

# MAGELLAN TRACKER 4.00

## GETTING STARTED

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### MAIN FEATURES

FDA 21 CFR part 11 functionality of Magellan Tracker software:

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#### User administration

Access controls and authority checks via user identification codes and passwords.

- Multi-level user access and permissions for Magellan Tracker users
- Configurable automatic logout after a specified time
- Encrypted passwords and password change possibility for all users
- Configurable password aging
- Detection of unauthorized use and reporting of security attacks to administrator
- Failed attempts are logged in the audit trail
- Audit trail of changes to access control list

#### Electronic records – audit trail

Computer generated time and date stamped audit trails.

- Original data is retained in the audit trail ensuring full traceability
- Complete audit trail of records for accurate and ready retrieval, WHO has changed WHAT and WHEN
- User can not accidentally modify previously recorded information
- Electronic records are stored in secure directories without modify/delete rights
- 'Save' creates a new version of a file with increasing version number
- Audit trails are stored together with electronic records and cannot be deleted
- Accurate and complete copies of records in human readable and electronic form
- Possibility to import record from Magellan Standard system (non-21CFR11) as basis for a new record on 21CFR11 system

#### Signature

Implementation of non-biometric electronic signatures.

- 'Sign a record' wizard for authorized users
- Signature of method and workspace files possible
- Usage of three electronic signatures is supported
- Signatures follow the required sequencing (review, approval)
- Signed records cannot be modified
- Signature is stored as part of the electronic record