

Product Information

PEL 3000 - Option Audit Trail

Audit Trail

Expands the PEL 3000 for

- Group and User management
- Logging of
 - production specifications
 - configuration changes
 - registrations (successful and faulty)
 - call sequences
- Registration via RFID cards or chips or user / password entries

Groups

Certain forms and keys can be assigned to a group with read or write rights. The number of groups is unlimited.

User

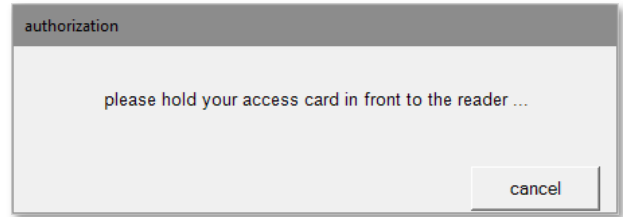
Each user is assigned to a group and thus retains the rights of the group. It is also used to determine whether the user is allowed to log on with the user name and password, or with an RFID tag. The number of users is unlimited.

RFID

Registration via RFID cards or smart card readers.

Two-Way Authorization

If the authorization is via RFID, the user can enter a user name and / or password.



Two-Man Rule

In the case of particularly critical applications the confirmation by a second person may be compulsory.

Decentralized user administration

All changes to group and user master data can be made by any PEL Touch Client or desktop PC in the network and are immediately up-to-date on all PEL PCs in the system.

Import from other applications

If required, audit trail files from other applications (for example WinCC Audit Trail) can be imported in CSV format. Advantage: only one interface to one system.

Logging and evaluation

Extensive filter functions allow targeted evaluations of the logged data

- PEL System (Unit)
- Form Source
- Type (Course, Production, System, Master data, Authorization)
- User
- Status (ok, not ok)
- Period of time

The integrated report generator makes the individual design of reports and export formats possible.

date	client	source	type	field	user	reason	description	state	old value	new value
10/10/2016 10:49:48 AM	CMLPC11	audit trail protocols	Authorization		administrator	authorization	access allowed	ok		
10/10/2016 10:49:45 AM	CMLPC11	audit trail protocols	Course		PEL System	form opened		ok		
10/10/2016 10:49:44 AM	CMLPC11	audit trail	Course		PEL System	form opened		ok		
10/10/2016 10:49:43 AM	CMLPC11	production	Course		Will Smith	value changed	color	ok	red	blue
10/10/2016 10:49:40 AM	CMLPC11	production	Course		Will Smith	form opened		ok		
10/10/2016 10:47:53 AM	CMLPC11	audit trail protocols	Authorization		administrator	authorization	access allowed	ok		



Dipl.-Ing. Christoph Muschner
 Bekassinenstraße 57
 D-28357 Bremen
 Tel. +49-421-27 69 767
 mobile +49-172-4511 336
 Fax. +49-322-235 644 63
 Web www.cmlog.de
 eMail info@cmlog.de

Legal requirements

Audit Trail facilitates the fulfillment of requirements in conjunction with the PEL basic system 21 CFR Part 11 in the pharmaceutical, pharmaceutical and food and confectionery industries as per EU 178/2002 and GMP standard.

