

# System Access Manager for GLP & FDA 21 CFR part 11 compliance

The System Access Manager is an account management module which strengthens your case for compliance by managing and maintaining user access.

The System Access Manager is beneficial to those who are required to comply with GLP, GMP and the FDA 21 CFR Part 11 Final rule on Electronic Records and Electronic signatures.

With full integration between System Access Manager and all Perceptive Instruments products, such as Comet Assay IV and Ames Study Manager, a fully compliant arrangement is achievable.

**Manages unique electronic signatures** in line with the principles set down by the FDA and OECD

**Secure user management module** is locked and invisible to end users

**Full and detailed audit trails** record all login attempts and changes to user accounts

**Highly configurable user account rules** including minimum lengths for electronic signature components; account validity and program access permissions

**Enforce regular password changes** and set rules on password reuse

**Login timeouts and lockouts** to prevent unauthorised access

**Comprehensively tested and validated** in accordance with our Quality Management System which is approved to ISO 9001:2008 incorporating ISO 90003:2004

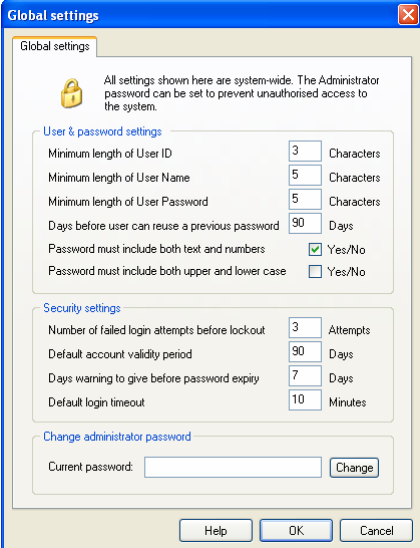


## Manage users in a compliant environment with the System Access Manager

Individual users are assigned unique user IDs and access rights to each product. The program manages user access via a wide range of password rules including expiry, length, use of characters and numbers and more.

User Administrators can add new end users to the database and assign them with a unique User ID, a User name and duration of password validity as well as defining a specific access level and time-out to each product.

A randomly generated password is communicated to the individual who then changes the random password into their own case sensitive text using an Update password utility. This ensures that the password is known only to the end-user concerned and, in conjunction with their User ID, constitutes the unique electronic signature.



Global settings

All settings shown here are system-wide. The Administrator password can be set to prevent unauthorised access to the system.

User & password settings

Minimum length of User ID: 3 Characters

Minimum length of User Name: 5 Characters

Minimum length of User Password: 5 Characters

Days before user can reuse a previous password: 90 Days

Password must include both text and numbers:  Yes/No

Password must include both upper and lower case:  Yes/No

Security settings

Number of failed login attempts before logout: 3 Attempts

Default account validity period: 90 Days

Days warning to give before password expiry: 7 Days

Default login timeout: 10 Minutes

Change administrator password

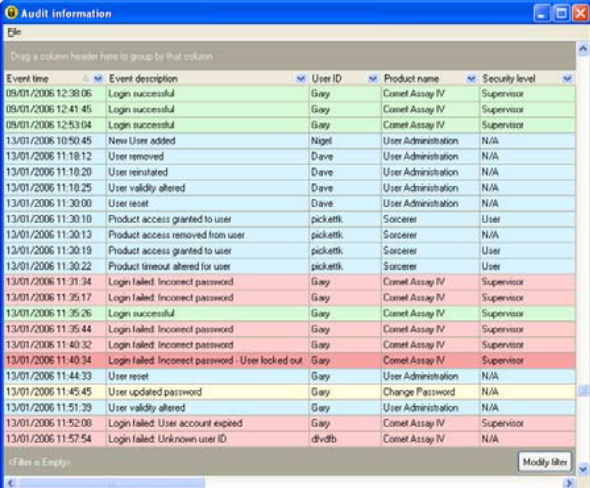
Current password:  Change

Help OK Cancel

## Comprehensive audit trails record all login events and user profile changes

The System Access Manager provides comprehensive security and full audit trails which record all login attempts and changes to a user's account validity or access permissions. The audit trails can be filtered on any field, such as User ID, event description or date. Audit trails can then be exported to Excel for printing or review.

Every login event or alteration to an account is recorded in the audit trail along with the name of the current logged on Windows user account, so it is possible to record which users have logged in, when they logged in and what actions they have taken. The main program where user accounts are managed is itself protected by a password, ensuring only authorised personnel can gain access to it. The System Access Manager is built around a secure Oracle database, providing complete security of user and audit data.



Event time	Event description	User ID	Product name	Security level
09/01/2006 12:38:06	Login successful	Gay	Comet Assay IV	Supervisor
09/01/2006 12:41:45	Login successful	Gay	Comet Assay IV	Supervisor
09/01/2006 12:53:04	Login successful	Gay	Comet Assay IV	Supervisor
13/01/2006 10:50:45	New User added	Nigel	User Administration	N/A
13/01/2006 11:18:12	User removed	Dave	User Administration	N/A
13/01/2006 11:18:20	User reinstated	Dave	User Administration	N/A
13/01/2006 11:18:25	User validity altered	Dave	User Administration	N/A
13/01/2006 11:30:00	User reset	Dave	User Administration	N/A
13/01/2006 11:30:10	Product access granted to user	pickett	Sorcerer	User
13/01/2006 11:30:13	Product access removed from user	pickett	Sorcerer	N/A
13/01/2006 11:30:19	Product access granted to user	pickett	Sorcerer	User
13/01/2006 11:30:22	Product timeout altered for user	pickett	Sorcerer	User
13/01/2006 11:31:34	Login failed: Incorrect password	Gay	Comet Assay IV	Supervisor
13/01/2006 11:35:17	Login failed: Incorrect password	Gay	Comet Assay IV	Supervisor
13/01/2006 11:35:26	Login successful	Gay	Comet Assay IV	Supervisor
13/01/2006 11:35:44	Login failed: Incorrect password	Gay	Comet Assay IV	Supervisor
13/01/2006 11:40:32	Login failed: Incorrect password	Gay	Comet Assay IV	Supervisor
13/01/2006 11:40:34	Login failed: Incorrect password - User locked out	Gay	Comet Assay IV	Supervisor
13/01/2006 11:44:33	User reset	Gay	User Administration	N/A
13/01/2006 11:45:45	User updated password	Gay	Change Password	N/A
13/01/2006 11:51:39	User validity altered	Gay	User Administration	N/A
13/01/2006 11:52:08	Login failed: User account expired	Gay	Comet Assay IV	Supervisor
13/01/2006 11:57:54	Login failed: Unknown user ID	dvdvb	Comet Assay IV	N/A

If you are interested in finding out more about the reporting and auditing features of the System Access Manager, and how you can benefit from the enhanced level of security the program provides, please contact us or visit our website at the address below.

