

TECHNICAL DATA SHEET

Console Software User Admin Package for compliance with US FDA Title 21 CFR Part 11

Console Professional in conjunction with the User Admin Package has been developed to enable organisations to comply with the US FDA Title 21 CFR Part 11. The User Admin Package was built to set up a database of Console Professional Users on a network or single PC. The User Admin Package will allow the access to the User Login and Electronic Signature features in the Console Professional software to be enabled. When the User Admin Package is not available these commands will be greyed out

As the User Admin Package is a separate piece of software, it can be installed on a server, thus restricting access to user data to the server administrator. The user database contains all the options necessary to establish unique electronic signatures and file tracking as required by FDA Title 21 CFR Part 11.

Due to the high security levels required for FDA Title 21 CFR Part 11 compliance, the ideal set up for the User Admin Package is in a network environment with general user administration in place. In order to ensure only the authorised user can produce a user database, the User Admin Package needs to be licensed by submitting a site code to their distributor and entering the returned site key into the registration dialog.

