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A fully automated system for LC/MS bioanalysis in regulated laboratories

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When performing bioanalytical LC/MS measurements in a regulated environment, it is necessary to ensure that the results have been obtained following established validated protocols. Deviations from established standard operating procedures may occur by intentional data manipulation or as a result of human error. We will describe the software tools used to control the user access and actions as well as automate data processing The software also tracks and documents all steps in the workflow process including the running of samples, method changes, processing the data and reporting and archiving results.

Study Manager is the software tool that schedules and manages all steps in the process while operating in compliance with the 21 CFR Part 11 Guidelines. Using Study Manager, users can begin with a Sample List produced by their LIMS system, schedule compound optimization, data acquisition, quantitation and report generation, producing output ready for the LIMS system. Examples will be shown to demonstrate the complete workflow starting from the LIMS sample list to data archival for long term secure storage.

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