Supporting tools for GLP / 21 CFR Part 11

Clarity provides the following tools to enable laboratories to comply with laboratory management regulations and general GLP practices such as 21 CFR Part 11. Details on how to set up Clarity in Regulated Environment can be found here.

1. **Certificate of Software Validation** (labeled as D021 Datasheet) certifies that Clarity was developed, tested, and structurally validated following a Certified Quality System conforming to GLP/GMP, GAMP and ISO 9001 guidelines. The certificate for the current software version can be downloaded from www.dataapex.com. The D021 Datasheet for older software versions is available upon request and can be found in *...\DOC PDF\DATASHEETS* section of the installation media (not in the Clarity installation itself).

2. The **Installation Qualification** (IQ) is an integral component of the station. This test verifies that Clarity and its components have been properly installed and records the results in a printable protocol.

3. **Operational Qualification** (OQ) validation is an optional package requiring SST extension (p/n A22) available for testing and validating the station. Depending on the HW setup, it can be performed using either a virtual or a physical (Validator) chromatogram generator.

4. **GLP Options** are station-level settings that enforce regulated behavior to protect data integrity. They can, for example, prevent user account deletion (ensuring complete list of users), require users to enter a reason for change, or hide the user list in the login dialog to ensure two-factor identification. Other options can restrict the use of the spike filter, or limit saving data to the current project only. (Not all available options are listed here.)

5. **User Accounts and Access Control** provide unique, password-protected user profiles that define individual rights within the station and restrict access to authorized instruments only. Password expiration and minimum length alongside other password restrictions can be enforced according to company policy.

6. **Electronic signatures** enable users to sign chromatograms electronically, either using their Clarity user credentials or personal digital certificates. Each signature record contains the signer's name, date and time, and the meaning of the signature (for example, *Measured by* or *Approved by*).

7. **Audit Trail** records all system actions, data modifications, and configuration changes in secure audit trails that are stored as one general file (Station Audit Trail) as well as parts of the corresponding files — chromatograms, methods, calibrations, and sequences. Each file therefore contains its own complete audit trail. Every modification entry includes the username, date and time, and can also contain the reason for change if this option is enabled in GLP Options. In addition to their own audit trail, methods and chromatograms contain a complete version history.

8. **System Suitability Test (SST)** – extension suitable for method performance and system consistency monitoring. (Required for OQ.)

9. **Printed reports** include page numbering and their contents are customizable. Among other options, it is possible to include the date and time of analysis and printout, and information about applied electronic signatures. Reports can be printed physically or as PDF files.