MultiQuant™ 3.0 Software: Address Challenges in Regulated Bioanalytical Labs with Enhanced Compliance

Robust Watson Digital Link with Secure Data transfer and Secure Reporting

Introduction

Bioanalytical quantitation in the regulated laboratory has benefited from several innovations in recent years. For example, automated sample preparation and ultra-high pressure liquid chromatography (UHPLC) have resulted in major gains in sample throughput and the amount of data generated. This has placed greater demand on faster data processing, which has remained a significant bottleneck. Peak integration capabilities, data review, and proper audit trail tracking are time consuming and labor intensive tasks. MultiQuant™ 3.0 Software was designed for the bioanalytical laboratory with the goal of improving efficiency and facilitating compliance through an easy-to-use interface and powerful functions. Integrated within Analyst® Software, the MultiQuant 3.0 Software user has the ability to use the same access controls and user roles that have been already configured in the Analyst® Software. This compatibility feature greatly simplifies install administration, access management, and ensures uniform data processing and review privileges. In addition to several access control benefits, MultiQuant 3.0 Software will help the user to follow regulatory guidelines with its enhanced compliance features. The GLP compliance and validation regulations can be addressed by a partnership between the user organization and the vendor who provides analytical instrumentation and software for data processing.

Key Features in MultiQuant™ 3.0 Software for GLP Bioanalytical Lab

1. **Robust Watson Digital link**-Secure data transfer with audit trail log
2. **Enhanced Compliance Feature**- Data integrity and secure reporting

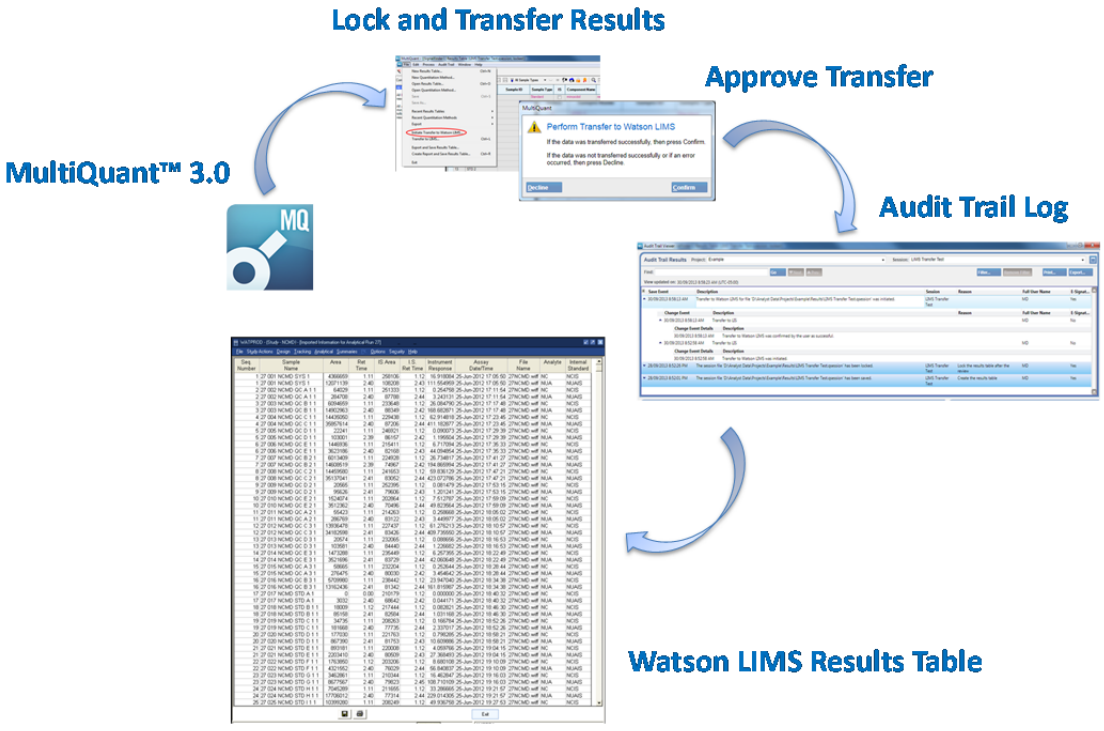

Figure 1: MultiQuant 3.0 software showing secure data transfer & audit trail log before exporting to Watson LIMS

Robust Watson Digital Link – Secure Data Transfer with Audit Trail Log

Watson LIMS is heavily used in bioanalytical labs from tracking sample shipments and storage to quant assay reports for clinical research studies. Many pharmaceutical companies have adopted Watson LIMS or some other LIMS software to accommodate sample throughput. Both Analyst® Software and MultiQuant Software has a proven track record with GLP bioanalytical labs. MultiQuant™ 3.0 Software has a robust link with Watson LIMS that allows the user to transfer their results in a secured and compliant environment, which allows the user to achieve higher productivity in their GLP laboratories. Key steps in secure data transfer between MultiQuant 3.0 Software and Watson LIMS were shown in figure 1.

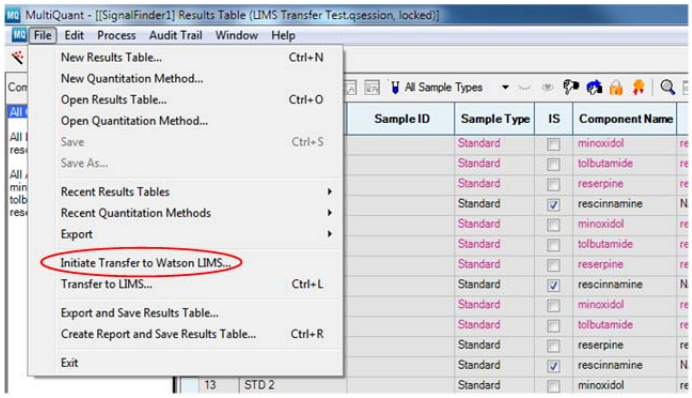

Figure 2: MultiQuant™ 3.0 software showing results transfer to Watson LIMS in file menu options

Enhanced Compliance Feature- Data Integrity and Secure Reporting

One of the most important features in GLP compliant software is data integrity. MultiQuant 3.0 Software validates integrity of file transfer through checksum and prevents tampering. MultiQuant 3.0 Software will reject data with an invalid checksum. If you have enabled the Data File Checksum feature, whenever you create a .wiff file (data file), the Analyst software generates a checksum value using an algorithm based on the MD5 public encryption algorithm and saves the value into the file. When you verify the checksum, the software calculates the checksum and compares the calculated checksum to the checksum stored in the file.

Secure Reporting: MultiQuant 3.0 Software includes powerful secure reporting functionality. The user who has GLP license will have access to secure reporting functionality. The user with the security permission can only edit the report templates from the software. The report templates will be encrypted as part of the software package.

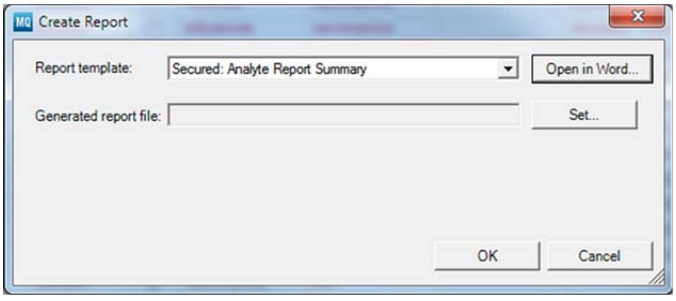

Figure 3: MultiQuant™ 3.0 Software showing secure reporting functionality. The user with security permission can only edit the report templates.

Key Benefits of MultiQuant™ 3.0 Software

1. **Increased efficiency** –MultiQuant software can handle large data sets with thousands of MRM transitions using intuitive user interface for fast data processing and data review

2. **Fast and easy software training**-Easy-to-use user interface reduces the amount of time required to train new operators, and improve consistency

3. **Single software solution** to process both small molecule drugs and biotherapeutics such as proteins and peptides. Process multiple data types such as MRM, MRM^3, TOF MS, SWATH® acquisition and MRM^{HR} on multiple instrument's such as SCIEX Triple Quad™, QTRAP® and TripleTOF® Systems

4. **Save time by reducing tedious manual integration**

    a. Powerful and robust integration algorithms such as MQ4 will increase performance by automating peak integration with minimal manual intervention

    b. Advanced query functionality will quickly identify samples that deviate from bioanalytical regulations

5. **Data Integrity and Security**

    a. Ensures data integrity throughout by supporting 21 CFR part 11 compliance with features such as locking of results, secure reporting, robust Watson digital link, audit trail log and e-signatures

    b. New and innovative audit trail functionality will allow easy search and present QA reviewers with track changes

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