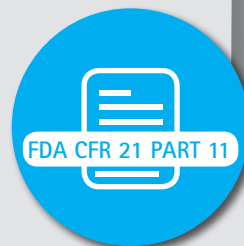


ADVANCED CFR 21 PART 11 SOLUTION

The CFR 21 Part 11 package works completely self-sufficient on the autoclave. No separate PC software required. There is no need to validate a PC. Difficulties with operating system updates (e. g. Windows) are a thing of the past.

- All data can be downloaded from the autoclave via USB or network interface* as PDF and/or CSV (Excel) files.
- Both the PDF and the CSV files are electronically signed by the autoclave.
- The electronic signature can be clearly traced to the respective autoclave.
- At the same time, the signature shows whether the exported files are valid. Any attempt of manipulation will immediately mark the file as invalid.

*The network interface requires the optional „Save to Folder“ feature for file transfer to a PC or server on the network



Save to Folder OPTIONAL

The „Save to Folder“ function automatically exports the current process log to the server once the program ends. The following servers are supported: FTP, SFTP, FTPS.

THE ADVANCED CFR 21 PART 11 SOLUTION INCLUDES:

★ Advanced user control:

With the advanced user control, up to 100 groups and 100 users can be freely managed for preset groups & users. The administrator receives the corresponding additional authorizations.



By comparison, standard user account management offers 3 preset groups, each with one user (administrator, operator, supervisor). The following points can be set with the standard user account management: which events require the entry of a password, minimum password length, maximum number of incorrect password tries before the user is blocked, expiration dates for passwords, and automatic log-off timer.

★ AuditTrail:

AuditTrail enables chronological documentation of changes to the system or process activities over time. All events with or without authorization requests are saved in the AuditTrail. This includes all user events as well as service and system events. When requesting authorization, the person making the request is also recorded in the log.

Examples of user events:

- Create, change, activate, deactivate, unlock users
- Create, change, activate, deactivate groups
- Create, change, activate, deactivate programs
- Change program parameters
- Change passwords
- Acknowledge error messages
- Open the door

The authorizations determine which groups/users are allowed to trigger certain events. Whether an authorization is necessary or not can be set via the device parameter list. If authorization is required for an event, the user must enter their User Name and Password.

With the help of the AuditTrail functionality, the sequence of user entries, system events, or process states according to international regulations, such as FDA CFR 21 Part 11 or EU-GMP guidelines, can be monitored and recorded in a way that cannot be subsequently manipulated.

The AuditTrail data can be exported using electronic data output and displayed on the touch display.

Note:

- With common use, data can be stored in the memory for at least 10 years.
- Regular backup of data such as the process memory is the responsibility of the operator.

Examples of service events:

- Calibration
- Device service (maintenance/servicing)
- Customize options
- Software updates
- Configuration via USB
- Registration of a service technician

Examples of system events:

- Power on/off
- Incorrect password entry
- Modification of the equipment (e.g. replacement of the hardware)
- Changes to the internal memory (reformatted or exchanged)

★ Extended electronic data output:

The extended electronic data output extends the standard electronic data output with a digital signature to ensure the authenticity of the data. The signature's authenticity can be verified in the PDF file via Adobe Reader or in the CSV file via OpenSSL



The electronic data output of the AuditTrail, the error log, and the process log can be either in PDF or CSV formats, respectively. 3 versions are available:

- Summary list: List view of the entire audit trail / error log / process log
- Detail: Detail output of the AuditTrail / error log / process log
- Search list + Detail: List of search queries and their details

Note:

- The content of the detailed output corresponds to the data stored in the error log / process log.
- For the detailed output, you can choose between Graph and Graph + Numeric outputs.

★ Electronic signatures:

Up to 5 fields for electronic signatures* to sign the exported PDF or CSV files on a PC (or another device with the ability to sign documents electronically). All exported data (batch logs, audit trail, error memory, process memory) are signed in a manner secure against forgery according to the X.509 standard. This enables GMP-compliant, paperless documentation.



*The electronic signatures are not included in this option.