WHITE PAPER

Laboratory Integration Solutions

Key Benefits

- Understand interfacing requirements at the beginning of the LIMS project
- Consider all instruments as candidates for interfacing
- Provide maximum automation while retaining control over the process
- Realize the full benefits of instrument integration with LIMS

Planning a Successful Instrument/LIMS Interfacing Project

Overview

As a provider of laboratory instrument interfacing solutions since 1986, we have accumulated valuable experience implementing, training and consulting with customers around the world on all aspects of instrument interfacing in the lab.

Out of that experience, we have developed a clear understanding of what it takes to plan a successful project for interfacing laboratory instruments with LIMS.

At first glance, the task may seem pretty straightforward, taking data from one location and moving it to another. However, creating truly productive interfaces between instruments and LIMS requires knowledge about the various interfacing possibilities along with a thorough understanding of laboratory data flow.

In this white paper, we will present some of the key concepts and considerations that lead to a successful interfacing project. One that benefits the lab by increasing the accuracy of reported data, reducing the cost of reporting that data and getting sample results into LIMS faster.

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The Nature of Instrument Interfaces

Types of Instrument Interfaces

There are two types of instrument interfaces:

Uni-directional interfaces are the simplest form of data transfer, typically defined as acquiring data from the instrument and reporting it to LIMS. This type of interface usually requires additional information (such as the sample identifiers) to be entered at the instrument or interface level, before committing the results to LIMS. Uni-directional interfaces are the easiest to implement.

Bi-directional interfaces are more intricate, as they involve the movement of information back and forth between LIMS, the interface and the instrument. A typical bi-directional interface would involve querying LIMS for a list of pending samples for a certain test. After collecting this list of samples, the interface would deliver the work list to the instrument. After analysis, the data is collected by the interface and reported back to LIMS. Bi-directional interfaces reduce the analyst's workload by eliminating the need to manually create sample work lists or sequences.

Levels of Interaction

Instrument/LIMS interfaces offer varying degrees of interaction with the user:

Black Box

A black box interface is defined as an interface that runs in the background with little or no user interaction at the interface level. Common examples include instruments with their own data systems and on-line analyzer applications.

Review and Approval

Review and approval offers the end users an opportunity to evaluate the test results prior to committing them to LIMS. This type of interface often employs automated limit checks and other calculations that the end user may want to view before reporting the data to LIMS.

A review and approval type of interface may also provide a platform for lab supervisors to sign-off on the results before they are transferred to LIMS. Any actions that take place within the interface can be monitored and recorded by the security system and audit trail.

Additional Data Entry

Some applications require that additional information be added to the collected instrument data, before it can be committed to LIMS. This data can be entered directly by the keyboard or through external devices such as bar code scanners. Balance applications are a common example of a test that may require additional information. As the samples are weighed, a bar code scanner could be used to automatically enter the sample IDs into the interface, thus allowing the data to be reported to LIMS.

Limitations of Drivers and Collectors

In the past, LIMS companies have tried using pre-defined instrument drivers or collectors to provide an interface between instruments and LIMS. In theory, this approach seems to make a lot of sense. Create a driver for each instrument, and in short order you have interfacing solutions for most common lab instruments.

In practice, this type of rigid solution isn't practical – no matter how sophisticated a driver is, it will only do what it is programmed to do.

An instrument driver or collector cannot adjust to each laboratory's unique interfacing requirements or offer the automation options that we have just reviewed. A more flexible solution is needed to properly integrate the interface with the laboratory data flow.

Understanding Laboratory Data Flow

The type of interface and the level of automation for the interface are best determined by the existing flow of data in the lab. The interface can either automate an existing data flow or it can present an opportunity to analyze existing data flow, develop improved procedures and then apply automation.

In order to determine how the interface will be used for an application, the existing data flow between various components needs to be identified and understood.

To understand data flow, you first need to identify the components of the system. Then you need to determine how the data flows between these components and identify the order in which events need to occur. Finally, you need to define which events can be automated, the levels of automation and the nature of the various interactions.

The Components of an Interfacing System

LIMS

LIMS can be both a destination for data and a source of data. Therefore, a LIMS interfacing project requires an assessment of how data can be extracted from LIMS, as well as how it will be reported.

Bi-directional interfaces require an understanding of the information (such as work lists) that resides in LIMS and can be used in running the analysis. It is more efficient to have the interface extract this information from LIMS rather than have an analyst enter it manually into another application.

Most LIMS transactions not only require specific sample information, but are also dependent on the order that the information is presented. At a minimum, the sample information will include a sample identifier and result, but will typically include other parameters such as Test IDs, LIMS group numbers and more. Not only are LIMS transactions unique to each individual LIMS, but a single LIMS can require unique formats for each specific test.

The interface will need to present the data in a format that LIMS is able to understand. Every LIMS has a unique format that is required for interface/LIMS communications. ASCII files, ODBC and proprietary transactions are among the most common methods of transferring data. To transfer data via ODBC or API requires a full understanding of LIMS tables and table structure.

Whenever possible a lab should consider instrument interfacing during the purchase and implementation phases of a LIMS project. Ignoring instrument-interfacing requirements at this point can lead to costly mistakes in designing and implementing LIMS. When the project moves to the interfacing stage, these mistakes may need to be corrected, either through changes to LIMS or by creating more complex and costly interfaces.

Points to consider when planning implementation of a LIMS:

- Naming conventions – should match as closely as possible with those in instrument data systems. For example, compound names that are used in a CDS (Chromatography Data System) should also be used in LIMS. This will save having to translate between the two systems.
- Transferring Sample Information – How will sample information get from LIMS to the bench? Will LIMS generate work lists, will samples be bar coded, etc.?
- How will LIMS match up results with samples? – What information does the interface need to have in order to send results to LIMS?
- Are samples always in LIMS before they are analyzed? – If not, how will the interface manage the transfer of results to LIMS?
- Where will calculations be done? – Are the results from instrument ready to report to LIMS or are their additional calculations that the end user usually performs? Can these calculations be automated in the interface or LIMS? Does the analyst need to see the result of the calculation before sending data to LIMS?

Understanding your instrument interfacing requirements and options at the beginning of LIMS project will make instrument interfacing easier, saving time and money.

Instruments and Instrument Data Systems

Which instruments should be interfaced?

All instruments in the lab should be considered as candidates for interfacing. While it is possible that some very old instruments will not have any data connection, making them difficult or impossible to interface, the vast majority of lab instruments can be interfaced.

Some laboratories may be reluctant to interface their older instruments because they think that when they buy a new instrument, they will also have to buy a new interface. However, a proper interfacing solution can be modified with a simple change in configuration and will require no programming to connect with a new instrument. Holding off on interfacing until a new instrument is purchased is false economy. That decision just delays the cost savings that a good interface will provide.

Many instrument data systems will claim to provide "LIMS connectivity" as one of their features. This is understandable as each instrument manufacturer wants to be competitive, and being able to connect with LIMS is a very desirable feature.

Unfortunately, it is very rare that the instrument software provides a true LIMS interface. In reality, what this usually means is that the instrument software will produce an ASCII file in a fixed format. Some type of interfacing solution is still required to complete the interface. As these systems often generate large volumes of data, it is important to ensure that the data is transferred to LIMS as efficiently as possible.

How complex is the data?

Instrument data can be as simple as a single balance result or as complex as a chromatography batch report. Surprisingly, simple data like a weight from a balance can be the most challenging to interface. The reason for that is the lack of information surrounding the data.

A weight typically comes from a balance without a Sample ID, Task ID, Analyst ID, etc. It becomes the job of the interface to match up the weight with all of this information so that LIMS will know what to do with the data when it receives it. Part of the planning stage in interfacing is to determine where this information will come from and how the interface will match it with the appropriate results.

For more complex data, like a chromatography report, the challenge is "too much information". Not all of the data that is generated in a report needs to go to LIMS. The interface needs to be able to recognize and extract just the relevant data and then format that for input to LIMS.

What needs to be sent to the instrument or instrument data system?

As we discussed with LIMS, the interface may also need to interact with instruments in a bi-directional manner. The interface system should be able to send sample information such as work lists and run parameters to applications like a CDS.

The interface may also be required to control the instrument. For example, a balance application may be made more efficient by having the interface send commands for opening/closing doors, taring the balance or obtaining results.

Can the interface be embedded in the instrument data system?

The newest interfacing technology allows the instrument interface to be embedded within some instrument data systems, such as Chromatography Data Systems. The analyst accesses the interface through a menu item in their instrument data system. The connection to LIMS is transparent.

In this scenario, the analyst does not need to have any knowledge of either the interface or LIMS in order to automatically query LIMS for a work list of samples. The interface can even automatically add standards and control samples to the work list before sending it directly to the instrument data system. This level of automation and integration makes the interface much simpler for the analyst to learn and to work with.

End Users

End user requirements determine the appropriate level of automation.

- What actions need to take place before the data can be reported to LIMS?
- Does the analyst need to review the results after analysis?
- Does a manager need to approve the results before they go to LIMS?

One concern that is often expressed going into an instrument/LIMS interfacing project is that the lab will lose control over the data. That can be a legitimate concern if the project does not include a well thought out analysis of how the analysts and supervisory personnel are interacting with the data under the current operating procedures.

Understanding the end user's requirements will determine the level of automation that is appropriate for the interface, whether it should be implemented as a black box solution, review and approval or provide for additional data entry.

Each interface should provide maximum automation while retaining the level of control that the laboratory needs to have over the process.

Display Requirements

Each analysis in the lab can have different requirements as to what information the analyst will need to see. This can range from tests where the analyst does not need to see the data at all, to cases where the analyst needs to review every result and add observations and/or approvals before sending the data to LIMS.

Maintaining a common display format for all instruments in the lab can increase lab efficiency and reduce the time necessary for training end users that work with multiple analyses. The challenge is to accommodate the full range of display requirements in a format that is consistent throughout the lab.

Ideally the display can be readily configured to meet changing requirements or to accommodate new analyses or new instrumentation.

Peripheral Devices

The current or desired data flow in the laboratory may include peripheral devices. These can include a broad variety of devices including bar code scanners, printers, environmental monitoring devices, etc. The interface may need to send data to, or acquire data from, any of the devices that are used in the lab.

In order to include these devices it is necessary to understand the data format of each device and the method of communication that each device uses. Examples of communication methods include keyboard wedge, TCP/IP or RS232.

Other Systems

The interface may be required to interact with other systems that are in place in the lab. These include such systems as Electronic Laboratory Notebooks, Scientific Data Management Systems or Enterprise Resource Planning systems like SAP. Additionally home grown and vendor database systems, such as calibration or inventory control systems may store information or require an update from the interface.

As with peripheral devices, it is necessary to understand the data format of each system and the method of communication that each system uses. ASCII files, ODBC and proprietary transactions are among the most common methods of transferring data to these types of systems.

Security and Regulatory Compliance Requirements

For laboratories working in regulated industries it is essential to ensure that the security of the interface supports their regulatory requirements. It is important to note that no single software component can guarantee regulatory compliance. Compliance only comes when the software is implemented in an environment and is used in a manner that meets the regulatory requirements.

Common security questions in a regulated environment include:

- Does the interface include the tools that we need to meet regulatory requirements?
- At which points in the process do we need to add electronic signature challenges to confirm the identity of the analyst?
- Do the electronic signatures include all of the components required by the regulation?
- Is there an audit trail in place to document activity and changes?
- Is the audit trail information retained with the electronic record?

For non-regulated environments, there can still be security requirements that are in place to ensure the integrity of the instrument data.

Common security issues in a non-regulated environment include:

- Should every analyst have full access to the interface, or do we want to control access to the interface?
- Which data can and cannot be altered/entered by end users?
- Who has permission to make these changes?
- How do we assign different levels of access?
- Who will administrate User IDs and Passwords?

All of these questions require that the laboratory have a thorough and documented understanding of their security requirements and procedures. They also require that the chosen interfacing solution be capable of meeting their security needs. A professionally developed LIMS interfacing solution will provide all of the functionality required to meet security and regulatory requirements.

Implementation

A key part of the planning process is to determine what level of involvement the interface solution vendor and the customer will have during the implementation stage.

Deciding which level is best for a project is a matter of assessing the availability of resources, both from the customer and the solution provider, the level of expertise of those resources – particularly on the end user side – and the timeline of the project.

Vendor Provides All Services

The interface solution vendor can provide all of the services related to the interfacing project. The end user is still an integral part of the process, but the vendor provides the expertise and performs all of the work.

The end user will need to take responsibility for signing off on requirements and specifications, as well as being trained on the use and administration of the system.

In this scenario, typical services provided by the vendor will range from initial development of requirements and specifications for the interfaces, through design and implementation of the interfaces themselves and concluding with providing full training in the use and administration of the interfacing system.

This is the best choice where the customer has limited resources to apply to the project, due to other projects that are running concurrently or simply because the customer does not have personnel with expertise in instrument interfacing. In assessing their level of internal expertise, the lab needs to keep in mind that they need to have a full understanding of all of the issues listed above to ensure success with a project.

Having the vendor provide all of the services can also be the best choice if a project has a very tight timeline. The vendor can allocate resources with the level of expertise required to meet the project deadline.

Customer Performs All Services

At the other extreme is a customer who can take full responsibility for the entire project from start to finish.

In this scenario, the customer only requires licensing for the software. On this type of project, the vendor may be asked to provide some training on the use of the software and the configuration of the interfaces. A technical support plan is usually kept in place in order to insure that the customer receives any software updates and to provide the customer with an expert resource for technical issues.

This is suited to a customer who has strong internal resources. It also suits a project with a longer timeline as internal resources tend to be sidetracked with other projects and day-to-day activities.

Vendor and Customer Share Services

There are numerous variations that fall within this category. Any of the services that are performed when the vendor provides all project services may apply to this scenario.

Many times the vendor provides all services for an initial instrument to LIMS integration project, training the customer as they go along. Upon completion of the initial project, the customer takes the responsibility for rolling the solution out to other laboratories or sections within the company.

The role of the vendor and customer can change over the lifetime of the project, as timelines and resources vary. Sometimes, the vendor may need to step in to the project to a greater degree or relinquish control of the project if the customer is able to take more ownership.

When properly managed, this scenario makes the best use of available resources both on the vendor side and the client side.

Keys to Success

Proper planning of an interfacing project gives the laboratory an opportunity to realize the full benefit of having their instruments interfaced with their LIMS.

Studies have shown that for instruments which are used routinely or for instruments such as ICP, AA, and chromatography that produce a lot of data per sample, the Return on Investment (ROI) for instrument interfacing is typically less than a year. A well-planned, successful instrument/LIMS interfacing project will continue to return that investment for years to come.

We have taken a quick, yet comprehensive look, at factors that contribute to planning a successful instrument/LIMS interfacing project. We have discussed types of interfaces, varying levels of automation, the different components that can be a part of an instrument interface and different scenarios for successfully implementing an instrument/LIMS interfacing project.

Proper planning for a LIMS interfacing project can best be summarized by these three keys to a successful project:

Understand your Laboratory Data Flow

Most importantly, understand your laboratory data flow. Instrument interfacing is more than just grabbing a piece of data and sending it somewhere. A good interface interacts with all of the data generation and data management systems in your lab. Having a full and detailed understanding of those systems and how they fit together will make it much easier to understand your interfacing goals and requirements.

Allocate Appropriate Resources

Don't underestimate the task and the resources that you have to assign to the project. If you have personnel that truly understand your laboratory workflow and the technology issues involved in automation, then definitely get them involved in the interfacing project and make sure it is their main focus. With the right interfacing tools, they may be able to complete the project on their own.

Don't Re-invent the Wheel

There is no substitute for experience. The most successful projects supplement internal resources with expertise from an experienced solution supplier. Partnering with a recognized and reputable interface provider will bring you the benefit of their years of experience in accomplishing what you are setting out to do.

For more information about PerkinElmer's informatics product offerings please visit www.perkinelmer.com/informatics

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