WinKQCL™ Software and the Seamless Integration to the MODA-EM™ Platform

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The laboratory landscape is rapidly changing due to the increased focus on informatics and its impact on electronic data. At Lonza, we are connecting the two industry leading software platforms, MODA-EM™ Solution and WinKQCL™ Software, to support the initiatives surrounding data integrity and compliance. Transferring data directly from the underlying WinKQCL™ Database to the MODA-EM™ Database, allows the analyst to transfer their data with no additional intervention. The security and compliance gained with the connector will further enhance the built in data integrity of the two systems.

Transferring data from one system to another to ensure data integrity and not introduce additional work for the end user is a significant challenge. Limitations of other systems are generally related to their core infrastructure being a flat result file rather than a relational database. In this scenario, this restricts the user to a manual, potentially error-prone process that creates additional steps in the workflow. Results entry of endotoxin data can be automated with the simple configuration of this tool. The WinKQCL™ Analyst will enter the MODA™ Barcode into their assay and the MODA-EM™ Task Service will pick up the signed results and insert them into the Result Entry step within MODA-EM™ Database. The data availability within MODA™ Software facilitates trending capabilities not otherwise realized with two separate data repositories.

How Do Typical Instrument Integrations Work?

1. **File Import**
   This method requires that a file be output from the instrument or software. This file is typically a file type such as .xml or .csv.

What Are the Challenges With this Approach?

   a. When exporting/importing a file, to maintain data integrity, the file must be controlled in a manner in which no changes can be made. This will require that restrictions be put on the exported files to ensure they cannot be changed prior to importing. This can be cumbersome to initially setup.

   b. Using the file export/import approach also requires the manual import of the software/device file for results entry. Depending upon the instrument, this may require that the end user correlate the samples that coincide with each other. This can sometimes result in the incorrect data being assigned to a sample.

2. **Direct Connection**
   This method requires that an instrument is directly connected to a computer that has the software running. The software will recognize the instrument and is able to import via the cable connection.

What Are the Challenges With this Approach?

   a. This approach requires that the computer be directly connected to the instrument that is collecting data. Depending on the amount of space available, class of room, type of sample being collected, and various other factors, this type of setup may not be ideal.

   b. Using the direct connection method also requires the manual collection of data from the instrument. This may require the user to associate data from specific locations to a specific sample. Over all, this causes the end user to spend more time making sure samples are collected and imported correctly.

What Are the Benefits When Interfacing WinKQCL™ Software With MODA-EM™ Database?

The integration between the WinKQCL™ Software and MODA-EM™ Softwares utilizes a database connection. This type of integration provides some tangible benefits for both the end user and the users who review/approve the samples.

1. **Utility Data is Trended Together**

   One of the most important features is that integration of sample data from WinKQCL™ Software allows for utility data to be trended together in a single software solution. Endotoxin results can be trended along with bioburden, TOC, and conductivity results allowing for better viewing and reporting consistency.
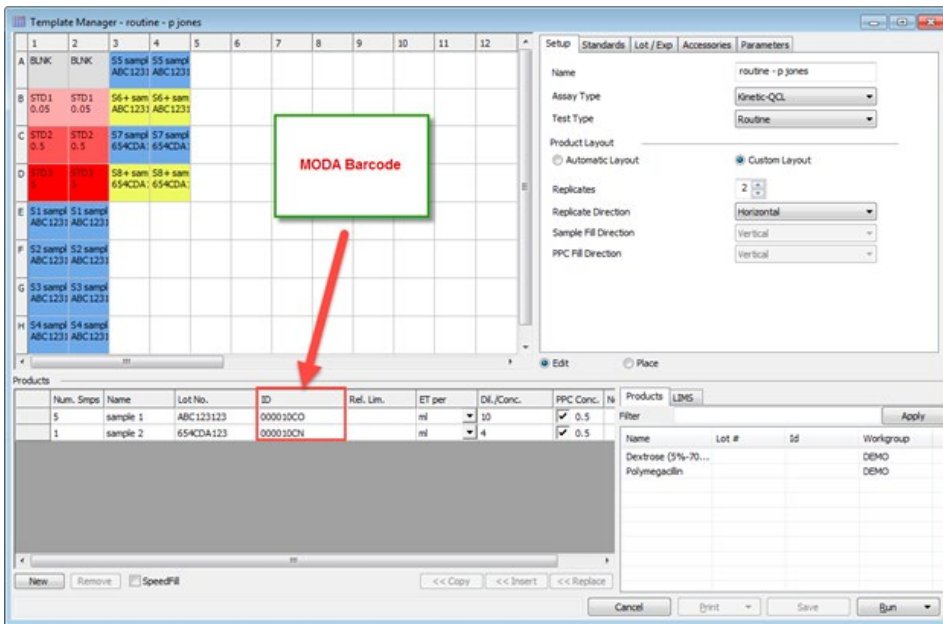
2. **The Entire Endotoxin Testing Process is Captured Electronically**

   The entire endotoxin testing process beginning with printing the labels for the sample collection vessels, all the way to entering the results, can be captured paperlessly and electronically in MODA-EM™ Software. No need for paper! In addition, the database integration allows the workflow and data integrity to be inherently managed by each system and ensures proper handling of the data.
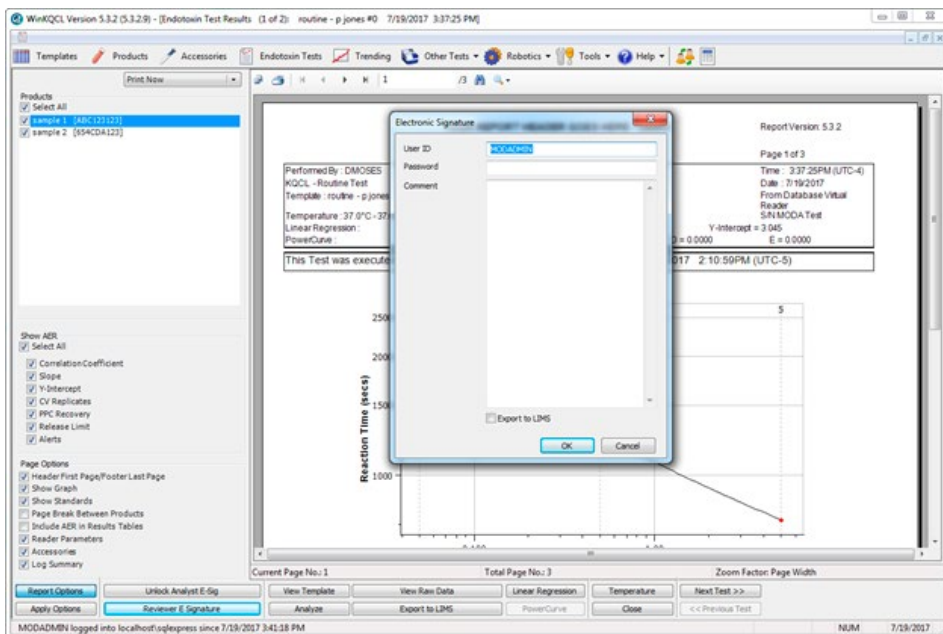
3. Automatically Import Sample Results

The integration of WinKQCL™ Data into MODA-EM™ Software allows for automatic transport of sample results into MODA-EM™ Database without the need of a direct connection cable or file import/export procedure. In addition, the results are automatically imported into the MODA-EM™ Software, once the results are reviewed in WinKQCL™ Software without anyone having to click a single button in the MODA-EM™ Software. This makes the integration seamless and saves time for the end user!

How Does the WinKQCL™ Integration Work?

1. During the setup of the endotoxin assay in the WinKQCL™ Software, the MODA-EM™ Barcodes for the endotoxin samples will be input into a specific field. This field could be Name, ID, or Lot Number.

2. Once the assay has completed in the WinKQCL™ Software, it will need to be signed for and reviewed electronically.

3. Once reviewed in WinKQCL™ Software, the MODA™ Task Service will automatically search for complete samples in WinKQCL™ Data with matching barcodes to those incomplete in MODA™ Platform and automatically complete them. There is no need for someone to log back into the MODA™ Platform once the assay is complete in WinKQCL™ Software. The sample results automatically import and the sample will complete.

The WinKQCL™ Integration into MODA-EM™ Platform is beneficial in multiple ways. It allows for better compliance mitigating potential data integrity issues with normal device interface options while also reducing potential transcription errors. In addition, trending various assay types from a single software system allows for consistency and on demand reporting. Data integrity is a significant focus that is fundamentally reshaping how laboratories capture and process information and managing this will be critical to the future of all QC organizations.

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