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
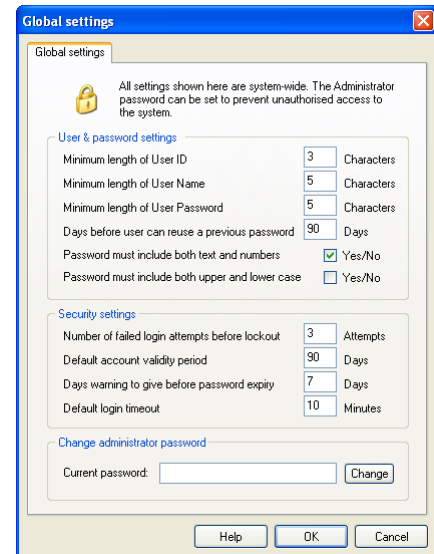
Manage users in a compliant environment with the System Access Manager

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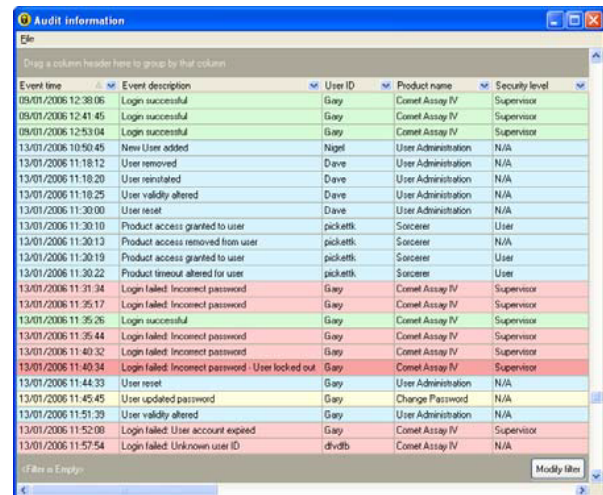
A randomly generated password is communicated to the individual who then changes the random password into their own case sensitive text using an Update password utility. This ensures that the password is known only to the end-user concerned and, in conjunction with their User ID, constitutes the unique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

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.

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.