

Become compliant with SoftMax Pro GxP Software

SoftMax Pro GxP Software is the latest, most secure software to achieve full FDA 21 CFR Part 11 and EudraLex Annex 11 compliance with streamlined workflows to ensure data integrity. Every step is optimized to simplify analysis and reporting to support our microplate readers.

Below are key guidelines that regulated labs are required to follow to become compliant.

User administration

Regulatory guidelines require that only authorized individuals have access to the system. SoftMax® Pro GxP Software allows user administration either via the GxP Admin Software, or users can connect to their company's Windows Active Directory (starting at version 7.1.1) system. This simplifies defining password criteria, reset, and change periods.

GxP Admin Software also comes with three predefined factory roles; Scientist, Lab Manager, and Lab Technician roles, to accommodate the document release workflow. Permissions are defined on a per role basis and assigned accordingly to a user within a project. Users can have different roles in different projects. Granular permission setting options are available to create custom roles based on your needs.

System audit trail

Regulatory guidelines require the use of secure, computer-generated audit trails that record date and time stamps of end user actions. Each SoftMax Pro GxP Software data document file has its own audit trail. The GxP Admin Portal software maintains filterable system audit trail information that reports end user activities within the software and database.

eSignatures and time stamps

Regulatory guidelines require that the electronic signatures be used to hold individuals accountable and responsible for actions. Electronic signatures should employ at least two distinct identification components such as an identification code and password. SoftMax Pro GxP Software is designed where electronic signatures are linked directly to their respective electronic records and cannot be decoupled from the records itself. Electronic signature functionality requires the entry of both username and password; and both must be re-entered for each subsequent application of an electronic signature.

Validation package

Regulatory guidelines require validation of the system to ensure accuracy, reliability, and consistent intended performance and the ability to discern invalid or altered records. The Molecular Devices Professional Services team of experts provide validation services to help end users achieve FDA 21 CFR Part 11 and EudraLex Annex 11 compliance.

Contact Us

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Check our website for a current listing of worldwide distributors.

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