

SOME EXPERIENCES WITH DATA SYSTEM VALIDATION (INCLUDING DATA MIGRATION, RETIREMENT AND 21 CFR 11)

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Computer system validation is concerned with producing documented evidence that the system in question was purchased using quality standards, was accurate when qualified and remains so throughout its operational life. The need for fully validated chromatography data systems used for Good Laboratory/Manufacturing Practice (GLP/GMP) submissions has been well documented over the past few years. As the pharmaceutical industry has adopted more computerised systems and begins to align itself for the implementation of e-records and e-signatures, as governed by the FDA rule 21 CFR part 11, a more rigorous validation approach has become imperative.

The aim of the work was to validate a new LC-MS data acquisition and quantitation system, whilst still allowing access to archived data with no interruption of the routine workload. This involved qualification of the new system and validation of the software on an NT platform. Followed by validation of data migration from a Mac environment and phased system retirement.

The validation plan, project management and summary of life cycle validation management will all be discussed. This will include the evaluation of the requirements phase (system selection, user requirements specification, GLP assessment and traceability matrix), evaluation of the implementation phase (certificates of software structural integrity and vendor audit), evaluation of the integration phase (purchase order, license agreements, installation and qualification of the LC-MS instruments and PCs, operational qualification of the software and system documentation), evaluation of the qualification phase (performance qualification test plan, training of users, test scripts, evaluation of performance qualification) and assessment of overall system quality (including compliance with electronic signatures, electronic records final rule).
