

SmartGraph2 Pharma

Meeting FDA guidelines, document administration

Audit trail electronic signature

Administration / user rights

The administrator can create as many users as required, who are then able to use the opportunities of the software restricted according to the different access rights.

The following user levels are typical

User: data only indicate

Main user: data indication and annotation

Administrator: data indication, annotation and management



A screenshot of a software window titled "create admin user account". It contains a form with the following fields: "user ID" (value: ADMIN), "password" (two masked fields), "first name" (value: Bill), and "last name" (value: Gates).

Electronic documents

Measured data intervals can be archived electronically to be tamper resistant

e.g. Qualification of systems

e.g. Long-term stability testing

To achieve this, relevant intervals from the measuring instruments are archived in "document types" and individual documents are archived. These can be freely defined by the users.



A screenshot of a software window titled "document information". It displays the following text: "name: Life cycle testing-20070126 based on: Life cycle testing", "created by: ADMIN at: 1/25/2007 12:00:57", "last changed by: ADMIN at: 1/25/2007 12:01:11", "document is not signed", "date from: 1/2/2007 00:00:00 to: 1/10/2007 23:59:00". Below this is a "signature information" section stating "document is not signed". At the bottom is a "device information" table:

device	DL001 Logger_1
device short	DL001 CPU10
logger ID	279
channel	temperature °C [dev]
channel short	Kanal1 [dev]
unit	°C
channel no	3

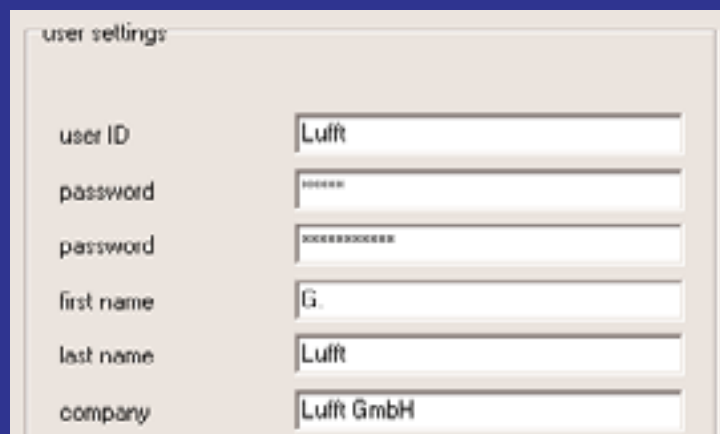
User rights

Electronic documents can be generated, acknowledged and / or approved.

The different rights are allocated in the user administration.

Signature regulations are entrained in the document as electronic signatures.

Signature is given via a password.

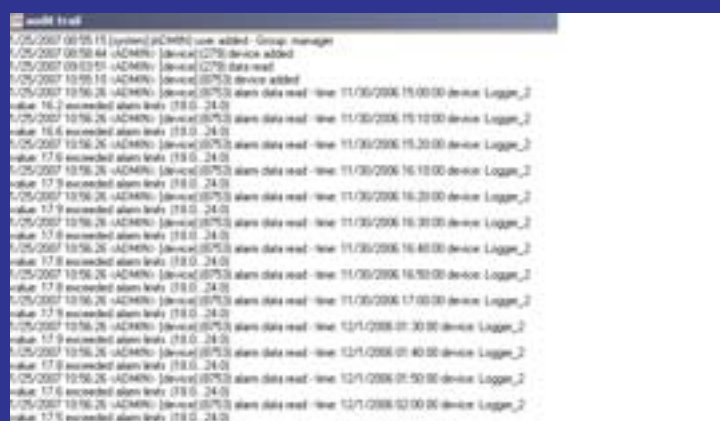


A screenshot of a software window titled "user settings". It contains a form with the following fields: "user ID" (value: Luft), "password" (two masked fields), "first name" (value: G.), "last name" (value: Luft), and "company" (value: Luft GmbH).

Audit trail

All actions (e.g. instrument selection, offset modification, software starting) including the limit violation are saved in an audit trail.

Hence the Pharma software meets the demands of "Part 11" (21 CFR 11).



A screenshot of a software window titled "audit trail". It displays a list of system events with timestamps and descriptions, such as "1/25/2007 00:05:11 [system] ADMIN user added- Group manager", "1/25/2007 08:58:44 ADMIN [device] CPU device added", "1/25/2007 09:03:51 ADMIN [device] CPU data read", "1/25/2007 10:55:15 ADMIN [device] CPU device added", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 11/03/2006 15:00:00 device: Logger_2 value: 16.7 exceeded alarm limit (18.0 - 24.0)", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 11/03/2006 15:10:00 device: Logger_2 value: 16.6 exceeded alarm limit (18.0 - 24.0)", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 11/03/2006 15:20:00 device: Logger_2 value: 17.0 exceeded alarm limit (18.0 - 24.0)", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 11/03/2006 16:10:00 device: Logger_2 value: 17.9 exceeded alarm limit (18.0 - 24.0)", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 11/03/2006 16:20:00 device: Logger_2 value: 17.9 exceeded alarm limit (18.0 - 24.0)", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 11/03/2006 16:30:00 device: Logger_2 value: 17.8 exceeded alarm limit (18.0 - 24.0)", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 11/03/2006 16:40:00 device: Logger_2 value: 17.8 exceeded alarm limit (18.0 - 24.0)", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 11/03/2006 16:50:00 device: Logger_2 value: 17.8 exceeded alarm limit (18.0 - 24.0)", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 11/03/2006 17:00:00 device: Logger_2 value: 17.8 exceeded alarm limit (18.0 - 24.0)", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 12/1/2006 01:30:00 device: Logger_2 value: 17.9 exceeded alarm limit (18.0 - 24.0)", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 12/1/2006 01:40:00 device: Logger_2 value: 17.8 exceeded alarm limit (18.0 - 24.0)", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 12/1/2006 01:50:00 device: Logger_2 value: 17.8 exceeded alarm limit (18.0 - 24.0)", "1/25/2007 10:56:26 ADMIN [device] CPU alarm data read - New: 12/1/2006 02:00:00 device: Logger_2 value: 17.9 exceeded alarm limit (18.0 - 24.0)".