Institute for Laboratory Automation

Laboratory Automation Engineering

Laboratory Management's Role in Scientific Technology Management

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Note:

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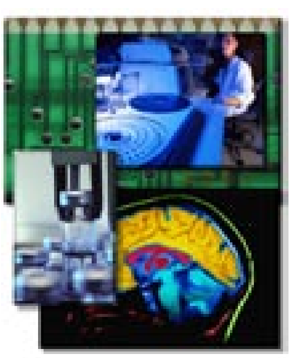
The nature of laboratory automation in life sciences has changed dramatically. Experimental bioassay setups that spanned feet of bench space and required considerable development effort to implement and support are now compact self-contained systems. Hyphenated instruments that combine separation and identification techniques generate large amounts of analytical data. Genome sequencing has been automated and lab-on-a-chip technologies replace larger experimental components. Lab work still requires scientists and technicians to develop and implement experimental protocols, but they can do that using modules with samples carried in standardized microplates. The process of conducting lab work has been streamlined through the use of microplates and the capability of instruments and automation producing large volumes of data.

That reality moves automation work into a new phase: Laboratory Automation Engineering covering technology management, workflow integration, and data life cycle management. Laboratory management has to take on the role of setting policies and practices to guide the implementation and use of intelligent instruments / automated systems and the data they produce. Organizations that take this approach should see reduced operating costs, more efficient operations, and improved cooperation with IT groups. More importantly, they should have better control over the knowledge, information, and data (K/I/D) produced in their laboratories.



Among the issues that need to be addressed are:

- **Asset Management** – the K/I/D produced in the labs. There are two points of concern. The first is to maintain the value of those assets, making sure that they are in accessible formats, easy to work with, and that compatibility issues are not a barrier to their use. The second is data life cycle management (DLM): ensuring the availability and usability of data from the time it is first collected until it becomes obsolete which could be decades in a regulated industry. Most examples and descriptions of DLM focus on corporate data (customers, sales records, etc.). Laboratory / scientific data is different since there is a structural hierarchy to data files as they move through successive stages of processing. Not only do the files and their contents have to be managed, but so does the relationship between data files and their use in higher-level systems, for example a liquid chromatography data station with the resulting analysis stored in a LIMS or electronic notebook.

- **Process Management & Integration** – the next stage in improving the effectiveness of laboratory operations is to provide integration within the lab processes, smoothing the movement of data between instrument systems, LIMS, and electronic laboratory notebooks. Laboratory management has to view equipment and software not only in terms of how it fills a particular need, but also how it fits into the overall work and data flow of the organization. Labs also need to consider the movement of data between organizations – an analytical laboratory sending test result to process control for example.

- **Security** – access control to systems, data, and facilities

- **Software Development Practices** – organizational standards for user requirements documents, coding standards, testing, file formats, etc. are necessary particularly if outsourcing of software development is being done.

- **System Retention** – products and companies have life-cycles. Instrument data systems in use today will be replaced due to improvements in capabilities, upgrades, or vendors dropping support for older products. The data collected today is a combination of the samples and the processes that convert them to a measurement. Labs have to consider how they are going to maintain data systems after vendors have stopped, and how they are going to demonstrate the validity of results done on what has become outdated equipment.

The development of policies and practices is an organization-wide effort, rather than one approached on a lab-by-lab basis. Organization-wide standards covering file formats and software processing routines for similar instruments would make it easier to integrate data from different sources and reduce costs. Lab management, working with IT groups, should define common policies and practices as part of a Laboratory Automation & Computing Architecture across labs. Each lab in turn, would complete the architecture by defining its own workflow model including the need to transfer information between labs. IT groups can be of assistance in the organization and management of large-scale data storage systems. Implementing storage systems will be an interesting exercise as several generations of storage media are superseded over the life span of current research and production data.

Technology management has become a factor in laboratory management. The systems, software, data storage, automated equipment, intelligent instruments, etc. are all examples of technologies that are undergoing almost constant change. The transition of one technology to another while maintaining a high level of effectiveness is going to be a challenge for laboratory management at all levels.