Supporting tools for GLP / 21 CFR Part 11

Clarity provides the following tools to enable laboratories to comply with laboratory management regulations, such as GLP and 21 CFR Part 11.

1. **Certificate of Software Validation** (labeled as D021 Datasheet) is a document that certifies that the software was developed, tested, and structurally validated following a Certificate Quality System conforming to GLP, GAMO, GMP, 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.

2. The **Installation Qualification** (IQ) test is an integral component of the station. This test monitors that the software has been properly installed, and the results can be accessed from a printed protocol.

3. Validator for **Operational Qualification** (OQ) is an optional package available for testing and validating the station. Validation is performed with the use of our chromatogram generator and a software utility.

4. **User Accounts** support the selection of rights and unique user profiles. This system allows the creation of unique password-protected profiles for each user. The user profile then defines in detail the user rights within the station (e.g., authority to affect changes in the methods of measurement) and may limit one's access to only certain instruments.

5. Optional **password expiration and minimal length.**

6. **Electronic signature implemented**. A user may sign their data. This electronic signature is stored with the name and date and supplemented with a set phrase (e.g., Measured by, Approved by, etc.). Two types of electronic signatures have been implemented:
   a) using user accounts
   b) using a certificate
   Signature information that indicates the printed name of the signer, date/time, and meaning (accompanying phrase/comment) is included in each readable form of the records (see par. 10).

7. **Audit Trail** of the whole system, chromatograms, calibrations, and sequences. Audit Trails are part of corresponding files. Detailed logs and histories of modifications enable users to maintain an audit trail. The station documents all parameters describing the conditions and methods of data processing for the user. This allows for easy access to a complete profile of information regarding any prior modification's effects.

8. **History of all methods and calibrations** as a part of chromatogram files.

9. **System Suitability Test** – method performance and system consistency monitoring.

10. **Printed reports** – page numbering, labeled with date and time of analysis and printout, includes information about applied electronic signatures. Reports can be printed as electronically signed PDF files.