LIMS and Empower: A Different Approach to Integration

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Overview

LIMS and Empower: A Different Approach to Integration

Why Integrate?
Challenges with integration
Integration options
Allergan’s Solution
Reasons for Integration

• High volume of Chromatography testing
  • Ease of data entry
  • Reduce entry errors
• Harmonization of processes
  • Easier method transfer between groups/sites in the future
  • Global methods instead of site specific methods for the same testing
• The driver at Allergan
  • No harmonization of processes between sites on where to perform calculations (LIMS or Empower)
Options

• The following options were considered through the process
  • Manual integration between Empower and LIMS
  • Use the Empower integration module provided by LabWare
  • Create a custom interface

• Not considered during the process:
  • Use of LabWare ELN functionality
No Integration

- The first option, manual integration between Empower and LIMS was quickly eliminated.
  - Pros
    - Minimal cost to the project
    - No impact to project timeline
  - Cons
    - Time consuming
    - No harmonization of processes
    - Does not meet URS requirements
    - Does not meet project goals and expectations
Next, we evaluated the solution provided by LabWare.

Pros
- Designed to work with our LIMS solution
- Vendor support
- Rapid implementation
- Straight forward validation

Cons
- Inability to capture all results from Empower
  - Some results are only in Empower reports
  - Some results are only in spreadsheets
- Result calculations differ between sites. This prevents a single solution for transfer of results.
Custom Interface

• This was the solution we chose
  • Pros
    • Ability to meet all user requirements
    • Ability capture all results from Empower
    • Ability to report results in different units depending on country
    • Harmonized interface process
    • Secure
  • Cons
    • High cost to project
    • Significant impact to project timeline
    • Complex to use and support
The Interface

- The interface we designed is comprised of four major software components.
  - LIMS (LabWare)
  - SDMS (OpenLab)/RSME
  - Microsoft Excel
  - Custom Utility (Labformatix)
Interface Workflow

- A batch is created in LIMS.
- Using a function ‘Get Samples’ in the interface workbook, import the LIMS batch into the interface.
- Upload the batch from the workbook to Empower 2 for processing (optional step).
- Download processed Empower 2 data into the workbook.
- In the interface, the data is reviewed and the workbook is locked and saved in SDMS.
- Data is imported into LIMS using a LIMS subroutine.
- Normal review and approval functions are performed in LIMS.
Interface Workflow

(1) Create batch in iLabLIMS

(2) iLabLIMS batch data downloaded into Interface worksheet.

iLabLIMS

(3) Batch data is uploaded into Empower 2 for processing from Interface worksheet.

(4) Processed Empower 2 data imported into Empower Import worksheet.

(5) Data is reviewed, worksheet is locked and saved into the Openlab data folder.

Interface Template Workbook

Interface Reviewed & Locked Workbook

(6) Passed data in LIMS_Export worksheet imported into iLabLIMS via iLabLIMS subroutine MNU_MM_INTERFACE_EMP_IMPORT

Interface worksheet results parsed by LIMS_Export worksheet.

Empower 2

Empower Import Worksheet
LIMS_Export Worksheet
Config Worksheet
• Chrom Assay Suite of Analyses
  • Summary Analyses - represent the Sample Preparation Average values. Results captured in this analysis represent the average of the sample injections.
  • Impurities - results for the average of all the injections, replicate totals and average of the replicate totals
  • Extractables - results for the average of all the injections, replicate totals and average of the replicate totals
  • Concentration - results for Strength and Label Claim. The strength values entered are the average of all the sample injections across all preparations. The Label Claim value is calculated based on the strength value.
**LIMS**

- **Batch template**
  - Primary use is grouping of tests.
  - Provides the reference between LIMS and the Empower Project and Sample Set.
  - Does not include standards, controls and blanks.

- **Background servers**
  - Execute LIMS calculations in the background to allow users to perform other tasks in the system.
    - One background server client for each time zone.
    - Background server clients can be used as secondary clients to facilitate timely processing of calculations.
  - Suppress Lot Refresh during the calculation process.
User Interface – LIMS Components
User Interface – LIMS Menu

• **Open Excel Interface**
  - Opens Microsoft Excel 2007 on the Citrix Server by executing the windows shell command from LIMS Basic.

• **Import from Empower**
  - Imports data into LIMS from the Labformatix Interface by DDE communication to the open Excel Workbook. The subroutine requests the data contained in a hidden worksheet `EMPOWER_IMPORT` in the Interface workbook.

• **Open ECM**
  - This program references a List table in LIMS that contains the path to Openlab ECM and the path to the working directory transaction file from Excel to LIMS.

• **Check Batch Import Status**
  - Evaluates all Chrom Assay analyses with the component Execute Calculations to determine which are complete. The subroutine checks to determine which items are complete and compares them to the Batch Object test records. The processing time is included in the log records.
SDMS/RSME

• Security
  • AD Groups are used for controlling access to site files, method template spreadsheets and data.
  • Distinct AD groups for users, authors and administrators at each site.

• Folder structure
  • Site level access to the method templates and data.
  • Segregation of Validation and Production data.

• RSME Module
  • Provides additional security and controls.
  • Provides cell level audit trails.
Labformatix - Overview

- Custom application
  - Excel/VBA
  - Master xlam file that controls security and configuration settings
  - Individual worksheets at each site

- Security roles within the worksheet
  - Administrator – full access
  - Author – creates and modifies method template spreadsheets
  - Users – read only access to templates, but write access for processing data
Labformatix - Configuration

• The Configuration Menu allows the Interface Author to set a variety of setup options for the Interface Workbook.
  • The **Database Settings** section contains the information required to connect to the LIMS database.
  • The **Empower Settings** section contains the information required to connect to the Empower 2 database.
  • The **Default Name** field allows the user to enter the default database to be used when logging in to Empower 2.
  • When the **Lock** button is clicked, the interface is secured by deactivating Excel editing functionality and protecting sheets so that they cannot be deleted or altered by the user except as allowed by the template author.
  • The **Key Field** section allows the user to enter the name of the specific field to link the iLabLIMS and Empower 2 databases.
When the **Empower Import** button is clicked on the main configuration screen, a **Select Results and Peak Data for Import** screen appears. After logging into Empower 2 and choosing the Project, the Interface Author can choose which fields to add to the Empower 2 Import sheet.
Labformatix - Configuration

- Additional configuration options available to the Interface Author include the following
  - **Default Values** - allows the Author to enter default values for Empower components when creating method specific workbooks. These default values are used when the component field is left blank in Empower after running batch samples and are used to conform to requirements.
  - **Optional Components** - allows the Author to manually add components to the spreadsheet.
  - **Translate Empower Names** - allows the Author to map component names between Empower 2 and LabWare when the names are dissimilar and not automatically mapped by the spreadsheet logic.
  - **Peak Mapping** - allows the Author the ability to define the Empower 2 field types for the Empower 2 data import on method specific workbooks. In particular this is used when the same peak name needs to be reported with different units.
  - **Attribute Mapping** - allows the Author to program attribute comments of a data item in the Interface worksheet.
The Labformatix toolbar allows the user to get samples from LIMS, Log into Empower to import results and lock worksheets for review.
User Interface – Selecting LIMS Batch

The **Get Samples** ribbon button opens the LIMS Connection menu. This menu allows the Interface User to connect to LIMS, choose the desired LIMS template and batch, preview the data in the batch and upload the data to the Method Template and Interface worksheets of the interface.
The Ad Hoc dialog box allows the Interface User to manually match Empower 2 results data with the associated LIMS data prior to importing into LIMS. This would occur in the event of an unnamed peak.
### User – Interface Spreadsheet

#### iLabLIMS Batch: 24465A_14MAY10-02

<table>
<thead>
<tr>
<th>Sample</th>
<th>Sample Name</th>
<th>Test Name</th>
<th>Test</th>
<th>Test ID</th>
<th>Component</th>
<th>Error Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>244655</td>
<td>529890</td>
<td>Enzymatic</td>
<td>Test1</td>
<td>Test2</td>
<td>Test3</td>
<td>Error4</td>
</tr>
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</tr>
</tbody>
</table>

#### Notes:
- **Data Performed:** 10-09-2009
- **Error Report:** 02-01-2010
- **Unexpected Event:** 01-02-2010
- **Unidentified Error:** 01-03-2010

#### Additional Information:
- **Analysis Method:** AP-123
- **Analysis Method Version:** 23
- **Performed By:** [Author]
- **Performed On:** 10-09-2009

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**Allergan**

Our pursuit. Life's potential.
Summary

• There are many options available for integration: Manual, integrated, third party or custom. We selected the option that best met our overall requirements.

• A custom solution provided the flexibility and security we needed immediately and the opportunity for additional harmonization in the future.

• Future integrations of a similar nature can use the same underlying technology, providing a consistent workflow in the labs.

• By using Excel for the interface, any transition in the future to other technologies (e.g. ELN) should be straight forward to manage.