

Delphinus, Inc.

Laboratory Automation Engineering

What is an Laboratory Automation Engineering Approach”?

How does an LAE approach to lab automation differ from current practice?

LAE implemented lab automation differs from current approaches:

Current Practice	LAE Approach
<ul style="list-style-type: none"> • Task-oriented, focused on bottle-necks, local work spaces, • A laboratory being viewed as a collection of individual task stations, • Technology-driven, how can a product’s technology be used to improve a given situation, • Automation-as-an-extension-of-the-instrument viewpoint, automation is used as a setup to instrumental analysis or as a post-run activity, supporting the instrument is the center of focus. 	<ul style="list-style-type: none"> • Engineered systems point-of-view, • A top-down structured approach, • Designed to protect the value of a laboratory’s products [knowledge, information, and data] and enhance the labs [and larger company’s] ability to gain value from those products.

One view of a working laboratory is that it is a place where people work at different tasks to achieve a goal [test results, running experiments, evaluating data, etc.]. From the standpoint of Laboratory Automation Engineering, a laboratory is a place where processes are used to carry out peoples work and those processes can be integrated into systems that can improve:

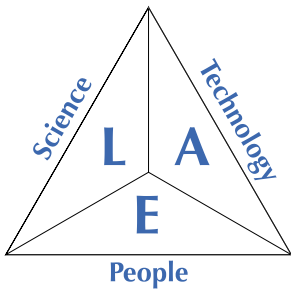
- A researchers ability to understand the results of an experiment and plan the next step in a discovery process,
- A technician’s ability to evaluate test results and release products for shipment,
- A scientists understanding of data integrated from multiple sensors and data sources.

The key difference is that in one situation technologies are used to help people carry out individual isolated steps in an otherwise manual process, while in the other, systems are designed to off-load people from managing processes to allow them to concentrate on planning, evaluating data, and discovering new knowledge.

The LAE methodology looks at how work is being performed in a laboratory, models the processes, and then designs process-directed automation systems to enhance peoples ability to work and integrate data flows from processes to make people more effective and productive. Product choices are based on their fitness for the application, ability to support the implementation of the process model, and meet integration requirements.

It eliminates layered procedures such as validation by integrating validation requirements into the projects design and implementation, avoiding duplication of work and delays in putting systems into service.





From Mapping Lab Processes to Mapping Corporate Information Flow

The initial stage of our engineering approach includes the development of a Laboratory Automation Architecture built on two items:

- the first is a set of management policies that establish criteria for evaluating alternative implementations for lab automation projects, and setting guidelines that must be met by project managers,
- the second is the development of models that describe how the processes in the lab work, and how the results of those processes are transferred to other groups. Both of these points are covered in detail in “*A Management Survival Guide to Engineering Laboratory Automation*”, currently under development.

Many of the concepts we are working with are applicable to companies and departments other than those concerned with laboratory automation and scientific computing. *The models for example can be used to create a computing / information / workflow architecture for an entire company*, showing how work is done for:

- each particular group,
- where that group gets its information, and,
- how it shares the results of its work with others.

This would be particularly helpful to Information Technology groups that have to develop and support an information architecture as well as a computing / networking infrastructure.

Using this the LAE methodology, we can provide:

- End-users with better systems [broad sense of the word, including computers, networks, and automated processes] that are easier to support, upgrade [continuous improvement], and, yield a better basis for product choices as well as communicating requirements to IT and vendors;
- IT groups and vendors with a better basis for understanding user requirements and positioning products and services.

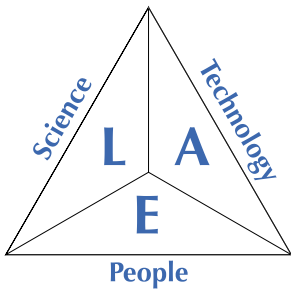
LAE Methodology’s Management Benefits

Most technology companies – and many non-technical through quality control labs – depend upon laboratories for new product development [R&D] or to determine / demonstrate product quality [QC labs]. The ability of those labs to run effectively and efficiently can have a direct effect on a company’s bottom-line finances; inefficient operations can result in:

- delays in product discovery / development [R&D],
- cause out-of-spec products to be released and invite regulatory complications that can lead to plant shut-downs [QC].

Laboratory work is an essential component of technological leadership in our economy. Biotechnology, pharmaceutical science, electronics, plastics, medical research, environmental work, energy research, oceanography, and many of the fields depend on laboratories as the source of new products and as a means of ensuring product quality when those products reach the production stage.

While labs are essential, they must also compete for financial resources to function and thus show themselves to be productive and economically efficient. Reaching those goals requires the introduction of automation where possible to improve productivity (faster development of new products in R&D, shorter turn-around time for sample processing in QC for example), data quality,



and reduced operating costs. That automation can take the form of improving the use of a device (automated pipettes) to integrated instruments and instrument-computer system combinations that process samples from their preparation for analysis through data reduction.

The LAE methodology provides managers with a framework for setting laboratory automation policies that are focused on:

- making lab work more effective,
- protecting the company's investment in the knowledge / information / data produces as a result of laboratory work, and,
- maximizing the potential use and value of that intellectual property.

Benefits of an Engineering Methodology to Laboratory Automation

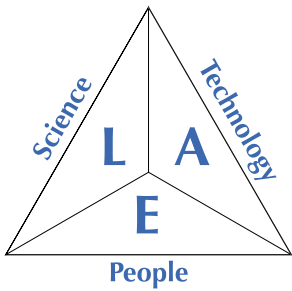
The application of automation to laboratory work can be done better than it is today. One article¹ argues that automation in pharmaceutical lab work is at least a decade behind work in other industries; a small survey resulted in input from 72 respondents in 47 companies showing that approximately 45% of the automation projects did not fully deliver the expected results². Beyond those points, effective automation can help fill productivity gaps created by retired workers. An article in *Lab Manager's* electronic newsletter³ discusses the issue of the number of retiring Baby Boomers and the lack of human resources to replace them.

We have to do a more effective job of designing and implementing laboratory automation systems to meet the demands of the marketplace and improve the way science is performed. The way to do that is to approach the subject from the standpoint of systems engineering rather than the current viewpoint of augmenting / enhancing an instrument.

Benefits of an engineering approach:

- Higher level of success and ROI for projects – by taking an engineering approach to systems design and development we'll be in a better position to determine project feasibility, costs, contingencies, and impact on other systems,
- Reduced cost for support and upgrades – well designed systems should be implemented with provision for upgrading components and increasing systems effectiveness as new technologies become available,
- Ability to meet the laboratories goals for productivity:
 - in research, the engineered automation systems should speed the investigators work;
 - in quality control, testing would be performed quicker with a higher level of data quality and reliability,
- Improved ability to meet regulatory requirements – well engineered systems should have built in provisions to meet validation requirements and not depend on a layered validation processes, and,
- Reduced cost of operations: cost/sample with faster throughput [QC], and, faster evaluation of product candidates [R&D].

The products of lab work, the reasons they exist and are funded, are the development of data, information, knowledge, and the training of students and scientists. These products are among the most valuable assets a company has; they form the basis of medical treatment, commercial products, new production facilities and fundamental understandings of how nature works.



That said, it follows that protecting these assets and ensuring that their value is maintained is a central management priority, shared by those who manage the lab, those who design and implement lab systems, and those who use them. “Ensuring value” includes the establishment of value as the lab’s products are developed – this includes the careful evaluation of the lab’s practices and procedures, training, and validation.

That “ensuring” process begins when the goals and function of the lab are described and management policies are put in place.

(Endnotes)

¹ Dulchinos, John & Massaro, Peter, “*The time is right for labs to embrace the principles of industrial automation*”, Drug Discovery World, 2005/6, pgs. 25-28

² Survey conducted by the Association for Laboratory Automation, and reported both in the “LABSnap” column (December 2006) of its website at http://www.labautomation.org/labsnap/askthe_labman/qom.php and “2006 ALA survey on Industrial Laboratory Automation”, Steven D. Hamilton, *Journal of the Association for Laboratory Automation*, August 2007, pgs 239-246.

³ DeMarco, Deanne, “*Overcome a Talent Shortage: Create a Gen-X Friendly Workplace to Retain Key Talent*”, Lab Manager email Newsletter, Wednesday June 20, 2007.