50 YEARS SPECORD®

analytikjena

SPECORD® PLUS

Compliance with Relevant Standards Guaranteed!


PHARMACY


PETROCHEMISTRY


COSMETICS


CLINICAL CHEMISTRY


MATERIAL ANALYSIS


CHEMISTRY/POLYMER INDUSTRY


ENVIRONMENT/WATER/WASTE


FOOD/AGRICULTURE

Quality control and GLP

According to GLP, all analytical data of an analysis must be accessible. Their accuracy must be ascertained and documented. With the software WinASPECT® PLUS the user has a variety of possibilities for the fully automatic monitoring of the precision and accuracy of measurements and drawing up a GLP conforming documentation of the data.

FDA 21 CFR Part 11

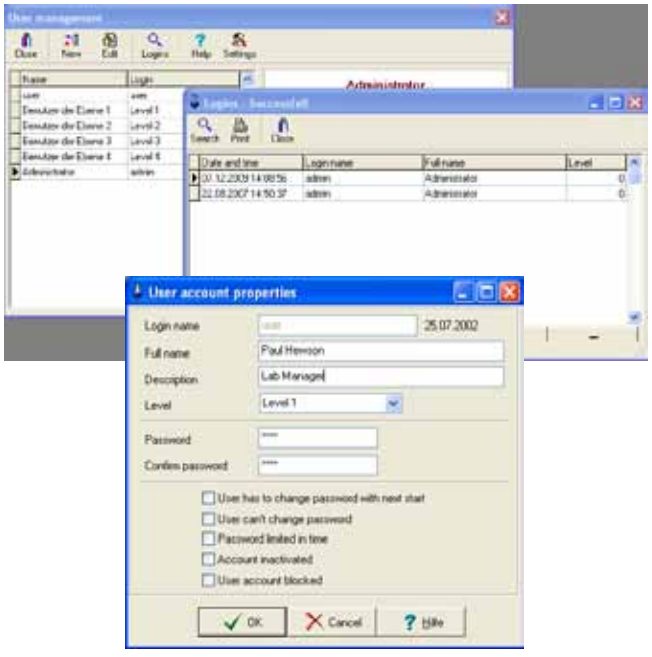
The FDA 21 CFR Part 11 determines concrete requirements for rule conforming analysis. That includes a comprehensive user management, an electronic signature facility and the Audit Trail. The functions integrated in WinASPECT® PLUS ensure data security as well as the reliability, lucidity and traceability of all actions throughout the measuring time. All processes are presented in easily comprehensible terms and with a clear layout.

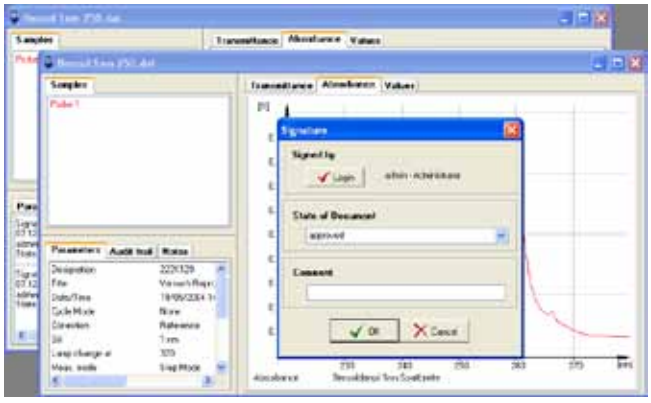
SPECORD® PLUS – Compliance with Relevant Standards Guaranteed

The FDA version of WinASPECT® PLUS includes a user management module and the possibility of electronic signature of measurement results.
Within the user management individual access rights of different users can be defined. Passwords with specified runtimes guarantee data security.

In the Audit Trail, all actions and accesses during the analysis are transparently recorded.
Together with the electronic signature every result can be traced back. By signing the files will be:

- encrypted,
- provided with a signature state and the data of the signing user,
- protected from further modifications.





WinASPECT® PLUS has the ideal tools you need for efficient work in everyday lab routine and yet conforms to FDA 21 CFR Part 11.

Device option	SPECORD® 50 PLUS	822-0050P-2
	SPECORD® 200 PLUS	823-0200P-2
	SPECORD® 210 PLUS	823-0210P-2
	SPECORD® 250 PLUS	823-0250P-2
Software option	WinASPECT® PLUS FDA 21 part 11 software	820-60205-P
	WinASPECT® PLUS validation software	820-60077-P
	Validation set (validation software with Hellma test filter set)	820-60073-P
Documentation	IQ/OQ with certificated standards	820-60011-2
	IQ/OQ with standards provided by customer	820-60010-2
	Installation, start-up, instructions including software validation compliant to FDA 21 CFR part 11 guide Europe Outside Europe	 820-60207-0 820-60208-0

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