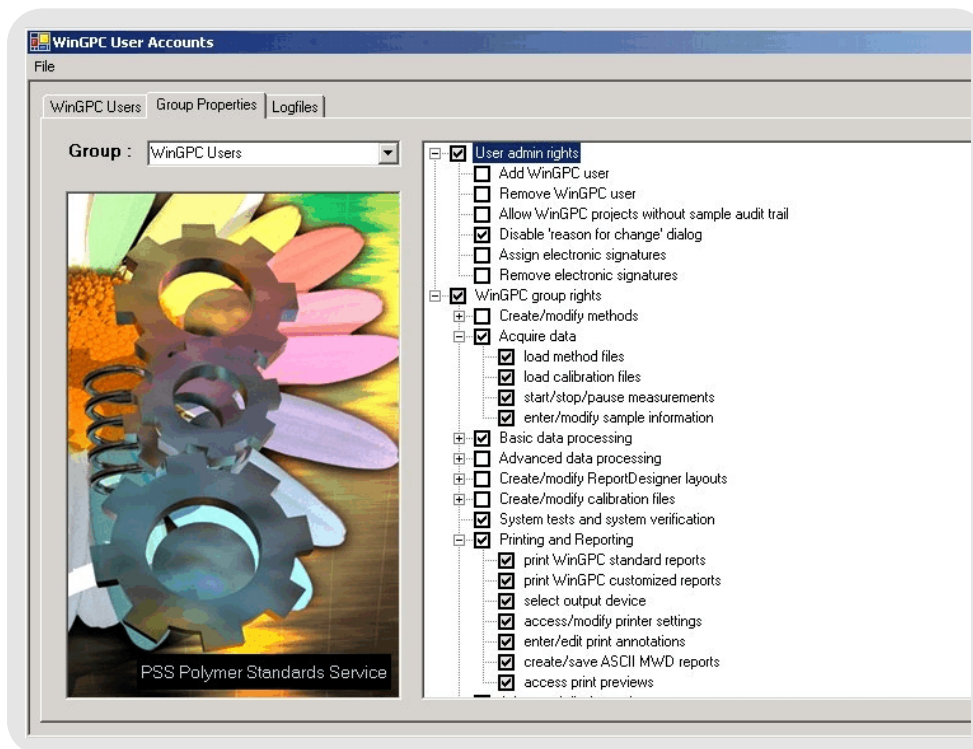




WinGPC Unity Compliance Pack

Compliant to GAMP 4, GxP, ICH, and FDA 21CFR11



Secure and Convenient Operation

PSS WinGPC Unity is a Macromolecular Chromatography Data System (MCDS) for data acquisition from different detectors used for liquid chromatography of polymers. It offers interactive and automated evaluation of one or more signals based on calibration with reference materials, viscometry, or light scattering measurements. WinGPC allows powerful and flexible reporting and the creation of comprehensive result reports, either as paper or electronic documents.

WinGPC Unity is a commercial off-the-shelf chromatography program and a closed system.

All data (raw data and evaluation parameters) are stored in a database that provides highest security and convenient usage due to intelligent automatic sample management.

Software Development at PSS

PSS WinGPC Unity is developed to internationally recognized design and development standards. The software life-cycle model with requirement analysis, design, implementation, and testing is applied to create software that can be validated. The development is registered to the DIN EN ISO 9001:2000 quality system.

WinGPC Unity is designed in a way that the installed product is always identical. The user accessible functionality is controlled by the WinGPC license key. This allows general validation and verification tools that can be directly executed by the user on-site.

It also reduces the validation and verification efforts and costs significantly, when new functionality (e.g. software modules for better in-depth understanding of samples or even complete instruments or detectors) is added.

Validation

PSS WinGPC Unity uses additional theoretical molar mass distributions to validate software algorithms and data flow path. The documentation of this validation is provided with every WinGPC license. The validation can be repeated on every customer workstation to prove operation and correct data flow path on the dedicated system.

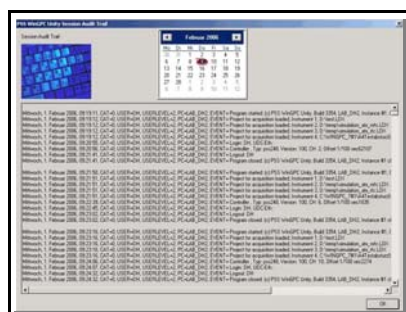
Traceability with Audit Trails

Four different audit trails independently record operator actions:

- WinGPC sample audit trail
- WinGPC session audit trail
- WinGPC system audit trail
- WinGPC administration audit trail

Audit trail entries are time stamped and document user, work-station, action, actual value, if applicable previous value, and if selected the reason for change. Audit trails are encrypted, only human readable in WinGPC and can not be edited or modified.

All audit trails rely on each other to fulfil highest requirements.



Validation Tools and Verification Options

WinGPC Unity offers tools for every step of the validation process (DQ, IQ, OQ and PQ) to be executed on site by trained users and/or by PSS validation specialists.

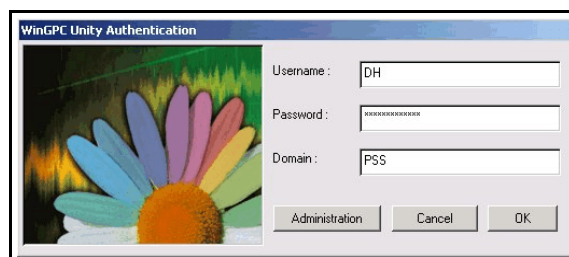
Electronic Signatures

Evaluations can be electronically signed by users who have the corresponding WinGPC right "Assign electronic signatures". For signing, username and password identification are required.

Electronically signed sample evaluations are clearly identified in WinGPC and electronic signatures are stated on every electronic and paper report.

Secure Login

Secure login to WinGPC is guaranteed by login with a unique username and a password A



direct link to the Windows authentication ensures that company policy is followed.

Administration and User Levels

The WinGPC Administration tool allows to add and remove users, to assign a user group and to set WinGPC administration rights and group rights. WinGPC Unity offers four different user groups:

- Administrator
- Advanced user
- User
- WinGPC guest

The default PSS settings for WinGPC rights can be adapted by WinGPC administrators to represent the tasks in the lab.

Sample database

All data are stored in a comprehensive and secure sample database that manages also metadata, method information, calibration information and evaluation parameters. Raw data are always save and can not be deleted, modified or accidentally be overwritten. The powerful search option ensures fast retrieval of data and all related information.

System requirements

| | |
|-------------------|--|
| Software | WinGPC Unity |
| Hardware, minimum | Pentium 3, 600 MHz, 256 MB RAM, 20 GB Hard disk, XGA Graphic Card, 17" Monitor |
| Operating System | Windows 2000, XP Professional |

Order information

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| 400-1011 | Compliance Pack |
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