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The development of a strategy for the implementation of automation in a bioanalytical laboratory*

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Abstract: Laboratory automation is equipment, instrumentation, software and techniques that are classified into four groups: instrument automation; communications; data to information conversion; and information management. This new definition is necessary to understand the role that automation can play in achieving the aims and objectives of a laboratory within its organization. To undertake automation projects effectively, a laboratory automation strategy is outlined which requires an intimate knowledge of an organization and the target environment to implement individual automation projects.

Keywords: *Laboratory automation; instrument automation; data to information conversion; communications; information management; automation strategy.*

Introduction

The role of a bioanalytical laboratory within most organizations is to provide information for effective decision making. Coupled with this, is the need for the laboratory to produce high quality information rapidly to enable effective decision making. While samples enter a laboratory where they are analysed, it is rare for the information to be used there; the decision makers usually reside outside a laboratory. Therefore, a laboratory should integrate with its client departments to become an efficient part of an organization.

The purpose of this paper is to outline one approach to strategy development for the automation of a laboratory. Although this paper is aimed at bioanalytical laboratories, the authors believe that any laboratory can use the principles contained herein.

Productivity increases

Many bioanalytical laboratories are in the pharmaceutical industry which operates under regulatory guidelines (e.g. Good Laboratory Practice). To comply with these guidelines, which ensure quality, there are increasing analytical requests and strict control of administrative procedures. To overcome this problem, laboratories need to increase productivity and curtail rising staff numbers or labour costs.

If productivity increases are sought then there are two possible approaches. The first approach is to simplify, change or eliminate procedures and this may not involve the use of automation [1, 2]. However this approach is not viable unless costs are reduced dramatically. The second approach is to use laboratory automation.

The aims of laboratory automation

The use of automation within an organization is an opportunity to create strategic advantage [1] which is manifested in one or more of the following factors: better decisions based on valid data — this leads either to more effective research and development innovation or to better products which due to their quality can increase customer satisfaction and market share; improved organization productivity; and reduced risk to employees.

From an accountant's perspective the main requirement is to reduce labour costs while achieving a general increase in laboratory productivity. To achieve these goals in reality a laboratory needs to be well planned, organized and managed. Bringing these aims down to a bioanalytical laboratory, the automation of a

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task should produce one or more of the following advantages:

Greater increases in productivity (either in numbers of samples assayed per unit time or speedier turnaround time) resulting in overall reduction of costs and increased productivity.

Automated systems should achieve the same or better precision and accuracy as existing manual methods. There will usually be improved quality with automation, e.g. reducing transcription errors.

Freeing of trained laboratory staff to do more creative or productive work than tedious tasks thus improving morale.

Reduced human contact with biological or chemical hazards.

Lower the consumption of sample and/or reagents used in an automated analysis.

What is Laboratory Automation?

The current automation definitions of IUPAC [3], Liscouski [4] and Mahaffey [5] only consider instrument automation and information management automation. Moreover, there is no mention of the specification, justification and application of the tasks to solve real problems. A requirement for the effective understanding and use of laboratory automation must include changing the culture of analytical chemists. Most purchase automation off the shelf; the ideal is a chemist that thinks of automation strategically and in business terms. Therefore to progress in the authors' opinion, laboratory automation should be reassessed based on the following considerations: the development of a strategic laboratory automation plan driven by business needs; the justification of individual projects from a business perspective; prioritization of individual projects according to potential payback with an appropriate business and scientific justification.

However before this can begin, laboratory automation must be understood more fully. To aid the understanding of laboratory automation a new definition is available [6]. With understanding comes the ability to integrate a laboratory into the total aims and objectives of an organization.

Laboratory automation is proposed as consisting of the following groups [6]: instrument automation; communications; data to information conversion; and information management.

Figure 1 shows the general scheme of laboratory automation, for a detailed explanation see ref. 6. This scheme is essential to understanding the tools and techniques that encompass laboratory automation.

A Laboratory Automation Strategy

Documented or not, every laboratory has some sort of automation strategy. This may simply be the replacement of all manual injectors with autosamplers or something more encompassing and complex. Most organizations have finite resources and to maximize the benefits of any automation intiative and to utilize the corporate facilities effectively, harmonization and rationalization are required.

The use of a local automation strategy

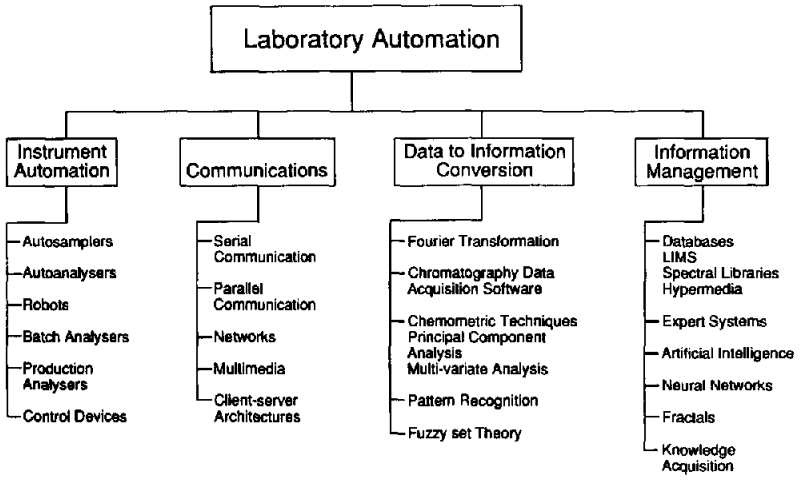

Figure 1
A comprehensive definition of laboratory automation (from ref. 6).

should focus on the needs required for a productive laboratory, while aligning the laboratory area with the corporate aims. This is shown in Fig. 2.

Strategy development is divided into four discrete phases: understanding the organization; analysis of the laboratory environment; generation of the strategy; and implementation of individual projects.

Figure 3 shows these and their contribution to a general plan for laboratory automation.

Understanding the organization

Understanding the organization and its operation is the cornerstone of the development of a successful laboratory automation strategy. To plan effectively one must understand the organization in terms of corporate IT status financial controls and culture.

IT status. Knowledge of the IT status within an organization allows an appraisal of the boundaries and potential of an automation strategy. Furthermore, one can see its impact on and communication with other automation projects and IT initiatives within the corporation.

A facilities and/or services review is a good place to start if the organization is sufficiently large to support a computing division or equivalent. The status review should incorporate: status of networking infrastructure; services and support offered including levels of expertise and availability; and corporate IT policy and mission statements.

Networking infrastructure. The type and status of communications networks within the laboratory environment and the organization must be understood. This is probably the most important item as communication is the foundation of any successful automation strategy as shown in the section on a strategy in practice. Understanding the state and the development of corporate networks and the effect the proposed automation initiatives will have on those networks in terms of loading and reliability is essential. A general networking review of the laboratory environment should be undertaken; specifically investigate the possible extension of networks, types of communications protocols needed and maintenance and support costs. These factors will have an impact on the initial costs of any individual project and affect the cost–benefit justification.

Services and support. This can cover a large variety of skills and services depending on the organization. Some organizations supply skills ranging from system analysts and architects to operational support and training while others rely on external consultants. In either case, it is important to understand what services and levels of expertise are available and how to schedule and pay for these services. Most computer divisions have guidelines for the hiring of contract and consultant staff and it is useful to understand these procedures before strategy development.

Mission and policy statements. It the corporation has an IT mission statement it is essential to develop the automation strategy with this. This approach will provide the most benefit to both the laboratory area and the corporate body. Note also any purchasing standards and policies which can significantly affect the strategy development within a laboratory. Adherence to these standards

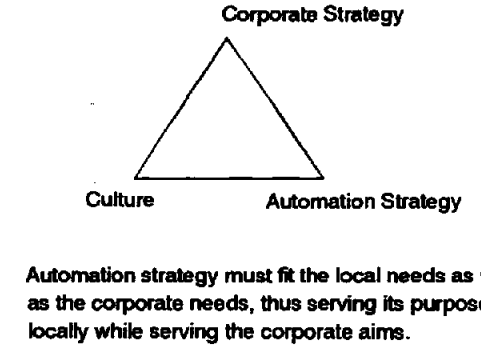

Figure 2
Aligning a laboratory automation strategy with corporate culture and strategy.

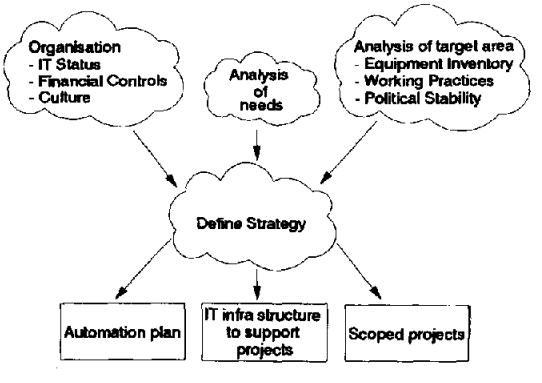

Figure 3
Development of a laboratory automation strategy.

benefits any strategy by reducing the number of interfaces that require development.

Financial controls

A clear understanding of corporate and local budgeting and purchasing policies is essential to the success of any automation strategy. The procedures to be aware of include the following.

Control and release of funds. Understanding what is required to obtain funding for an individual project is usually straightforward. More important, however, is knowing how much time is available to spend the money. Phased payments to vendors can occur in large-scale projects and can raise concern within purchasing departments when payments span financial years. Ramifications of delayed payments on budgeting must be understood. Budgets for capital and revenue funds can be planned and spent quite differently and one must be aware of this within an individual organization. Sometimes budgets are allowed to accrue from one year to the next, elsewhere the funds are absorbed by the organization with the project losing funding as a result.

Policies on overspending should be understood at the outset before problems are encountered. With a large purchase one would be well advised to obtain assistance from the purchasing and legal departments to write a contract between the organization and vendor. This serves to protect the organization's interests and secure the best payment terms that can be negotiated.

Budgeting for services. The use of services either in-house or external to the organization obviously incurs charges of some description. These generally require advance budgeting and approval. During the initial stages of planning the strategy, funds are generally provided on an *ad hoc* basis and are supported or championed by a user-manager. This is necessary to create the space for the development of the strategy and project proposals which when approved will require budget planning. These budgets may need to be subdivided into capital and revenue expenditures with a timetable of expenditure. The budget and the timetable should be updated as the strategy and individual projects progress over time.

Authorization. This is usually forgotten when considering a strategy or an individual automation project, but it may involve much time to brief managers where the strategy or project has impact. One must understand that each area of an organization can have different priorities and operational procedures and allow the appropriate amount of time for circulation, review queries, correction and authorization.

Justification. Justifications are internal reviews to satisfy the investors of a corporate need and tend to cover financial, scientific and managerial support for any automation project. The size, cost and scope of an individual project within an automation strategy will decide the extent of justification required. Standard items within a justification include cost–benefit analysis, risk assessment and a feasibility study to present a good business case.

Culture

Most organizations have a general operating philosophy for the development and implementation of projects. This may not be written anywhere but is part of the general culture. One can note, by historical reference to previous projects, what this philosophy is and how best to utilize it. It is worth noting if individual projects have been planned, driven by management directive or conceived on an *ad hoc* basis and how each integrates with other projects. The success and failure of earlier projects will give a good background to automation within an organization.

An understanding of the work ethic of the organization must be gained. An overview of the corporate direction, changes in IT strategy and status, staff turnover, attitudes and abilities are important. A general identification of problem areas should also begin at this stage. Each of these can profoundly affect the type of strategy developed and the likely success of any individual project. Any corporate mission statements should be identified and reviewed with the objectives of the laboratory environment.

There are many layers of subculture within an organization all of which interact as shown in Fig. 4. Division, departments and teams can be critically influenced and modulated by the ethics or tone of the representative head. Management backing of a strategy will ensure a greater chance of success. Note that manage-

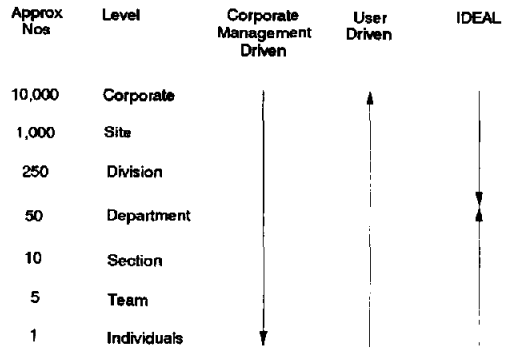

Figure 4
The development of sub-cultures within an organization.

ment backing will not guarantee success; there are many other factors involved, but it is a major influence on user attitudes. Investigate the communication pathways at each level and the interaction between levels in the laboratory environment. The success of the strategy is dependent on a common understanding of the goals of the laboratory, the organization and individual projects. Each level must be aware of their place in the organization and be clear about the role each is expected to play. There can be no assumptions.

The goals and objectives of any project should be made clear to everyone. The general aims of laboratory-based projects are to provide a better quality and more efficient service to the client groups within the organization. This can be measured by reduced payroll expenditure, faster throughput (quicker generation of information) meeting or exceeding quality of regulatory guidelines and consistency of working practices.

Analysis of the laboratory environment

The analysis of the laboratory environment provides the information required to set a starting point for the development of the automation strategy. It should include the following.

Objective and goal identification. The definition or clarification of the goals and objectives of the laboratory area is a key factor in strategy development. This aids in the focusing on the core requirements of both the laboratory and the organization. Identification of factors critical to meeting these objectives can be determined as well as any associated problem areas.

Inventory of equipment. This inventory should cover all areas within the laboratory area such as types of laboratory instrumentation, office automation, existing computing equipment, both hardware and software and the existing networking infrastructure. Special attention should be given to any processing power, interfacing requirements and specialist equipment. The relative age, level of complexity and capacity of the equipment should be considered. This should provide information for planned upgrades or for the replacement of existing systems and will help the planning for automation of the laboratory environment.

Working practices review. A review of the current working practices in the laboratory area is essential. The review provides an objective picture of current practice which can be surprisingly different from the perceived practice. Its main purpose is to provide insight into bottlenecks, inefficiencies and any practical inconsistencies.

The review should cover standard working practices, individuals, organogram structure, communication pathways and client requirements. When the staff of the laboratory area are reviewed, special note should be made of individuals about flair, quality, motivation, expectations, IT literacy and natural leadership skills. Problem staff should also be recognized. Both can be managed and utilized to the advantage of the laboratory area during project implementation. The natural leaders can become target users and assist with the development of problematic staff.

An organizational chart detailing the levels of staff should be generated and checked for balance. Anomalies in the structure should be noted and thought should be given how to overcome them, e.g. a recruitment policy for staff with the required skills.

Communication pathways within the local area must be reviewed for efficiency and effectiveness. This should also include communications betweeen the laboratory and its clients. Actual client requirements such as the quality of results, format, interpretation, reports and turn around times should be defined, also the interfacing and integration of equipment and software required to achieve this.

The working practices review can be undertaken in a variety of ways. In the authors'

experience, a team approach has provided the most benefit and objectivity. The team should ideally consist of a systems analyst and a user-manager. Report the findings and circulate them for review by high level laboratory management or management teams.

Political stability. This facet of strategy development must not be underestimated. For success, ideally one should have political stability to cover the time span identified for the automation strategy. This political stability should be local, corporate and cover any associated vendors. In real life, however, this is rarely attainable. At a local level, management support, usually as a 'champion', is necessary to provide the control over the resource and continuity of the laboratory environment required to implement automation successfully.

Thus, it is imperative to develop natural breakpoints or fall back positions. This will increase the flexibility of the strategy and increase the chance of success without compromising the benefits to the laboratory area and corporation.

Develop the Strategy

Successful automation strategies are developed from a deep understanding of both the organization and its direction and the laboratory environment. The strategy should be project or initiative independent and encompass the perceived objectives and goals of the laboratory area. It is an outline which covers a reasonable period and considers the initiatives at corporate level.

All information should be collated and the laboratory needs prioritized. Once this has been accomplished then an outline of initiatives/projects can be developed. These initiatives should be tested to see the fit with other current projects and refined to be consistent with the general corporate direction.

If more than one initiative is identified prioritization of implementation should be considered. Give the most basic initiatives such as networking and the setup of computer hardware the highest priority as all the other initiatives will be dependent on their success or failure. It is generally unwise to initiate too many projects at once; review this in light of resources available and acceptable levels of disruption.

Once identified, write a project proposal for the highest priority initiative to present an organized case outlining the business need and to gain support and authorization for the organization. Proposals may be rejected for any number of reasons but most commonly because they attempt to achieve too much. In most organizations proposals can be refined or simplified to cover core activity and to shorten time frames so that less resource is required and disruption is minimized. This refined proposal can then be resubmitted to the authorization body. If there is a true business need and the proposal fits well with the general corporate direction authorization and funding are usually forthcoming.

Implementation plan

Once the proposal has been authorized and accepted an implementation plan should be drafted. This plan is needed to successfully manage and to help the implementation of the project. This should be developed with any project control mechanisms and the general automation strategy.

The strategy should be maintained and kept current with information from each project's implementation plan. This enables the successful management and implementation of concurrent laboratory projects while keeping account of corporate developments and changes. The use of project management software to control implementation can also evaluate the impact of delays, etc. Such software provides current information on project status also a historical view to monitor progress.

An Automation Strategy in Practice

A complete implementation of a strategy for laboratory automation is shown in Fig. 5; individual systems have been installed in achievable stages as shown by the numbered sequence. In this illustration, the strategy starts with an analytical instrument (1) to analyse a sample and acquire data. This is not the only way to achieve an automated environment but is a method chosen to illustrate a strategy in practice. This instrument can be automated or manual but inevitably has a microcomputer for local control of the system as well as data capture and reduction. Such instruments are inevitably successful and cost effective and lead to the purchase of a second instrument (2). There now being the problem which the presence of an automation strategy should

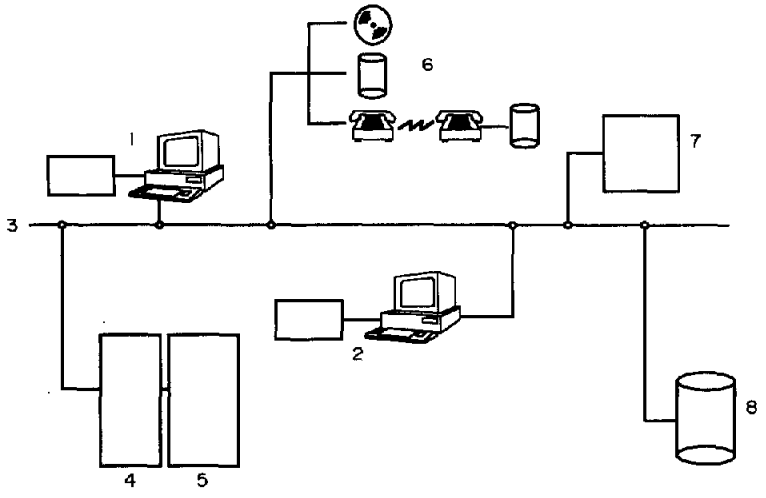

Figure 5
A laboratory automation strategy in practice. 1 = First analytical instrument; 2 = second analytical instrument; 3 = network; 4 = data capture computer; 5 = laboratory information management system; 6 = additional computer; 7 = library; and 8 = corporate database.

avoid: the rapid generation of data which have nowhere to go leading to backlogs and bottlenecks.

The key to any automation strategy is the installation of a network (3). This is the conduit along which data and information will flow within the laboratory. Furthermore it is the means to integrate the laboratory with the parent organization. Once a network is installed it is relatively easy to add additional instruments, computers, software, etc. to integrate all laboratory functions and provide an expansion route in the future. Moreover it is essential that the network complies with the corporate computing standards. No network, no laboratory integration.

Once the network is complete, a data capture computer (4) and a laboratory information management system (5) can be installed to centralize the functions of data reduction, sample tracking, report production and information generation. The centre of the automation strategy within the laboratory is the LIMS. The network also provides the ability to add additional resources such as an additional computer (6), which can have data to information conversion programs running that integrate with the LIMS. Alternatively this computer can act as a file server to the PCs within the laboratory to serve programs across the network. The advantages of this latter approach mean that just a single copy of an application program is maintained within the laboratory for control, ease of maintenance and upgradability also ensuring data integrity and sharing information within an application.

Further extensions of the network can reach the library (7), here optical disks and internal and external databases can be searched for information and current literature. Finally, for true integration of a laboratory, connection to the corporate database (8) to allow the accumulation of information and knowledge of a process or product is essential.

Conclusions

When developing a strategy and conceiving of projects, one must think in broad terms, be sensible in approach and choose targeted and achievable initiatives. Common sense is a term that comes to mind that is often missing in automation projects.

The key points to remember in the whole process are:

Accountability: the system/project should have clear lines of responsibility and accountability that are communicated throughout all levels. There should be one person responsible to sign off the system as acceptable when complete and at each milestone.

Objectives: objectives of the project and boundaries should be clear and understood by both users and managers. This is important in the management of expectations.

Time scales: a rough rule of thumb states that either a development or implementation phase should take no more than 6 months.

When either runs longer there are generally changes in requirements, loss of project inertia also a possible loss of political stability.

Resilience: teams should be built for each project to add resilience, depth and breadth to the project. A good team is synergistic and provides many times the benefit of each individual involved.

Structured changes: any changes to the strategy project, etc., require structure documentation and management.

Each automation project should consider core activities first with more sophisticated functions following later.

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