The Workflow Driven Lab

Introduction

Many companies have recognized that their internal business units operate as a set of business processes. These business processes can also be called *workflows*. Modern Laboratories are highly suitable to this workflow driven approach. In fact, laboratories are already process driven by a large extent due to the nature of what they do on a day to day basis. Surprisingly, the laboratory software solutions which have been prevalent have not adapted to this primary need.

Workflows and the Laboratory

So what is a workflow? According to wikipedia a workflow: consists of a sequence of connected steps. It is a depiction of a sequence of operations, declared as work of a person, a group of persons,^[1] an organization of staff, or one or more simple or complex mechanisms.

A laboratories overall daily workflow is an overarching construct that itself may be comprised of several subprocesses. Each of the sub-processes can be further defined as a sequence of steps that a person or group follow to achieve some end result.

In thinking about how your laboratory operates, it is easy to see that there are discrete processes that occur everyday. It is even possible that you already have some defined workflows written in procedure guides. Lab experiments\tests themselves are nothing other than explicitly defined step by step workflows that are often outlined by equipment providers in their documentation.



In fact, the lab environments successful operation is predicated on the successful definition and adherence to workflows. It could be said that a modern laboratory is an advanced process implementing construct. In making this statement we are separating the research process that determines what processes will be performed and interpretation of experimental results as separate from the lab even though these researchers are tightly affiliated with the lab.

Because of the above truisms, the lab is as dependent on workflows as any business unit in any domain today. Furthermore, the dynamic nature of the laboratory requires agility in the adaptation of old workflows to updated processes and the quick implementation of new processes as new technologies are adopted by the lab.



Sapio Sciences Llc 400 E. Pratt St, Suite 800 Baltimore, MD 21202 What's interesting is that while the lab is operating as a workflow processing machine, the LIMS software generally has not been upgraded to support the reality of process driven, dynamic laboratories. This leads to long and costly implemention timeframes, long learning curves, inflexible software and dissatisfiled end users. It is time to align your information technology with the essential needs of the modern laboratory.

A Workflow Example

An example of the processes in a genetics core facility might be as follows:





If you perform genotyping in your lab, it is likely that at a high level the above process is familiar to you. It is be clear looking at the above that this is indeed a workflow, and in fact, is multiple workflows. We might break down this overarching process into the following discrete processes:



So the question becomes how this is implemented within a laboratory management software package (LIMS). Realistically, all software packages allow you to track certain information related to the above processes in some manner. The question is how this is done. In most cases, the workflow is really a set of instructions on paper or in some document that says something like:

- 1. When receiving a new sample, login to the LIMS and go to the sample section. Then click the "Add new Sample" menu option under the file Menu.
- 2. Enter the sample ID, then click to submenu for phenotype information entry and enter that information
- 3. On the main sample screen, find the button labeled "print barcode", and press it to print the barcode for the sample.
- 4. And on and on with menu clicks, button clicks, submenus etc.

The problem with the above is it is a non-linear process that requires the end user to navigate to many different sections of the LIMS through the life cycle of the samples from receipt to processing to results. In addition, there is no intelligence built into the process itself. For example, certain steps in a process should not be doable until certain other steps are completed. This is not reflected in the above process other than via the documentation of the process.

Even Microsoft Excel can track data of this nature, but no one would ever call it workflow oriented software engine. The same is true of LIMS that operate as above; they are not workflow driven but screen\menu driven. A new approach is needed to mirror the lab environment.



Workflow Requirements

If you were designing a LIMS to operate in this process driven environment, what would you want? Following is a list for your consideration:

- The ability to easily define a workflow with no programming and give it a meaningful name
- The ability to define the discrete steps of a workflow (i.e. Tasks) with no programming
- Support for many tasks types, such as:
 - Tasks that add things to the LIMS for me (e.g. samples, experiments, projects, plates)
 - Tasks that produce barcodes
 - \circ Tasks that display a form to the user to collect relevant data for this task
 - o Tasks that run product extensions
 - Tasks that import data
 - o Tasks that integrate with external systems or lab equipment
- Support for a single workflow to work with more than one "item" at a time. Such as 32 samples or 4 plates, or one project, etc.
- Support for easily defined task dependencies with no programming so the flow through the workflow can be controlled (e.g. – step 5 cannot be done until steps 2 and 4 are done)
- The workflow should provide an easy click through step-bystep process whereby all the steps are easily visible and intuitive to the end user. This means no menu clicking or extra product knowledge is really required by the end user to use the workflow
- The ability to mix and match



different records in a single workflow. For example, you might be working with a Project at the beginning of the workflow, then an Experiment then Samples and then Plates.

- Each task should provide easily accessible help for the end use with a single click and without the user having to exit the workflow
- Workflows should be able to be paused and resumed days later
- Workflows should allow me to implement business rules that verify data and perform other actions within the context of the workflow.



- It should be easy to see what steps of the workflow have been completed, and what steps are yet to be done.
- Tasks should be usable across more than one workflow to facilitate reuse.
- The ability to export a workflow definition and share it with other labs.

This is a good list of requirements for a workflow system. If these items are in place in your LIMS you have positioned yourself to implement processes that will mirror your lab processes, reduce training times and increase throughput. This is not all that matters however; the underlying *data model* and its flexibility will have a major impact on the utility and adaptability of both the workflows and the LIMS in general.

The Data Model

It would be easy to not think about the data model underlying the LIMS. In fact, most vendors don't really want to discuss the data model at all. But the reality is that the flexibility of the data model is extremely important to the workflows. The reason is that workflows are built on top of the data model. If the data model is not well defined, is not easily configurable and does not offer the necessary control to the customer than the utility of the LIMS will be greatly diminished and its cost will go up. So what do we mean by configurability and flexibility in terms of the data model? Here is a list of things you should look for in a LIMS data model configuration toolset:

- The LIMS should provide the ability for the customer to define new data type(s) to be tracked (Data Types may also be referred to as "Objects".) Data Types refer to real world (e.g. "Illumina Sample") or theoretical ("Project") items that are to be tracked by the LIMS. With this capability you can track literally anything you ever want to track. You should not be limited to the data types and relationships that the software vendor has defined for you.
- The ability to define relationships between data types in the system. Data Types are not standalone entities. They will have relations to other data types such as master-detail type relations. An example of this is a "master Sample" that may have many "Aliquots" under it. This type of relationship should be easy to configure in the LIMS with no programming.
- The ability to support one to many and also many to many relationships between data types. Support for complex relationships is a nontrivial exercise for most applications in any domain. The LIMS should enable these relations to be easily defined with no programming. These should also be changeable at any time by authorized administrators.
- The LIMS should provide the ability to easily define and arrange these data fields as well as group them together on forms. Data fields describe Data Types and are what the user enters data into on forms. Examples include "Sample Id", "Sample receipt date", etc. There should be support for a variety of data fields such as Date, Pick lists, Text, integer, check boxes, etc. These should also be changeable at any time.



This list of features should all be done via a configuration. This means that *no programming* is involved and *no Database Adminstrator* is needed. These types of changes should be doable by the lab manager with little or no training on the LIMS. This ensures not only rapid project implementation timeframes and drastically reduced costs, but long term viability of the LIMS to quickly adapt to new technologies that come into the lab.

The Workflow Driven Lab - Summary

The combination of a powerful, configurable workflow engine with an extremely flexible and configurable data model virtually guarantees you will have a LIMS with high utility that will serve as an aid in support of laboratory processes instead of being an obstacle to getting work done. There are other LIMS features to consider as well such as the user interface design and the Application Programming Interface (API). These are covered in detail in our white paper titled "How to Choose a LIMS – The 5 Question RFP".

To schedule a detailed technical demonstration of how Exemplar LIMS measures up to these requirements, please contact us at <u>sales@sapiosciences.com</u> for more information.



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