



# SoftMax Pro 7.1 GxP Software

## Address your compliance needs

SoftMax® Pro 7.1 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: 7.0.3

#### File-based audit trails

- Compromised data integrity
- Hard to track individual events without filtering options

#### File-based databases

- Files were stored in a Windows file-based system
- Had size limitations and couldn't be upgraded

#### Manual document status system

- Difficult to track document progress
- Renaming workarounds created compliance issues

### NEW version: 7.1

#### 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

#### 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

## Previous version: 7.0.3

### Risk of lost or compromised data

- Predefined data storage and file location was needed to avoid loss of data
- Risk of losing compliance data without an auto-save feature

### 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

### Couldn't import legacy files

### Time-consuming to manage several software packages

### Contact Us

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## NEW version: 7.1

### Improved auto-save functionality

- Documents can be defined at the design stage
- Documents are automatically saved before and after a read to prevent the loss of data

### 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. Roles are then assigned to a user within a project
- Users can have different roles within different projects
- Very detailed permission setting options (over 50) 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

### Legacy file import

- Allows users to import data documents or protocols from SMP GxP 6 and 7 versions
- The imported documents will be assigned the status "IMPORTED" and can be pushed into "IN WORK" via "Save as"
- The audit trail of the documents is also imported

### Windows Active Directory and classic GxP Admin Option

- User Administration can be done via GxP Admin or users can be connect to the company Windows Active Directory System
  - Simplifies password administration and reduces IT support
  - Password criteria options increased to meet diverse password needs
  - Access to the system audit trail given separately