

# SoftMax Pro GxP Software Suite

SoftMax Pro GxP Software Suite version 7.2

## IT Configuration Guide

## SoftMax Pro Microplate Data Acquisition and Analysis Software IT Configuration Guide

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The SoftMax Pro Software Validation Package tests were developed by software engineers and domain experts at Molecular Devices. The tests are done as part of the in-house testing process before the release of the SoftMax Pro GxP Software version 7.1.x. Our product development process requires that all tests must pass before the product can be released. The software used to check the mathematical calculations includes Microsoft Excel and GraphPad Prism.

Release of the SoftMax Pro Software also requires that an extensive battery of over 5000 automated functionality tests must be passed. These tests are always run before a new version of the software is released.

The objectives, procedures, and expected results are intended for use only as guidelines for users who do their own software validation. Other scripts or modified scripts might be required to create a complete, customized validation of the SoftMax Pro GxP Software and the GxP Admin Software. For more information, visit [support.moleculardevices.com](http://support.moleculardevices.com).



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# Chapter 1: About Molecular Devices, LLC



# 1

Molecular Devices®, LLC is called “Molecular Devices” in this document. You can download the SoftMax® Pro GxP Software Suite installation package or have it shipped via a USB drive. This USB drive contains the installation files and the Software Validation Package. The Validation Package is also available as a stand-alone purchase to validate the SoftMax Pro Software - Standard edition.

Molecular Devices offers a wide-ranging portfolio of bioanalytical products and systems for life science research (BioResearch), drug discovery, and development (BioPharma), as well as bioassays and biotest design (BioTesting) to help customers detect biology, decode data, and drive discovery. Our customers are in highly regulated industries. Our products are for research use only.

## Locations

Molecular Devices has offices and manufacturing plants in Austria, Canada, China, Germany, India, Japan, Korea, Singapore, United Kingdom, and the United States.

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## Chapter 2: SoftMax Pro GxP Software Suite

# 2

SoftMax Pro GxP Software Suite controls Molecular Devices absorbance, luminescence, and fluorescence microplate readers and detection platforms and offers data analysis tools. The SoftMax Pro GxP Software Suite extends the SoftMax Pro Software - Standard edition into regulated laboratories that work under GMP, GLP, and FDA 21 CFR Part 11 guidelines for secure electronic records. Users must log on to the SoftMax Pro Software - GxP edition with a username and password. Permissions regulate user actions and user actions trigger events that are recorded to an audit trail for electronic records.

The software provides extensive data calculation and analysis capabilities under a Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) work environment for pharmaceutical, biotechnology, academic, hospital, and government customers.

The Protocol Library contains over 160 protocols that contain instrument settings and formulas. You can customize the protocols in the Protocol Library to facilitate the data analysis and report creation.

SoftMax Pro Software is widely integrated with industry-leading robotics systems.



**Note:** In this document, all references to the SoftMax Pro Software - GxP edition use the term SoftMax Pro GxP Software.

### Documentation

The SoftMax Pro Software installation places a copy of the microplate reader user guides (.pdf files) in the following location on the computer:

C:\ProgramData\Molecular Devices\User Guides

Use the following link for the most up-to-date microplate reader user guides on the Molecular Devices Knowledge Base:

[Spectranet](#)

To access the Knowledge Base from the software:

- Select the **Help** tab, click **Contact Us**, and then select **Knowledge Base**.

## Chapter 3: Important Software Installation Considerations

# 3

This guide is intended for IT professionals who will be supporting the installation and configuration of the SoftMax Pro GxP Software Suite. You can configure the SoftMax Pro GxP Software Suite to perform operations on multiple computers or on a single computer. This guide contains critical information that helps you configure a system to best meet the needs of your users. The information in this guide is subject to change without notice. You should review the documentation on the Knowledge Base for the most up-to-date information.

Use this document to plan the installation of the SoftMax Pro GxP Software Suite version 7.2. For detailed installation instruction see the following documents:

- *SoftMax Pro Data Acquisition and Analysis Software - GxP Edition - Installation Guide for the Multi Computer Setup*
- *SoftMax Pro Data Acquisition and Analysis Software - GxP Edition - Installation Guide for the Single Computer Setup*

### Scalability

The SoftMax Pro GxP Software Suite scales with the size of your laboratory environment. Depending on the size of your implementation, you can install the interdependent SoftMax Pro GxP Software Suite components on multiple networked computers. For the smallest of implementations, it is possible to install the components on a single computer. You should consult with your Molecular Devices representative and your network administrators to plan and scale your implementation according to your requirements.

SoftMax Pro GxP Software Suite components:

- **SoftMax Pro GxP Software:** The SoftMax Pro GxP Software (client) controls the microplate reader for data acquisition and statistical data analysis. These computers must have access to the dedicated server on which you install the GxP Admin Software.
- **GxP Admin Portal Software:** The GxP Admin Portal Software is the user interface that you use to interact with the GxP Admin Software. These computers must have access to the dedicated server on which you install the GxP Admin Software.
- **GxP Admin Software:** The GxP Admin Software (server) is the database and security back-end application that you install on a dedicated, centrally located server with a static IP address. This server must be accessible to all computers that run the GxP Admin Portal Software and the SoftMax Pro GxP Software.

When you use the multi computer setup, all services for the SoftMax Pro GxP Software Suite components must have the same version number after the installation or an update to the software. This requires a coordinated approach to install or update the software on all computers running any SoftMax Pro GxP Software Suite component. The GxP Admin Portal Software Login page must display the same version number as the GxP Admin Software services and the SoftMax Pro GxP Software services.

The GxP Admin Software has no user interface. On the computer running the GxP Admin Software, open the Windows Services dialog and select the GXP\_AU\_DATA service, the GXP\_AU\_WEB service, GXP\_AU\_REPORT service, and the GXP\_AU\_ADCLIENT service. The version number displays in the Description field.

On the computer running the SoftMax Pro GxP Software, open the Windows Services dialog and select the GXP\_AU\_DATA service and GXP\_AU\_WEB service. The version number displays in the Description field.

## Required Computer Settings



**Note:** Disable your anti-virus program before you install the software. Anti-virus programs can interfere with the installation process. If your computer hibernates or turns off during data acquisition, the transfer of data from the instrument to the software can be interrupted.

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To prevent data loss, turn off all sleep and hibernation settings for the hard disk, the CPU, and the USB ports.

To define computer settings in the Windows Control Panel:

1. Open **Control Panel**.
2. Click **Hardware and Sound**.
3. Under **Power Options**, click **Change When the Computer Sleeps**.
4. Click **Change advanced power settings**.
5. In the Power Options dialog, set **Hard disk > Turn Off Hard Disk After** to **Never**.
6. Set **Sleep > Sleep After** to **Never**.
7. Set **Sleep > Hibernate After** to **Never**.
8. Set **USB Settings > USB Selective Suspend Setting** to **Disabled**.
9. Click **OK**.

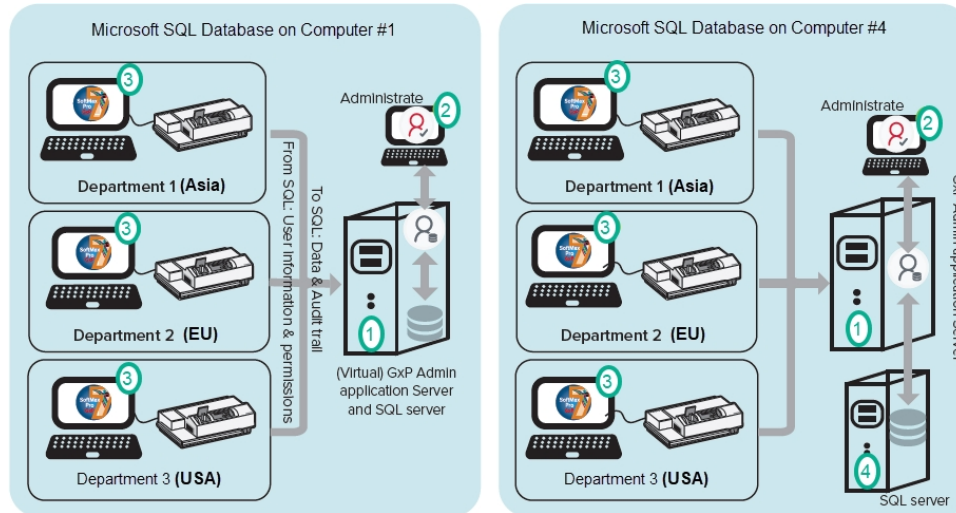
### Decimal Symbol Must be a Period

For the SoftMax Pro Software to parse or execute calculations, the regional options for the computer must use the period symbol (".") for the decimal symbol. This can be an issue if the Region and Language setting for the computer is something other than English.

To set custom regional settings, go to **Control Panel > Clock and Region**.

## Multi Computer Setup

The SoftMax Pro GxP Software Suite multi computer setup software installation requires you to understand the topology and security parameters of your company's network. The installation is script-based which requires knowledge to use Windows PowerShell and enter parameters into the scripts. Use the PowerShell `Get-Help` commands to access the help documentation in each script.



### Multi Computer Setup Installation Configuration Options

Setup	Software Application
1	GxP Admin Software (Can also contain the Microsoft SQL database)
2	GxP Admin Portal Software
3	SoftMax Pro GxP Software
4	Microsoft SQL Server Standard or SQL Enterprise database on computer #4

See the *SoftMax Pro Data Acquisition and Analysis Software - GxP Edition - Installation Guide for the Multi Computer Setup* for installation steps.



## Computer System Requirements Multi Computer Setup

Install each component in the multi computer setup on computers that have the following system requirements.

### Server Computer for GxP Admin Software

Item	Required
Operating system For GxP Admin Software only (with or without the database)	*Windows Server 2019 or Windows Server 2016
Operating system For 5 or fewer client computers OR if you intend to install the SoftMax Pro GxP Software (client) on the same computer as the GxP Admin Software (server)	Windows 11 Enterprise or Windows 10 Enterprise Windows 11 Pro or Windows 10 Pro
Processor	Intel Core i5 with 8 or more cores or equivalent
Memory	16 GB RAM
Storage	50 GB of available space, or more
Database	Microsoft SQL Server 2019 or Microsoft SQL Server 2017
Additional software	Windows PowerShell 5.1 must be 64-bit and able to execute scripts
Domain Name Service (DNS)	Configured DNS must be active for all computers participating in the multi computer setup

\*If you use Windows Server 2019 or 2016, you cannot install the SoftMax Pro GxP Software on the server computer that runs the GxP Admin Software.



**Note:** The server computer for the GxP Admin Software cannot be a Domain Controller.

### SoftMax Pro GxP Software and GxP Admin Portal Software Computer

Item	Required
Operating system	Windows 11 Enterprise or 10 Enterprise, Windows 11 Pro or 10 Pro (all 64-bit)
Processor	Intel Core i5 with 4 or more cores
Memory	16 GB RAM (minimum 8 GB to install)
Storage	50 GB of available space, or more (Disable File and Folder Compression)
Additional software	Windows PowerShell 5.1 must be 64-bit and able to execute scripts



**Note:** If you intend to use Active Directory Single Sign On, your network infrastructure must support Active Directory.

## Ports

For the typical multi-computer installation, network communication from the computers running the SoftMax Pro GxP Software to the server running the GxP Admin Software require unidirectional communication on TCP ports 8210 and 8211. The GxP Admin Software binds TCP ports 1433 (default SQL, can be customized static port), 8210, 8211, 8220, 8230, and UDP port 1434 (default SQL, may not be required). SoftMax Pro GxP Software binds TCP ports 1947, 8099, 8210, 8211, and 9000. Firewall rules and/or Router Access Control Lists may be required to support the application suite. Customization of some network ports are possible but some applications that also require these ports may be incompatible with the SoftMax Pro GxP Software Suite.

## Backup

The multi computer setup assumes that your company network has standard backup and recovery procedures in place for the SQL database.

## Troubleshooting

For the multi computer setup, when you install the GxP Admin Software on the same computer as the Microsoft SQL database, if you reboot the computer and you cannot log in to the GxP Admin Portal Software, you should check the GxP\_AU\_Data service and the GxP\_AU\_Web service to confirm that both are running. To correct this, you can set up dependencies or delays to ensure that the database is up and running before the services time out.



**Note:** If the SoftMax Pro GxP Software loses connection with the GxP Admin Software database for more than 30 days, protocol data will not be saved to the database. You should resolve any database connection issue within 30 days.



**Note:** Communication between the components in the SoftMax Pro GxP Software Suite is encrypted using HTTPS. Do not change the communication to use HTTP as this is not a secure communication method.

## Functionality Not Included in the Software

The SoftMax Pro GxP Software Suite currently does not include the following functionality:

- You cannot connect the computers that run the SoftMax Pro GxP Software to a server that runs the GxP Admin Software with a different database. For example, to accommodate Test, Staging, and Production environments.
- You cannot install multiple instances of the GxP Admin Software to use a single database. There is a one-to-one relationship between each GxP Admin Software implementation and its database.
- You cannot connect the GxP Admin Software to different SQL databases.
- The software cannot search Windows Active Directory sub-domains.
- The software does not support security certificates which specify SANs (Subject Alternative Names) using IP addresses.
- You cannot import an existing certificate.

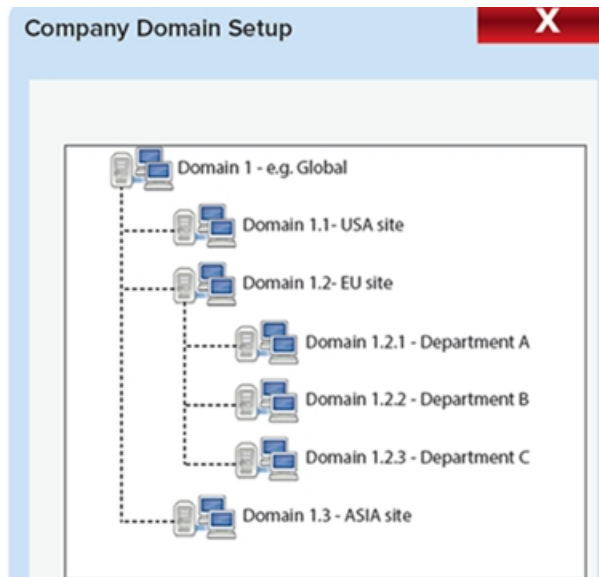
## Domain Structure Considerations for Active Directory Users

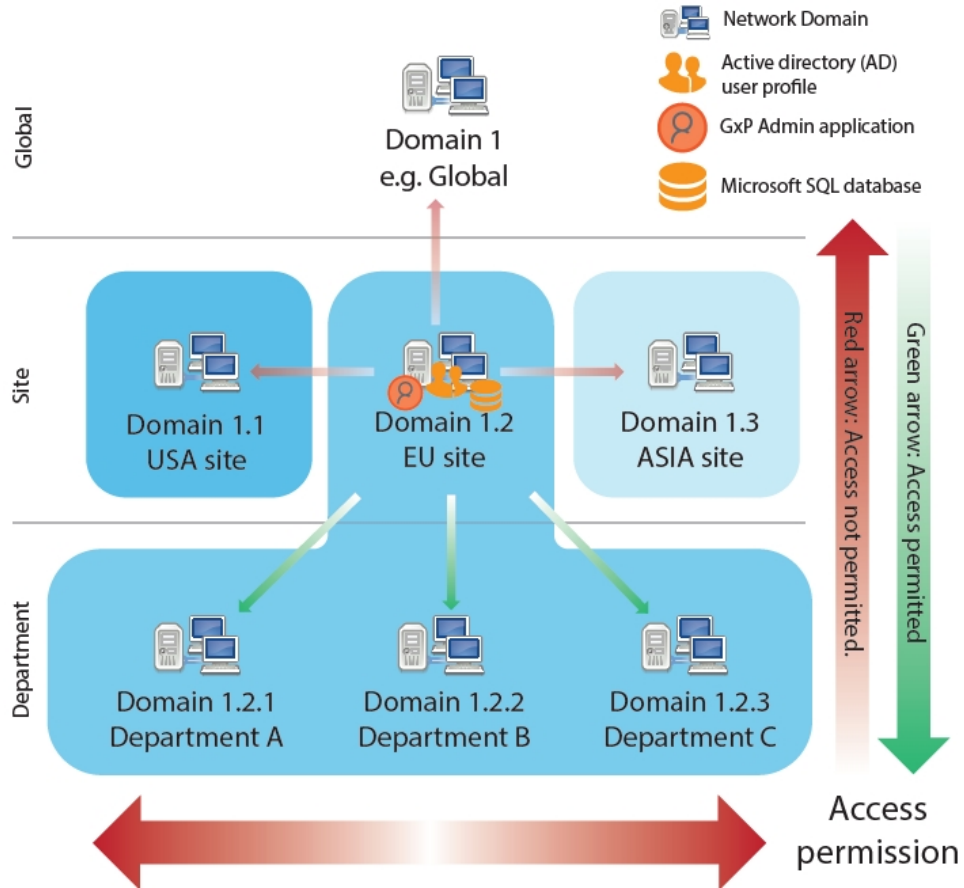
The SoftMax Pro GxP Software Suite multi computer setup supports the creation of both Custom Credentials users and the integration with Windows Credentials, Active Directory (LDAP) users.

- **Windows Credentials:** For users you create with the Windows Credentials login mode, password management is maintained through the Active Directory. Windows Credentials login mode users cannot change their password in the GxP Admin Portal Software or the SoftMax Pro GxP Software. The password maintenance settings in the GxP Admin Portal Software do not affect Windows Credentials login mode users. Windows Credential login mode users with the SoftMax Pro Access permission must have a license and must be a member of at least one Project. Their activity within the SoftMax Pro GxP Software is restricted by their Role permissions.
- **Custom Credentials:** For users you create with the Custom Credentials login mode, the software creates a randomly generated alphanumeric string of characters to be their password. This password grants users with the appropriate Access permissions access to the GxP Admin Portal Software and the SoftMax Pro GxP Software. Both software applications require Custom Credentials login mode users to change their password upon initial login. Both software applications allow Custom Credentials login mode users to change their password as often as they want. The GxP Admin Portal Software has settings to manage password strength and password aging to require Custom Credentials login mode users to change their password at the interval you specify.

If you want to create users that use your company's Windows Active Directory login credentials, determine the best location and under which domain to install GxP Admin Software so that the GxP Admin Software can access your company's Active Directory database.

The following shows an example how a domain tree looks in Windows.





Consider the Active Directory system as a permission pyramid. Access to domains above or sideways is not possible.

- Example 1: If a user or application is located in the Department A domain, then this user cannot log in at a computer that is located in the Department B domain.
- Example 2: If a user should be able to access Department A/B/C then the user's Active Directory user profile and the GxP Admin Software need to be located at the EU site level (Domain 1.2).



**Note:** You must create a Domain User Service Account in your Active Directory that the SoftMax Pro GxP Software Suite can use.

## Understanding Installation Files

The installation wizard unpacks the installation files to the SoftMax Pro GxP Components folder. The relevant files are the Script files that have the .ps1 file extension. Use the PowerShell `Get-Help` commands to access the help documentation in each script. The following is the file structure that the installation wizard creates:

### SoftMax Pro GxP Components

#### Application

#### Configuration

#### Configuration Utility

#### Examples

- ClientInstall.ps1
- Configuration.ps1
- DeleteServices.ps1
- InstallationQualification.ps1
- PortallInstall.ps1
- ServerInstall.ps1
- Test-DnsResolve.ps1
- Update.ps1

#### Installation Qualification

- InstallationQualification.ps1

#### lib

- utils.ps1
- config.ps1

#### Manage Certificates

- Manage-Certificates.ps1

#### Manage Configuration

- Manage-Configuration.ps1

#### Manage Database

- Manage-Database.ps1

#### Manage PSModules

- Manage-PSModules.ps1

#### Manage Services

- Manage-Services.ps1

#### Manage System

- Manage-System.ps1

#### Manage User

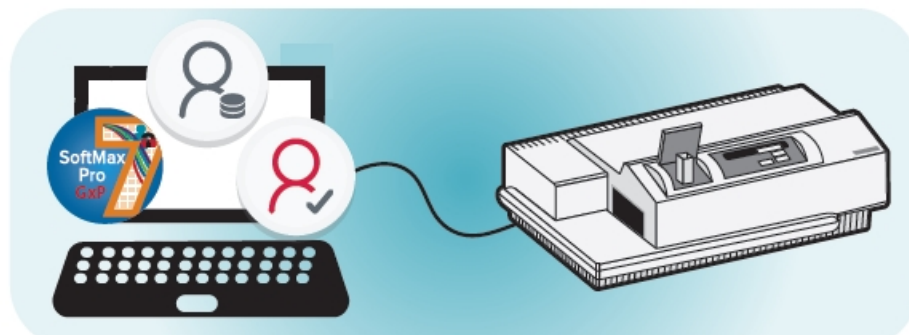
- Manage-User.ps1

#### Migration

- Migrate-gxp-data.ps1

## Single Computer Setup

A single computer setup installation means that the computer connected to the microplate reader is also the same computer that houses all components of the SoftMax Pro GxP Software Suite. This is the only computer that runs the SoftMax Pro GxP Software, the only computer that acquires data from the microplate reader, and the only computer that stores the data in the SQL database.



The SoftMax Pro GxP Single Computer Setup Installation Wizard installs all components on a single computer:



- SoftMax Pro GxP Software



- GxP Admin Software with the Microsoft SQL Database



- GxP Admin Portal Software



- GxP Admin Backup Tool (optional)

See the *SoftMax Pro Data Acquisition and Analysis Software - GxP Edition - Installation Guide for the Single Computer Setup* for installation steps.



**Note:** You must have Admin rights on the computer.

### SoftMax Pro GxP Software Suite - Single Computer Setup

Item	Required
Operating system	Windows 11 Enterprise or 10 Enterprise or Windows 11 Pro or 10 Pro (all 64-bit)
Processor	Intel Core i5 processor or higher w/ 8 or more cores (min. 4 cores to install)
Memory	16 GB RAM (minimum 8 GB to install)
Storage	50 GB of available space (File and Folder Compression must be disabled)
Network card	Configured and enabled
Database	Microsoft SQL Express will be installed by the wizard (10 GB storage limit)
Additional software	Windows PowerShell 5.1 must be 64-bit and able to execute scripts



**Note:** For a new installation, the computer cannot have Microsoft SQL installed. For a new installation, the SoftMax Pro GxP Single Computer Setup Installation Wizard installs a SQL Express database. When you update from GxP Admin Software version 3.x, the existing SQL Express database content is retained.

Windows 10/11 Home edition and Mobile edition are not supported.

### Ports

For the typical single-computer installations, the SoftMax Pro GxP Software Suite binds TCP ports 1947, 8099, 8210, 8211, 8229, 8230, 9000, and UDP port 1434. Firewall rules may be required to allow localhost network communication. Some applications requiring these ports may be incompatible with the SoftMax Pro GxP Software Suite.



**Note:** The single computer setup creates a database that is for the implementation of the SoftMax Pro GxP Software Suite on that computer only.

For the single computer setup:

- You cannot share files in the database over a network.
- Files you export from the database will no longer have the system audit trail intact.
- You cannot use the Windows Credentials login mode (active directory).



**CAUTION!** If you have multiple installations of the SoftMax Pro GxP Software Suite, you cannot interchangeably use the databases from one installation to another installation and you cannot merge the databases.

## Backing Up the GxP Admin Database

For the single computer setup, the SoftMax Pro GxP Single Computer Setup Installation Wizard optionally allows you to install the GxP Admin Backup Tool. If you do not have standard Microsoft SQL backup tools, you can use this tool to schedule recurring database backups and to do a backup on an as needed basis.



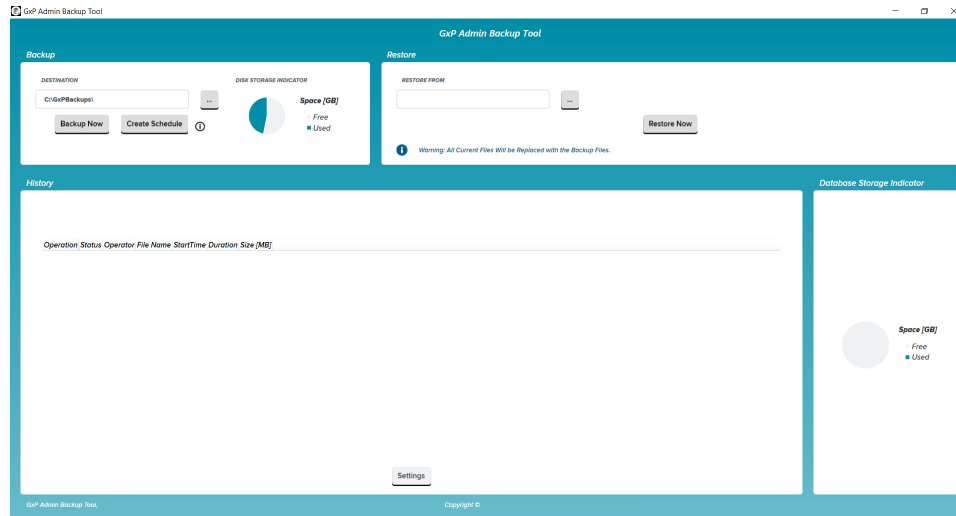
**Note:** The GxP Admin Backup Tool is not applicable for the multi computer setup because it is assumed that your network has standard backup procedures in place.

If a backup occurs while the system is in use, there is the possibility that the backup audit trail information could be inconsistent. For example, if a user is actively creating new plates when the backup starts, the backup may save the audit trail entry before the changes to the document are saved. The user continues to work, and the active database is fully consistent. However, the backup contains the audit trail information for the new plates and does not contain the document version with the latest plate added. This is only relevant if you restore the database from such a backup.

The GxP Admin Backup Tool places the backup files in the following location on the local computer which should not be changed:

C:\users\public

See the *GxP Admin Portal Software User Guide* for instructions related to the GxP Admin Backup Tool.





## Chapter 4: Administratively Controlled Access

# 4

The GxP Admin Portal Software is the interactive user interface for the GxP Admin Software. Use the GxP Admin Portal Software to create users. You grant users Access permissions to allow them to use the software applications to which they need access. You then assign users with the SoftMax Pro Access permission to Projects that limit their access to only the documents they need to access. For each Project, you assign users to a Role that allows them to perform the tasks for which they are responsible.

### Application Access Permissions

Use the three Access permissions to restrict each user's access to the software applications.

- **GxP Admin** - Users with this Access permission have access to all GxP Admin Portal Software functionality. GxP Admin Access permission allows management of the users of both software applications including workflow permissions and password resets. GxP Admin users manage application settings such as password strength requirements and event notifications. Users with this Access permission have the System Audit Trail Access permission by default and can view the System Audit Trail in the GxP Admin Portal Software. These users cannot log in to the SoftMax Pro GxP Software unless they have the SoftMax Pro Access permission.
- **System Audit Trail** - Users with this Access permission can view the System Audit Trail in the GxP Admin Portal Software. These users can confirm that the GxP Admin Software meets compliance requirements but cannot change user settings, cannot change application settings, and cannot log in to the SoftMax Pro GxP Software unless they have the GxP Admin Access permission and/or the SoftMax Pro Access permission.
- **SoftMax Pro** - Users with this Access permission also require a user license to log on to the SoftMax Pro GxP Software. These users are granted permission to access the SoftMax Pro GxP Software based upon their assignment to Projects and their Role in each Project. These users cannot log in to the GxP Admin Portal Software unless they have the GxP Admin Access permission or the System Audit Trail Access permission.

### Projects - Document Access Restrictions

Each user with the SoftMax Pro Access permission must be a member of at least one Project. Use Projects to limit which documents the user can access. Each user can be a member of multiple Projects.

### Roles - Workflow Permissions

Each user with the SoftMax Pro Access permission can have one Role in each Project. Each user can be a member of multiple Projects and can have a different Role in each Project. Use Roles to restrict the user's responsibilities in the SoftMax Pro GxP Software.

For a description of each permission, see the *GxP Admin Portal Software User Guide*.

## Document Workflow

The document life cycle in a compliant lab consists of multiple different development and review steps and requires a system to indicate the document state. The status system allows a Project team to track and approve documents while the document moves through the pipeline of development, review, release, and usage in a controlled environment.

There are two types of documents:

- Protocols contain instrument settings, notes, statements, group settings, graph settings, and so on. Protocols do not contain data.
- Data documents contain everything from the protocol plus the data that the instrument collects and the results of the formula calculations that are set up in the protocol.

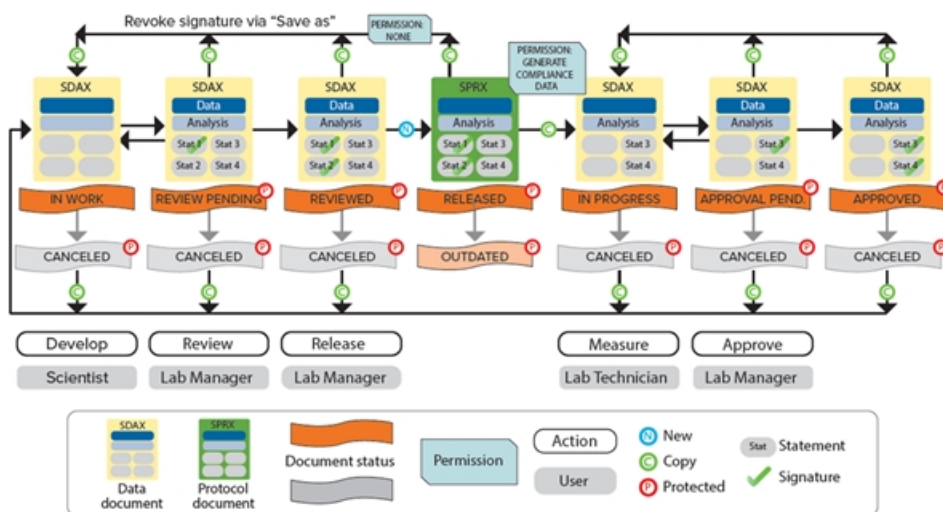
### Document Statuses

The SoftMax Pro GxP Software Suite installation includes three default Roles: Scientist, Lab Technician, and Lab Manager. The default permissions for these Roles correspond with the document statuses that are present in the SoftMax Pro GxP Software. You can modify the default Role permissions, if needed.

SoftMax Pro GxP Software document statuses:

- In Work
- Review Pending
- Reviewed
- Released
- In Progress
- Approval Pending
- Approved
- Outdated
- Canceled

The following diagram illustrates the correlation of each document status with the permissions assigned to the default Roles.



The following section provides an example of a document workflow that corresponds to the default Roles. Your laboratory can define Roles and document workflows that meet your needs.

### **In Work Document Status - Scientist Role**

Scientists open and save new data documents and define instrument settings in Plate sections and define data analysis formulas in the Group sections and Note sections. The software assigns a new document the status In Work. Scientists add statements to the document to provide communication to the other users responsible for the document. Scientists sign the first statement to prevent further edits and set the document status to Review Pending.

### **Review Pending Document Status - Lab Manager Role**

Lab managers review data documents with the status Review Pending, sign the second statement, and set the document status to Reviewed.

### **Reviewed Document Status - Release Protocol - Lab Manager Role**

If the data document with the status Reviewed is correct, lab managers then release the documents as protocols. The software saves protocols with the status Released to enable reuse.

If the document has a newer iteration or is incorrect, lab managers can set documents that have the status Released to the Outdated status.

### **In Progress Document Status - Lab Technician Role**

Lab technicians open protocols with the Released status and the software prompts the lab technicians to save protocols as data documents before they can run the experiments. Because the Lab Technician Role has the Generate Compliance Data permission, the software sets the data documents status to In Progress and removes the two signed statements. This allows lab technicians to run the experiments and generate compliance data.

When lab technicians finish their work, they sign a statement to prevent further changes and set the document status to Approval Pending.

### **Approval Pending Document Status - Lab Manager Role**

Lab managers confirm that documents with the Approval Pending status meet regulatory requirements, sign a statement, and set the document status to Approved.

### **Canceled Document Status**

Users with appropriate permissions can set the document status to Canceled at the applicable points in the document workflow.

## Obtaining Support

Molecular Devices is a leading worldwide manufacturer and distributor of analytical instrumentation, software, and reagents. We are committed to the quality of our products and to fully supporting our customers with the highest level of technical service.

Our Support website, [support.moleculardevices.com](https://support.moleculardevices.com), has a link to the Knowledge Base, which contains technical notes, software upgrades, safety data sheets, and other resources. If you still need assistance after consulting the Knowledge Base, you can submit a request to Molecular Devices Technical Support.

You can contact your local representative or Molecular Devices Technical Support at 800-635-5577 x 1815 (North America only) or +1 408-747-1700.

In Europe call +44 (0) 118 944 8000.

To find regional support contact information, visit [www.moleculardevices.com/contact](https://www.moleculardevices.com/contact).

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