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Hardware and Software Validation of Analytical Instruments

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Accurate and reliable analytical data in laboratories can only be obtained with validated equipment, methods and processes for data validation. Regulatory agencies and independent third party auditors expect equipment and laboratory processes used during the generation of analytical data to be validated.

One of today's commonly accepted definitions of validation can be found in the guideline *General principles of validation* from US FDA "Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes." Most important in this definition are the words documented, high degree of assurance, specific process, consistently, and predetermined specifications.

From the user's view, the 4Q model is useful. The process is divided into four phases.

☐ Design Qualification (DQ) for setting functional performance specifications.

☐ Installation qualification (IQ) for performing and documenting the installation in the selected user environment.

☐ Operational qualification (OQ) for testing the equipment in the selected user environment to ensure that it meets the previously defined functional and performance specifications.

☐ Performance qualification (PQ) for testing to see whether the system performs as intended for the selected application.

Also, we should comply with 21 CFR part 11 when computers are used to create, modify, maintain, archive, retrieve, or transmit data.

This presentation is intended to help audiences reach a common understanding on the validation of software and computer-controlled analytical systems including 21 CFR part 11.

* FDA : Food and Drug Administration
* CFR : Code of Federal Regulations
  – collection of all regulations issued by US government agencies.