Supporting tools for GLP / 21 CFR Part 11

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

1. **Certificate of Software Validation** (labelled 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 Datasheet for current software version can be downloaded from www.dataapex.com. D021 Datasheet for older software version is available upon request, eventually can be found in …\DOC PDF\DATASHEETS section of the installation media.
2. The Test **IQ** (**Installation Qualification**) 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 **OQ** (**Operational Qualification**) is an optional package available for testing and validating the station. This is accomplished simply with the use of our chromatogram generator and a software utility.
4. **Logon with Password**
5. **User Accounts** – selectable rights, unique user profiles. This system allows to create a unique password protected profile for each user. The user profile then defines in detail the user's rights within the station (e.g., authority to effect changes in the methods of measurement) and may limit ones access to only certain connected instruments.
6. **Password expiration and minimal length**
7. **Electronic signature implemented**. A user may sign his or her 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 signature have been implemented:
   a) using user accounts
   b) using a certificate

   The signature information associated with the signing that indicates the printed name of the signer, the date/time, and the meaning, is included in any readable form of the records (see par 11).
8. **Audit Trail** of whole system, chromatograms, calibrations, and sequence. 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 performance.
9. **History of all methods and calibrations** as part chromatogram files
10. **System Suitability Test** – method performance and system consistency monitoring
11. **Printed reports** – page numbering, labeled with date and time of analysis and print out, includes information about applied electronic signatures. Reports can be printed to electronically signed PDF files.