



COMPARISON SHEET

SoftMax Pro 7.1.2 GxP Software

Address your compliance needs

SoftMax® Pro 7.1.2 GxP Software is the latest, most secure software to achieve full FDA 21 CFR Part 11 compliance with streamlined workflows to ensure data integrity. Every step is optimized to simplify analysis and reporting to support our microplate readers. Our expert team will partner with you to establish environments to conduct GMP/GLP (GxP) compliant work.

What's new?

Previous version: 7.1.1

Importing files

- Only SMP 6 and 7 file formats could be imported into the database.

Previous versions: 7.0.3 and lower

File-based audit trails

- Hard to track individual events without filtering options

Folder-based data storage

- Files were stored in a Windows folder-based system on a hard drive

NEW version: 7.1.2

Legacy file import

- The system supports the import of SMP 4.0 – 5.4 documents (*.pda & *.ppr)
- The system supports the import of SMP GxP 4.3 – 5.4 documents (*.eda & *.epr)

System audit trail

- The system audit trail tracks and records all actions for easy identification
- Electronic signatures and date/time stamps provide paperless documentation
- Filtering information simplifies quality control and handling during audits making data export to Excel unnecessary

Microsoft SQL Express database

- Enterprise-level document sharing with complete control over file access permissions
- Windows folder permission system is no longer needed
- Can be easily upgraded later to a regular SQL database for larger amounts of data
- Reduced support from IT departments

Previous versions: 7.0.3 and lower

Manual document status system

- Difficult to track document progress

Projects feature was not available

- Couldn't give project teams access to the same folder
- Setting permission levels was time intensive

User-based permissions

- User-based permissions made it difficult to track which user had what permissions
- Changing permissions for user groups was time intensive

Signed XML files and PDFs were not available

Time-consuming to manage user logins for several software packages

NEW version: 7.1.2

Document workflow and status system

- The paperless, document status system maintains data integrity with control over document workflows
- Project teams can track documents while they are moving through development, review, release, and usage in a controlled environment

Projects feature

- Can quickly create various project teams and increase usability
- Project team members only have access to projects they are assigned to, eliminating the need for IT to create Project folders with custom permissions

Predefined permission schemes

GxP Admin comes with three predefined factory roles:

- Scientist, Lab Manager, and Lab Tech to accommodate the document release workflow
- Any number of additional roles can be created and customized
- Permissions are defined on a per role basis and then assigned to a user within a project
- Users can have different roles within different projects
- Over 50 permission setting options to accommodate for individual SOPs

Improved auto-export functionality

- Data can be exported to a location outside the database. Various file formats are available to support the import into other data collection and storage applications—specifically LIMS or SDMS (Scientific Data Management System) packages
- Signed XML files provide state-of-the-art data integrity
- Multiple formats can be exported at once
- PDF exports provide a convenient way of archiving data outside the database or to create a snapshot

Windows Active Directory option

- User Administration can be connected to the company Windows Active Directory system
 - Simplifies password administration and reduces IT support
 - Password criteria options increased to meet diverse password needs

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