing parameters and an audit log. The audit log records user actions including; datafile generation, data modifications (e.g. manual integration and calibration point exclusion) and the acceptance and review of the dataset. Also, signatures and reasons may be added when altering the dataset to track data integrity and assist quality review.

CONFIGURED ACCESS

MassLynx Basic Security is designed to assist with your laboratory compliance through the implementation of laboratory roles and responsibilities for Waters IVD System Solutions. With MassLynx Basic Security, you're in control.



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Waters Corporation
 34 Maple Street
 Milford, MA 01757 U.S.A.
 T: 1 508 478 2000
 F: 1 508 872 1990
 www.waters.com