NIR spectroscopy and compliance: software that helps you adhere to pharma regulations

Electronic signature and user management

Vision Air offers customised as well as predefined reports, which include sections linked to the digital signature that indicate the ID and the name of the signer, a time stamp, and the meaning of the signature, as required by CFR Part 11.50 (a). Meanings are managed within the organisation. Being linked to unique user IDs and passwords in Vision Air, electronic signatures are specific to one person. They are stored in a database and can therefore not be excised, copied, or transferred, in line with CFR Part 11.70. Users with appropriate rights can revoke electronic signatures; however revocation needs to be signed as well and is documented together with the time, the user ID, the name, and the reason for revocation.

CFR Part 11.200 (a) further requires that electronic signatures that are not based on biometrics employ at least two distinct identification components, such as an identification code and password. Correspondingly, a login and password combination has to be entered in Vision Air for every signature. To ensure that only the combination’s genuine owner can use it, signing processes can be set to consist of two levels that need to be performed by different individuals. Users can be assigned three different levels of authority, which define their abilities to place and withdraw signatures. This limits system access to authorised individuals as stipulated by CFR Part 11.10.

CFR Part 11.300 requires controls to ensure the security and integrity of persons using electronic signatures. Security and integrity are ensured in Vision Air by unique user IDs that cannot be deleted once created, only disabled. Also, after a definable number of unsuccessful login attempts, a user is locked. Such critical events are logged in the audit trail. Additionally, selected users can be notified by an automatically generated email.

Electronic records and audit trails

Vision Air includes user name, date, time, and the reasons for configuration changes in its automatically generated reports. In addition, the implemented surveillance function gives a complete overview over all measurements, user events, and performed instrument diagnostics. By using operating procedures, the software ensures that all steps of an analysis are performed in the correct order. Guidance is given by mandatory sample registration fields, which have to be filled out by the user during measurement. Users are also guided in the process of changing configurations. Configuration changes can only be applied after performing a two-level signing process, which must be done by two people.

Fulfilling requirements for the regulated environment is a time-consuming and complex process, which requires the implementation of technical, administrative, and procedural controls. Vision Air offers all technical requirements demanded by the 21 CFR Part 11 to support customers working in regulated environments in achieving and maintaining compliance more quickly and easily.

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