

flexibel

individuelle Abstimmung

mittelständisch

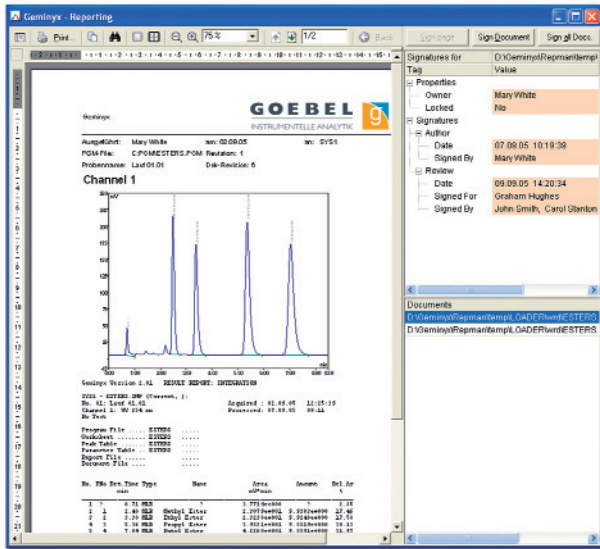


Komplettlösungen HPLC & Photometrie

kompetent

HPLC
SOFTWARE
PHOTOMETRIE

Geminyx FDA 21 CFR Part 11 Compliant Version

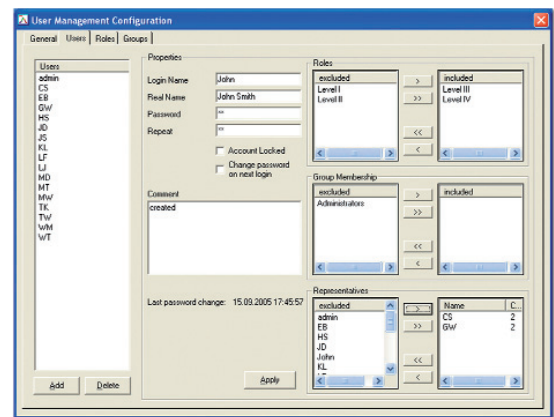


- Complete User Management, configured by administrator
- Access rights definition for each individual function by user group
- Complete audit trail automatically records each action
- Total revision management for absolute traceability
- Electronic Signature on all data sets and documents supporting various levels
- Comprehensive Document Management System based on Oracle or MS SQL server
- Client/Server architecture using one configuration for all connected clients

Complete User Management and Audit Trail for Data Integrity and Traceability

User Identification & Data Access Restriction

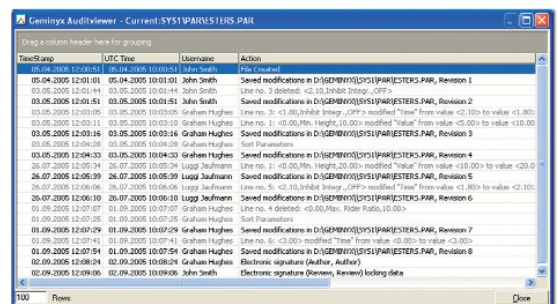
- General password conventions, e.g. minimum length, maximum validity and minimum difference
- Detailed access rights definition for each individual application function per user group
- Definition of representatives for Electronic Signature
- System start is only possible with valid user log-in and password
- Only functions defined by the user's role are available
- Automatic log-off after configured time-out without any user interaction



Audit Trail

Any action is recorded in the Audit Trail indicating:

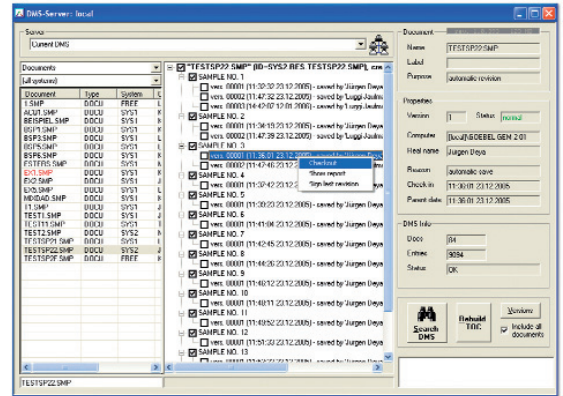
- Date & time of the action plus the time zone
- Full user name
- PC client name from where the action was performed
- Importance level
- Detailed description of the action itself



Total Revision Management

Whenever a data set is saved, a new revision is logged into the database for:

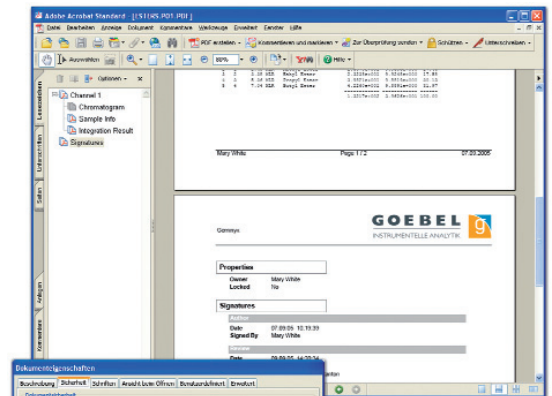
- All method information
- All sample raw data
- All calculated results including their calculation conditions, parameters and calibrations
- All generated report documents
- Any revision can be restored from the database



Paper-Free Archive for Documents and Data Sets

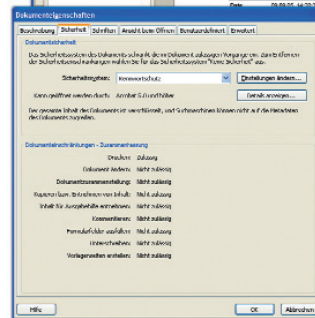
Electronic Signature

- Electronic Signature for any kind of data set and or documents
- Electronic Signature for levels Author, Quality Management, Review and Final
- Viewing conventions, e.g. checking each page, is defined by the administrator
- Data sets can be locked after signing
- Representative signature(s) can be defined
- Electronic Signatures are indicated on the document itself



Archive Protected PDF Documents

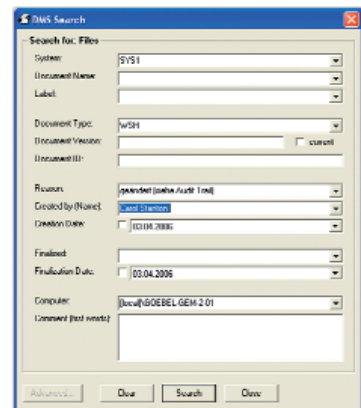
- At the highest level the sample can be finalized
- Mandatory signatures before finalization are defined
- After finalizing no further calculation step is possible
- The document is protected against any manipulation using 128 bit encryption
- The document can be shown and printed using the standard Adobe Acrobat Reader; the Geminix application is no longer needed for generating a paper printout



Obtain a paper-free archive

Built on Sequel Server Database

- Supporting Microsoft SQL as well as Oracle databases
- Small installations can work under a local Jet database (license-free)
- Maximum protection against manipulation
- Application oriented filters allow specifying advanced keyword search



Goebel Instrumentelle Analytik GmbH

Mainburger Str. 8 • D-84072 Au i.d. Hallertau • Germany

Tel.: +49 / (0) 87 52 / 86 708 - 0 • Fax: +49 / (0) 87 52 / 86 708 - 20 • WEB: www.goebel-analytik.de • E-Mail: analytik@goebel-analytik.de