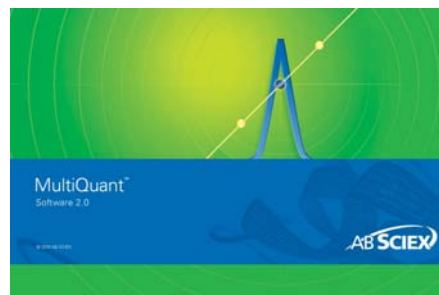


# MultiQuant™ Software 2.0: The New Standard in Productivity and Compliance for the Regulated Bioanalytical Laboratory

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, review, and proper audit trail tracking are time consuming and labor intensive tasks.

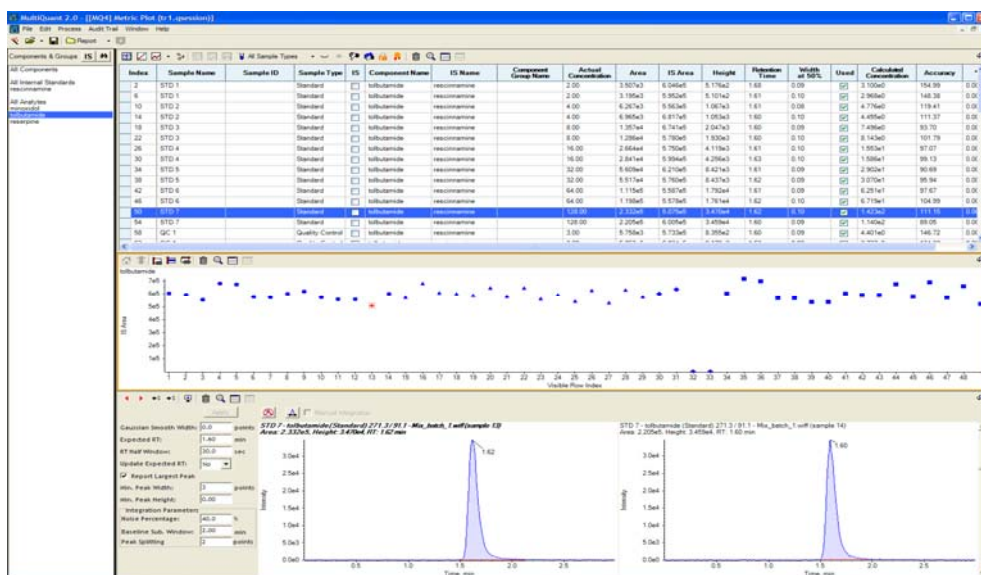
MultiQuant™ Software 2.0 was designed for the bioanalytical laboratory with the goal of improving efficiency and facilitating compliance through an easy-to-use interface and powerful functions. Integrated within Analyst® software, the user has the ability to use the same access controls and user roles that have been configured in Analyst Software. This greatly simplifies install administration, access management, and ensuring uniform data processing and review privileges.

Here, innovative new features in MultiQuant Software 2.0 are highlighted which significantly improve data processing speed, with powerful regulatory compliance and audit trail features.

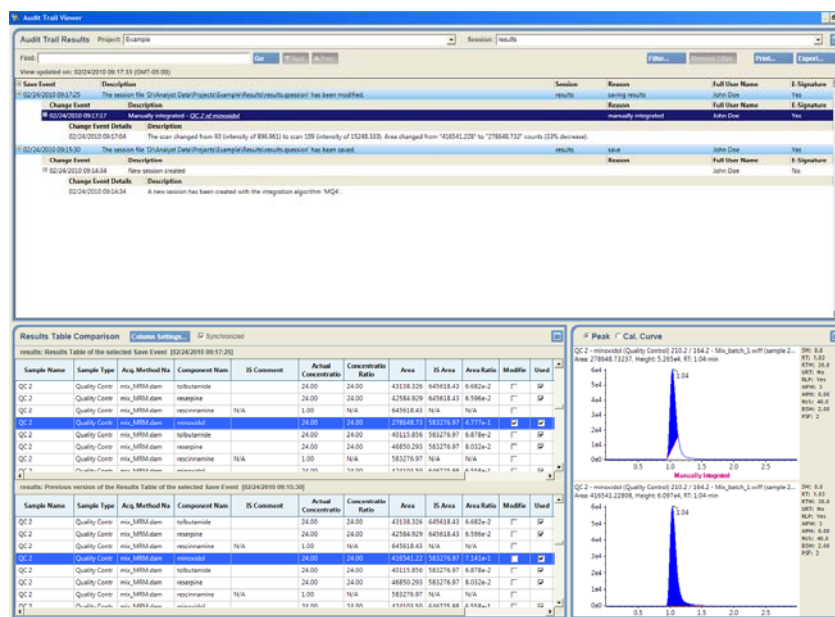


## Key Features of MultiQuant Software 2.0 for Regulated Bioanalysis

- Fast and user friendly interface with linked panes, custom queries and one click metric plots.
- New audit trail with robust management and precise control.
- All versions of the calculated results are stored, and hyperlinked to the audit trail which allows the reviewer to quickly see the data before and after a change.
- Results table locking feature and secure export.
- Audit trail allows search for specific events or samples across all results tables within a project, allowing easier QA review.



**Figure 1. Easy-to-Use Interface.** Intuitive user workspaces make data navigation easy, with dynamic linking of panes displaying results, analytes, integration and one-click metric plots.



**Figure 2. Powerful Audit Trail Viewer.** The viewer displays events and the associated data with hyper-linking. The data is shown before and after each audited event. The reviewer can quickly spot the impact of a change. Results tables and peak review are automatically linked to the audit trail.

## Speed and Ease-of-Use

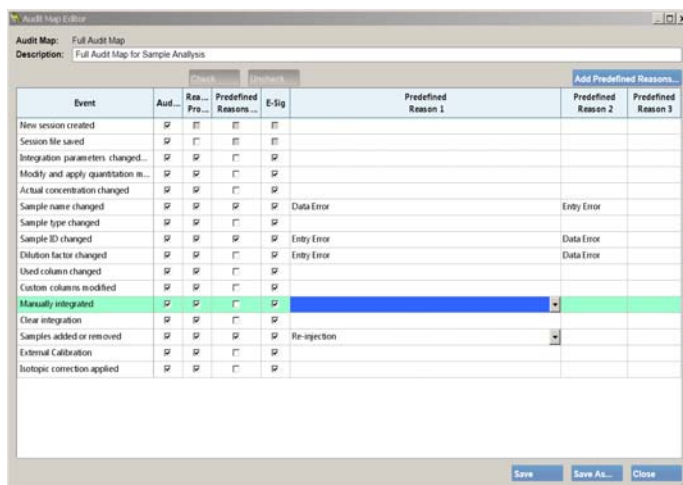
MultiQuant™ Software has been designed from the ground up with an intuitive easy-to-use interface. During data processing, the user can quickly build a new processing method and review data in linked panes which automatically display the chromatographic peaks and integration when a sample is selected (Figure 1). In a single click, the user can view all analytes or a specific analyte. The results tables and peak review are automatically updated.

In addition, metric plots such as an internal standard trend can be generated instantly with a single mouse click. Custom queries can also be set to aid in data review and allow the analyst to focus their review efforts on specific samples.

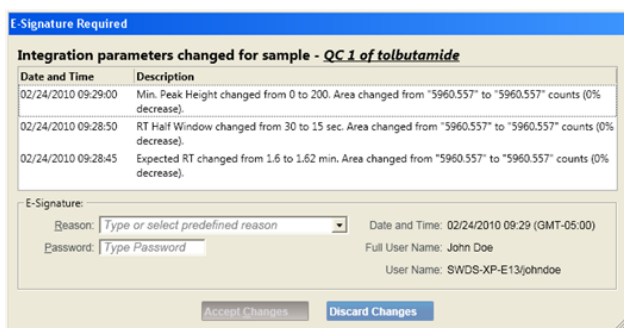
## Innovative Audit Trail Functionality

MultiQuant Software introduces a new, robust audit trail, with innovative features such as Grouped Audit Events and powerful audit trail management and review functionality.

The new Audit Map Editor allows the laboratory administrator precise control over audit trail functionality using an intuitive interface (Figure 3). For example, when a user is prompted to enter a reason for a specific auditable event, the administrator can pre-define the reasons to ensure consistency. The user can be allowed to type in a reason as well, or be restricted to a specific list of allowed reasons. Furthermore, this can be configured separately for each auditable event.



**Figure 3. New Audit Map Editor.** The editor provides intuitive control over auditable events. The administrator can specify which events are audited. For each event, a list of pre-defined reasons can be specified and E-signatures can be required.



**Figure 4. Grouped Audit Events.** The system logs multiple changes to integration methods in the audit trail and prompts for electronic signature once.

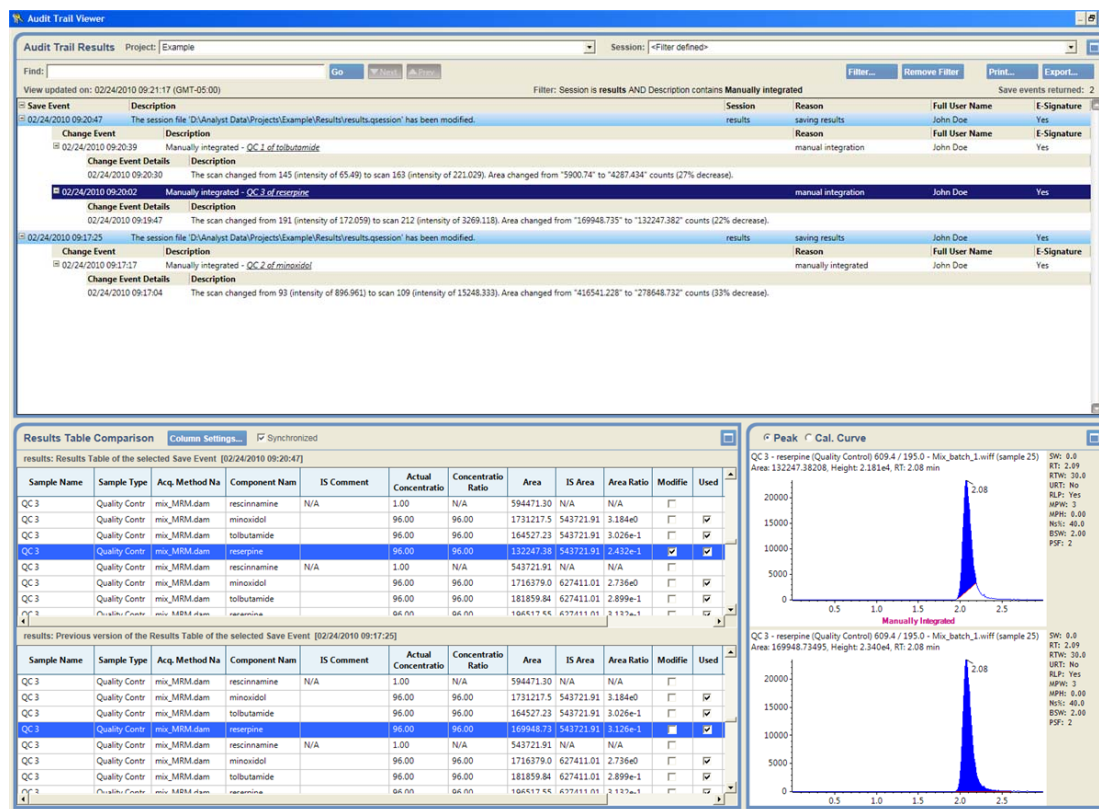
Electronic signatures are handled more efficiently through Grouped Audit Events (Figure 4). For example, when the user enters the “expected concentration” values for a multi-point standard curve, the software will prompt *once* for the electronic signature. The audit trail will still recognize each event separately and record the times for each event in the audit trail, while prompting the user for the signature only once. The software recognizes other

Grouped Audit Events such as multiple changes to the integration parameters. Each change is recorded individually in the audit trail, while prompting the operator once for the signature. This improves the speed of data processing without sacrificing compliance. Changes in the data and their associated audit map events are saved at the same time.

## Powerful Review Functionality

MultiQuant™ Software 2.0 introduces dedicated data review functionality. The audit trail and the data are linked, and all versions of the data are stored. Therefore, a reviewer can now view the data before *and* after an auditable change (Figure 2). Data review and audit trail view panes are linked for easy and efficient data review.

The software also prevents accidental changes in the data by warning if the data has been changed during review. This warning feature can be activated by the administrator.



**Figure 5. Audit Trail Search Capability.** All manual integrations within a project can be quickly located and relevant versions of the data automatically displayed and linked to the audit trail.

## Quality Assurance (QA)

MultiQuant™ Software 2.0 has been designed to facilitate QA and supervisor review of the results, including review across multiple batches within a project. For example, all result tables in a given project can be searched to find a specific event or action captured in the audit trail (Figure 5).

In addition, the reviewer can track a single sample across multiple batches, easily locating the original injection and re-injections in different results tables. The raw data for each injection and the integration can be easily check and tracked.

## Data Integrity

Data integrity is assured throughout the results table generation process. The software allows locking of the data to prevent further changes. Locking / unlocking authority is defined by the administrator who can also require that data be locked prior to exporting to LIMS or printing a report. The software also requires the operator to save the results prior to printing or exporting.

Data export to LIMS has traditionally been identified as a weak link in data integrity since text files have the potential to be tampered with after export and prior to import into the LIMS. To address this issue, MultiQuant Software gives the option of securing the exported data through encryption. Using compatible LIMS software, the data can be decrypted upon import, assuring integrity.

Finally, a dedicated data review function has been added to allow review without the potential of accidentally changing the data.

## Conclusions

- MultiQuant Software 2.0 has the potential to significantly reduce the amount of time required for data processing and review.
- The software is intuitive and easy-to-use which reduces the amount of time required to train new operators, and improve consistency.
- MultiQuant Software 2.0 helps to ensure data integrity throughout with features such as locking of results, requiring that a results table be saved prior to printing or export, and secure export of the data.
- The audit trail can be easily searched, even across multiple results tables within a project to find a specific auditable event or to track the history of a sample across multiple runs.
- MultiQuant Software 2.0 stores all versions of the data and automatically links them to the audit trail allowing the reviewer to easily see the data before and after a change was made.

## References

1. To download a trial version of MultiQuant™ Software please visit:  
<http://licensing.absciex.com/download/MultiQuant/2.0/>
2. "MultiQuant™ Software 2.0 with the SignalFinder™ Algorithm: The Next Generation in Quantitative Data Processing". AB SCIEX Technical Note, 2010.

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