zenon

FACT SHEET #21
Standards and Protocols

FDA 21 CFR PART 11

zenon consistently meets the criteria of FDA 21 CFR Part 11 throughout all its modules. The zenon principle of setting parameters instead of programming, the high object-orientation and the multi-project administration save up to 90% in validation costs for new projects. FDA 21 CFR 11 stipulates that all electronic data must correspond to particular requirements, in order to ensure comprehensive documentation of all processes that is secure from manipulation. A significant element in FDA 21 CFR Part 11 compatible projects is, therefore, the audit trail.

FDA
21 CFR Part 11

AUDIT TRAIL IN THE EDITOR

zenon logs all project changes in the Editor without exception (new creation, changes, deletions, copy and XML import). The amended object, type of change, time stamp, the user, the workplace, the old value, the new value and a free text comment field are recorded. The data is saved in the project database. The data can be displayed in a clear list, filtered or exported in CSV format. This enables full traceability in the Editor. In addition, zenon's version administration ensures project restore points can be created at any time.

AUDIT TRAIL IN RUNTIME

The Chronological Event List (CEL) acts as an FDA-compliant audit trail. All relevant changes are logged here in a manner that cannot be manipulated and on a lasting basis. This covers target value requirements as well as recipes and changes to archive entries. The following is noted in the protocol: The CEL log documents which have changed, the old and the new value, date and time of change, the user, the computer on which the change was made and the signature for signed actions.

Plus, a comment on each entry can be saved in this way. The alarm administration acts as an audit trail for the alarms. Here too, all information on alarm acknowledgment is logged in an FDA compliant manner. This guarantees complete traceability in zenon Runtime.

USER ADMINISTRATION AND SIGNING

In accordance with FDA 21 CFR Part 11, no unauthorized access is possible, even when systems that are protected by a username and password have a logged in user and the user leaves their workspace for a short period of time. zenon ensures this with its signature concept: Each user must verify themselves before using the system, even if they are already logged on to the system. This signature procedure is saved in the CEL. A editable signature text is also recorded, so that the action carried out can be logged precisely.

ZENON EDITOR MAKES VALIDATION EASIER

- Project versioning
- Templates
- Pharma Wizard (only Pharma Edition): Template administration; project properties can be saved as a profile (then just needs to be validated once)
- Configurable functions (code not necessary) which are ready to use
- Automatic project documentation

FAST FACTS

- Fully FDA 21 CFR Part 11 compliant
- FDA 21 CFR Part 11 conformity at the click of a mouse
- Consistent environment for HMI, SCADA and MES applications
- Integrated solution throughout all modules
- Version-independent

FDA 21 CFR PART 11

Active Directory	Supports Windows users as HMI/SCADA users
Additional product classification	GAMP software category 4
Audit trail	▸ In zenon Editor ▸ In zenon Runtime
Multiple project administration	Can be used in line with FDA 21 CFR Part 11
Validation efficiency	▸ Set parameters instead of programming ▸ Predefined functions