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The evaluation and management of risk during a laboratory information management system or laboratory automation project

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Abstract

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This tutorial outlines some of the common risks that may be associated throughout the development and implementation of a laboratory information management system or a laboratory automation project. It presents a scheme for undertaking risk analysis and evaluation to help assess the degree of risk associated with each of these factors. In the case of high risk factors, suggestions are presented to manage or help avoid the problem. Risk assessment should be carried out at the start of a project and at intervals throughout the project to re-evaluate and see if any factors have changed or new ones have emerged.

CONTENTS

1. INTRODUCTION

There are many laboratory information management system (LIMS) and laboratory automation projects that have collapsed or failed to deliver the expected benefits. Furthermore, surveys of information technology (IT) projects frequently show that many have run over budget and nearly all projects ended up with a changed specification from that originally described. When organisations used IT within laboratory areas in the 1980s, any failures were either covered up or if a project failed, it was written off as 'one of those things' which should be put down to experience. However in the 1990s, companies are far more cost conscious and sensitive of failed projects. Although failure is a powerful learning experience, it is usually not incorporated into a corporate knowledge base for use by similar projects in the future [1].

A project is a single activity with a well-defined set of end results such as the successful implementation of a LIMS or a robotic system. It follows a systems development life cycle (SDLC) from inception to completion [2]. A project does not exist in isolation and must often be coordinated or interfaced with other projects within the parent organisation. Projects involve high levels of interdisciplinary communication and co-ordination with groups of specialists who are not usually used to such interaction. To aid the delivery of successful projects, project management provides an organisation with the tools to plan, organise, implement and control the activities necessary to achieve this [3].

The complexities and multidisciplinary nature of projects require that the many tasks and deliverable parts of each be put together so that the prime objectives of performance, timescales and cost are achieved. There is a relationship between these three factors that has to be traded off by the project manager. Some of these trade-offs can involve risk in varying degrees. In an earlier tutorial in this journal [4], the selection of a LIMS risk analysis was covered briefly. This tutorial aims to discuss some general risks and their management to ensure a successful outcome of an automation project.

2. RISK ANALYSIS

To overcome possible poor implementation or failure of a LIMS or laboratory automation project, risk analysis and management should be carried out at most stages of the system development life cycle. Risk analysis should be used in conjunction with project management techniques to manage the overall project. Therefore identification of the risk factors should allow better management of a project, and identify specific areas where additional expertise or care should be taken.

2.1. Definition of risk

Risk is defined for the purposes of this article as: 'the chance or probability of an event occurring that may alter the progress or outcome of a LIMS or laboratory automation project'. Risk analysis is defined as: 'the identification and assessment of the risks, and the levels of each risk, faced by a project'.

In addition to the identification and assessments of risk are approaches that should be taken to manage risk at various stages of the systems development life cycle.

2.2. Risk assessment and management

There is little written in the scientific literature on risk. Most risk analysis and management is intuitive and undertaken informally by project managers or teams as a result of their experience or common sense. However, inexperienced individuals or project teams may have problems that could be mitigated or eliminated by the advance knowledge of common risks associated with LIMS and automation projects.

Risk assessment and management is not a one-step operation, but should be carried out at key stages of the SDLC. A project starts with a high degree of uncertainty and hence risk. As it progresses, uncertainty in some areas is reduced but in others it can increase, hence the need for repeating the risk analysis and plan approaches to counter any identified risks.

The overall approach is shown in Fig. 1. At the top of the figure, a project definition document is written, from which the individual tasks can be identified. Using the knowledge and experience of the project team members, risk analysis can be carried out and potential risks identified.

Once the high-risk tasks have been highlighted, it is possible to prepare plans and countermeasures to overcome the risk. These are implemented within the project plan by the project manager. Milestones of the project can be identi-

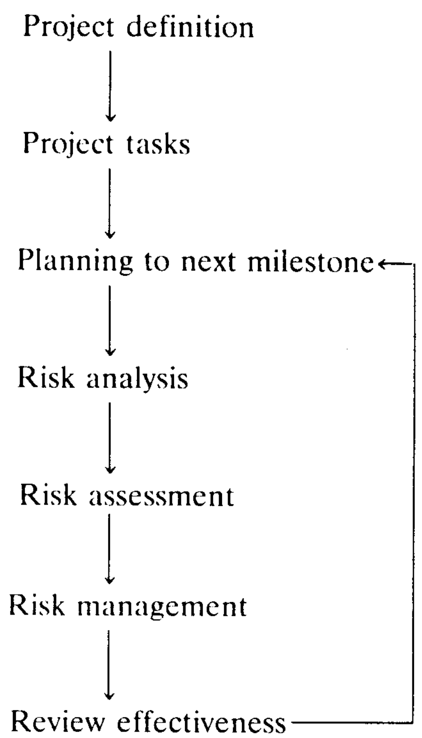

Fig. 1. A flow diagram showing risk analysis, assessment and management during the lifetime of an automation project.

fied and progress of the project reviewed against these; the same is true of risk factors. Once the progress of the project has been evaluated this can be fed back into the system for an updated risk analysis. As can be seen, risk analysis is linked very closely with project management and the two approaches should operate intimately.

2.3. Areas of risk in the system development life cycle

As laboratories depend so much on automation, and LIMS in particular, it is essential that management, users and the project team should do as much as possible to minimise the risks to ensure a successful implementation. If a LIMS is not functioning effectively then work within the laboratories will be disrupted and productivity will suffer. However when the LIMS is not working or operating badly, then the customers do not obtain their information and the reputation of the laboratory suffers.

The three main areas of risk within the SDLC are:

- project definition and start-up (described in Section 3 are the common risk factors);
- evaluation and selection of the proposed system (Section 4 describes the common risk factors);
- implementation of the system (factors of risk are presented in Section 5).

2.4. Risk factor tables

The factors highlighted in the following tables will allow continuing assessments of risk to be made of individual projects at various stages of the SDLC. As there is usually an underestimate made of the technical complexity of systems development, risk can never be eliminated totally from a project. However, if the significant factors can be contained or contingency plans made to manage them at the start and continued throughout the project, then the greater the chances of success. Over-optimism, especially of planning, is a chronic problem, resulting in projects being over time and over budget. Therefore contingency time and money should be included in all plans.

Risk can be assessed as probable (high risk), possible (low risk) and improbable (negligible). Another approach is to allocate each factor a numerical value, say ten, for the highest risk and zero for negligible risk. Risk can now be evaluated as a continuum which can be useful for an assessment of risk for a number of projects such as a prioritization exercise. However in the tables presented in this tutorial, only high and low risks have been evaluated as it is preferable, in the authors view, to keep the scheme as simple as possible.

3. RISK FACTORS DURING PROJECT DEFINITION AND START-UP

The risk factors that can be encountered during the start-up phase of a project can be divided into four main areas:

- project definition;
- sponsorship of the system and user commitment;
- the impact of the system on the organisation;
- management of the project.

3.1. Management of risk during project definition

Outlined in Table 1 are some of the key issues that should be considered for risk analysis during the definition of and writing the proposal for an automation project. The areas of low and high risk (relating to possible and probable risk respectively) are highlighted in the two right-hand columns for each factor. Every factor will be considered below with suggested ways of managing the risk posed.

The main effort in this phase of a project is common sense management. There are no excuses.

3.1.1. Project definition and deliverables

Before starting a project it is common sense to ensure that the overall scope and tasks the new system will replace or carry out are defined. It is important for all concerned that this is achieved in a project proposal or definition document. The content should explain, in non-technical language, what is to be achieved. As this is the baseline for all future work on the project it is an essential deliverable. Moreover the users, their management and senior management must accept and underwrite the content of this document. The alternative is a poorly defined project with no focus: thus it is easy to introduce trivial or non-essential functions which can waste time and effort, or worse, functions with little practical use. Moreover, a poorly defined project can select the wrong system to meet business needs.

The deliverables expected throughout the SDLC should be outlined at the start to avoid not meeting user, management and regulatory expectations. Therefore time should be spent discussing with the users, management and especially the project team members, the importance of any deliverables. Within a regulatory environment, these deliverables will form the basis of the quality development and validation of any automated system.

3.1.2. Business benefits defined

To avoid premature cancellation of the project some time in the future, due to budget cuts or management change, the business benefits that

TABLE 1

Risk factors associated with project definition stages

Risk factor	Low risk	High risk
Project scope	Well defined	Vague
Project deliverables	Well defined	Not defined
Benefits of the system	Quantified business impact	Unclear
System requirements	Straightforward	Complex
Personnel providing application knowledge	Know both IS and user areas	Lack user area knowledge
Project members who have experience of business area	All	None
Status of documented procedures in user area	Complete and current	Nonexistent or outdated
Number of computer applications which the system should interface with	None	Two or more
Status of these applications	Operational	Under development
Resource required	< 5 resource years	> 15 resource years
Time to develop the system	< 12 months	> 3 years

the system is anticipated to deliver should be defined and if possible quantified. This information will be needed by senior management for approval and continued management support is essential for longer-term projects. The advantages of direct benefit to the organisation and the user should be outlined. To obtain the information to write this authoritatively, involve experienced staff from the user environment and the laboratory customers.

The business benefits are useful in defining, in another way, the target of the system to be developed. This definition can be of positive use in helping to make decisions about which functions are to be evaluated during selection and development.

3.1.3. System requirements and documentation of current procedures

At the start of a project, the system requirements are relatively vague and can hide a number of complex technical, procedural and even organisational issues within them. However, even at this early stage, the requirements of a project and the operations carried out within the target laboratory should give an understanding of the degree of complexity involved. If the system to be implemented appears to be complex, a number of approaches to reduce the risk can be suggested:

- A complex system could benefit from a detailed system analysis to understand the information and data inputs, internal operations and outputs. This should give a better understanding of the requirements and may help the new system support decision making.
- As users often find it difficult to explain exactly what functions they do or are uncertain what they want the system to do, this may suggest a prototyping development. This approach should help the users to debate and develop what they require [5,6].
- A review of the working practices of the laboratory should also reveal if the processes undertaken can be changed prior to the introduction of a new system.

If current procedures are documented, these will help define the current practices and system. In contrast poor, outdated or no documentation can cause assumptions, perhaps wrong ones, to be drawn and requirements defined from incorrect information. Great care must also be taken not to assume that even if practices are defined, say in standard operating procedures (SOPs), that the current working practices in the laboratory match them. No assumptions should be made in this respect; enlist the help of expert users to help define the current system.

It is essential to define current working practices and map them onto a proposed system to help selection.

3.1.4. Knowledge of the project team members and users

The skills of all of the project team members should be assessed before the start of the project. Clearly where the IT and laboratory automation members have been involved successfully with similar projects in the past, especially within the same area, there will be a high degree of confidence and technical skill. In contrast, a team which is new and has little experience will require team building and technical training, ideally, before the project starts.

Equally the experience of the user representatives working with the project team members may not be adequate enough to get a high performance team working immediately. Therefore some on-the-job training in project team membership may be appropriate.

An issue of major concern will be the degree and depth of understanding and knowledge each member has in the other team member's disciplines. When there is none, a level of common understanding has to be developed. Equally important is the degree of knowledge and understanding the computer staff have in the laboratory. In the author's experience, this understanding takes much effort to acquire but is a worthwhile investment. A corollary is that carefully trained computer staff must be retained by the project, otherwise momentum will be lost. Here management has the responsibility to ensure that the team is formed, and has the required level of knowledge and understanding to do the job, before the project is fully underway to reduce risk.

3.1.5. Interfaces to other systems

This aspect is not always identified in project proposals but, for integration to form an efficient organisation, IT projects should interface with each other to provide an integrated information environment. If the system is a stand alone one, no interfaces with other systems are deemed necessary and development can proceed unhindered. In contrast, if the system has to interface with one or more systems this adds complexity and risk. The interfaces, especially the data input and output must be carefully defined and documented along with the responsibilities of who does what. This is acceptable if the systems already exist and are functional as the interfaces are tangible.

Problems can arise if the interfaces are with proposed, or partially developed systems, as interfacing with these applications increases the risk assessment. Now additional time is required to identify where the projects overlap and how they should interface; liaison between projects is essential. Liaison may include sharing project team members, planning inter-project dependencies, or identifying the other project's deliverables.

3.1.6. Resources and time for project development

Smaller projects carry less risk. Therefore, to minimise the risk for larger projects there are a number of measures that can be used to reduce the risk to acceptable proportions. These include:

- Ensure formal project planning and monitoring with clearly identified deliverables and milestones, although this can be time-consuming and project team members could lose enthusiasm for the project. It is essential to focus members on the original aim of the project.
- Large projects can be broken down into smaller ones with discrete end-points. These smaller projects when complete and aggregated together constitute the overall system. Alternatives are to reduce the original project scope and produce a minimum working system that can prove its effectiveness before additional functions are added or a phased development approach.
- Large projects developed over long time periods can cause problems in maintaining enthusiasm and user commitment. Moreover any organisational changes could result in changes in sponsorship and less commitment or resource for the project.
- Large projects could justify the use of application development tools, such as computer-aided software engineering (CASE), to enhance productivity and decrease the time taken for various phases of the project. If the team have used this approach before successfully this would be beneficial to the project. However, if this approach means introducing new technology, it may increase risk instead of reducing it.

3.2. Risk factors associated with sponsorship and commitment

Presented in Table 2, and described below, are the risk factors associated with sponsorship of the proposed system and commitment of the users to

TABLE 2

Risk factors associated with system sponsorship and user commitment

Risk factor	Low risk	High risk
Project sponsor	Identified and has a strong user influence	Unknown
Attitude of user management	Fully support the project	Resistant and sceptical
Attitude of the users	Understand and support the project	Resistant and sceptical
Organisational maturity	Able to use the system effectively	Unable to understand rationale for the system
Relationship of the project to the strategic IT plan	Included in the plan	Not included in the plan

accept it. Although presented here as factors associated with the start-up of a project, they must be reassessed during the project in the light of any changes in senior personnel, organisational rearrangements and influences on the users. This is especially so in a project that has a long timescale or has been delayed.

3.2.1. Sponsorship of the project

If the project sponsor is not strong, political battles within the organisation units under him can result in project delays due to a lack of decision or management commitment, especially in large projects. Therefore to avoid these problems a procedure for resolving disputes should be instigated by the user management.

3.2.2. Attitude and commitment of user management

The attitude and commitment of the user management is essential for the success of any project. Apparent lack of commitment may indicate they are unaware of the potential benefits that the system may bring or planning a change in the laboratory's direction. The manager of the user area should be briefed of the benefits that the system should deliver and its ability to enhance the business objectives of the area.

3.2.3. Attitude of the users

Even with total commitment of the project sponsor and user management, users can cause serious problems throughout the whole project by refusing to cooperate during all stages of development. This may be the result of fears of radical change that would result from the operation of the system. Mechanisms for effective communication to representatives of the user community need to be established by regular status reports or meetings which should be continued throughout the development cycle. Concerns of the users should be communicated to the project team and management. If there are organisational impacts of the system (see Section 3.3.4.) these should be identified and communicated to the users and discussed to obtain a consensus agreement.

The maturity of a user organisation to support a LIMS effectively is a factor to be considered early in a project. If, in the judgement of the project team or user management, the organisation is not capable of supporting an automated system, an education programme should be undertaken.

3.2.4. Relation of the project to the strategic plan

If a project falls outside of the scope of a strategic automation or IT plan, then the risk increases. Then conflicts may result from an unplanned project being given priority and resources over existing ones. It is best to find out the reasons for a new system which is outside of an existing plan. If there has been a change in the business strategy, then the IT strategy should be revised accordingly. The place of the new project and any dependencies between other projects should be identified. A strong and committed project sponsor may be required.

TABLE 3

Risk factors associated with the impact of the system on the organisation

Risk factor	Low risk	High risk
The new system	Replaces an existing one	A completely new system
Effect of the system on the computer operations of the organisation	Little change	Much change
Procedural changes required by new system	Little change	Much change
Organisational structures	None required or no changes to existing ones	Not considered
Policy changes required to support the new system	None	Extensive

3.3. Risk associated with the impact of the system

Described below and presented in Table 3 are some of the risk factors to be considered when examining the impact of the new system on the organisation.

3.3.1. New or replacement system

A replacement system should not present too many problems with respect to the impact on the organisation. However, a new system tends to impact on many areas, staff might be unsure of their duties and responsibilities when it becomes operational or they could resist its introduction. To counter these areas, the management should assess the impacts of the new system on the organisation and the users. Communication of the benefits of the new system to the users should be undertaken but remember to keep the statements realistic to manage expectations of the users. This discussion can be achieved in groups or individually in person.

Involvement of the users in all stages of the project is essential. Areas where this can occur are: planning the project, analysis, testing prototypes and implementation. Request input on how to structure and phase the training to use the new system. A champion(s) for the system should be identified and involved throughout the project.

3.3.2. Impact of the system on computer operations

As systems become highly integrated environments and work in close cooperation over networks, a new system can have different levels of impact. If there is little change on the operation and management of the computer there will be few problems apart from negotiating the facilities management contract. At the other end of the spectrum, there must be enough capacity or bandwidth on the network to accommodate the anticipated data flows from the laboratory to the computer and sufficient input and output devices to access the system effectively; in short ensure there is sufficient capacity for the new system to operate effectively.

If new hardware, operating systems and/or application software is being acquired this will have an impact on the support staff and will increase risk accordingly. The organisation should have the skills and experience to run these new items efficiently. If not, they have to be acquired by training existing staff or recruiting new personnel. The input from operations staff to the project team during evaluation and selection can identify many of these areas. To reduce the risk and aid communication between various applications the first intent should be to purchase or develop a system that is consistent with the current systems in place within the organisation. This aspect will be considered in more detail in Section 4.1.1. The author would advocate this even in the light of the current moves with open systems.

Documentation of system procedures, coupled with effective training, to use any new hardware and operating systems should be in place before the system goes live.

3.3.3. Changes in procedure required by the new system

The failure to recognise the need for any new or revised procedures early in a project, then to plan and implement them rapidly can greatly increase the project risk. The current working practices should be reviewed and the level of user commitment to change procedures should be established. If change is resisted, do not implement change via the computer system but change procedures, if possible, by altering the manual ones first. This is a relatively cost-effective way as small modifications can be undertaken easily and rapidly until the new manual procedure is streamlined and effective. Then overlay the new system on top of the modified manual one. In this way problems can be resolved with the new procedure without the computer being used as a scapegoat by dissatisfied users.

3.3.4. Changes in organisational structure

Computer systems have the power to cross functional and organisational boundaries with ease [2]. The failure to recognise and plan for any changes may result in staff not knowing new responsibilities or roles or disruption occurring from reorganisation of organisational units. Hence an increase in risk to the project.

The impact of any organisational changes should be documented clearly during the design and development, although it may be alluded to in the project proposal wherever possible. There should be change management of any such changes over a specified time period. Always, if possible, allow time for the changes to settle down before implementing the new application to avoid too much change in a short time period. Again the communication of the realistic benefits of the new system to the users should be undertaken.

3.3.5. Policy changes to accommodate the new system

Changes to policies should be identified and controlled by the user management. Since these are not always identified until the detailed design or the development stages, any delay in implementation could delay the operation of the project. The resolution of these policy issues must be made before development can take place. Policy changes may be the result of the introduction of new technology, organisational changes or modification of procedures caused by the new system. Therefore it is important to identify and resolve any policy changes rapidly but not before considering the impact of the changes. If large numbers of policy changes have to be made, there should be a mechanism in place to document and inform all staff of them, a user appointed as a coordinator might be one approach to use here.

3.4. Risk factors associated with management of the project

Presented in Table 4 are the common problems that can give rise to risk when assessing how the project is managed and the membership of the project team.

3.4.1. Experience of the project manager

An inexperienced project manager may have difficulties developing an efficient project plan and modifying that plan as the project progresses. Moreover, not all tasks may be identified or the project plan is not broken down to a sufficient level to enable accurate scheduling. Taken together, this often results in delays to the project and missed deadlines with tasks rescheduled or additional ones included, often at short notice. The impact of this can be damaging to the project as budgets may be increased, there may be loss of confidence by the users or cancellation of the project as benefits have not been obtained in a timely manner.

To counter this problem, the project manager should be trained in project management techniques. When drawing up the plan allow more time for the completion of the tasks to allow for slippage or allow slack time. Regular reviews of the project progress should be set up. To gain from the experience of others, read the status reports and reviews of similar projects completed within the organisation.

TABLE 4

Risk factors associated with project management

Risk factor	Low risk	High risk
Experience of project manager	Three or more projects	No prior experience
Managing the project	Full time	Part time
Project team assigned	Full time	Part time
Experience of team members as a team	All worked together before	All are strangers
Number of times that team members have implemented this application	More than once	No experience with this application
Team location	In one place	In several locations

3.4.2. Full-time project manager

Depending on the size of the project and the resource available, it is preferable to have a full-time project manager. This avoids conflicts of interest with line management responsibilities [3] and the ability to focus on key issues that could occur if it were a part-time position. In some respects this is a management decision about the amount of time and resource allocated to a project. However, there is also the onus on the project manager to inform management if he feels overworked with dual responsibilities.

3.4.3. Full-time project team

Whilst it is common for the project manager to be allocated full time to the project, the team members are usually allocated on a part-time basis. Here the line/matrix conflicts outlined in the last section will become apparent as the project competes with the line for the resource of these skilled individuals. In this situation, errors could be made or delays occur which could impact on the project, the ordinary work or both.

To manage this situation effectively it is important to define accurately the amount of time that a project team member should spend on his respective duties. This will reduce the amount of time available for line work and accordingly the manager of the individuals should negotiate with the clients the deadlines of work involving these staff. If specific tasks for the project such as in-house evaluation require an individual's time, this must be negotiated with the supervisor well in advance of the event.

3.4.4. Project members operating as a team

When the project team is composed of members who have not worked together before, some delays may occur in the initial stages of a project. Team members need time to get to know other member's personalities, understand their skills, strengths and weaknesses and learn how to work together. Risk rises if the team lack skills or understanding of the technology involved or the knowledge to complete the project successfully.

To overcome this and reduce the risk, attempt to use staff who have worked together as a team. Working to the strengths of an individual is always preferable to training another member, although this approach carries the risk that IT and automation skills can often be in short supply and one individual can often be carrying out several tasks and conflict with line duties. A means for skill transfer should be included where feasible, and time and resource allow.

3.4.5. Experience with the application

Often the majority of project team members from the user areas have little or no experience with a new type of application. Without experience the team will not have the insight to avoid mistakes or blind alleys. Additional time may be required for reviews and revisions of the plan and its execution.

If similar projects have been introduced in the organisation utilize the knowledge from some of the team members as an internal consultancy role. Ensure that more time is allowed for the project to allow for these problems.

3.4.6. Multi-site projects

The concept and introduction of corporate LIMS may involve a project developing an application for two or more sites. Whilst from the corporate viewpoint this is an effective use of resources for development and maintenance, and the benefits will be significant over point solutions being developed at every site that may be different, there will be problems encountered. By its very nature, a project covering more than one site tends to be larger and more complex, and hence more expensive than one at a single site. Senior management look carefully at these projects as a significant proportion of their IT budgets will be involved.

Communication may be difficult, especially if there are time differences involved greater than one or two hours; this can be overcome by the use of electronic mail facilities or a bulletin board for common interest items. Progress updates will need to be regular for all sites and held centrally in one location for the control of the overall project.

There may be lack of coordination at the sites where the project manager is not located. Travel, often extensive, will be involved for the manager and several key members; the budgeting of money for this and the associated subsistence is essential. Different sites may have different working practices, policies and organisations. These typical issues, raised by a standard system, will have to be resolved at senior management level before much progress can be made. In companies working on a global basis there will also be cultural differences, methods of working, statutory holidays and even the length of the lunch break to be taken into account. The time scales for the project will need to be increased to account for these factors. However the overall benefits to the organisation should outweigh these difficulties.

4. EVALUATION AND SELECTION OF THE SYSTEM

In this section, it has been assumed that a commercial LIMS or laboratory automation package is being selected. However, if an in-house system is being developed from components that the organisation will integrate and develop, a few modifications will allow Table 5 to be useful in this instance. The general factors involve the technology used in the application, the mode of selection and the vendor. Each will be discussed separately.

4.1. Technology components

Factors involving the technical components of a system that influence the risk during the selection process are presented below.

4.1.1. New or non-standard system components
Increased risk to a project will be incurred if new or non-standard system components are se-

TABLE 5

Risk factors associated with system selection

Risk factor	Low risk	High risk
New or non-standard hardware or system software required	No	Yes
Team has experience using the tools and techniques for this application	Expertise available	Used for the first time
New language(s) required by the project	None	Used for the first time
Data base used in the application	Well established in the organisation	New in the organisation
The system requires	Batch processing	Distributed system
On-line response required	> 7 s 90% of time	< 2 s 90% of time
System availability must be	95%	> 99%
Technology mix (data base, network etc.)	Existing or simple architecture	New or complex architecture
Team's knowledge of the package	Previous experience	No knowledge
Organisation has worked with the vendor	Three or more times before	Never
The package matches the system requirements	Well (little customisation required)	Poor (major customisation required)
Computer department involvement in package selection	High involvement	Not involved
User department involvement in package selection	High involvement	Not involved
Vendor reputation is	Good	Poor or unknown
Data complexity (number of entities and relationships between them)	Not complex	Very complex

lected for the application. Under this category are included:
- hardware and operating system;
- networking protocols or components;
- application software including languages, data bases, tools, techniques or utilities.

The risk in selection of non-standard components is manifested in several ways. The development team and the support staff need to become familiar with the respective components. This may require training which may be extensive as well as costly. The extent of integration between these new components and any existing applications may raise technical problems at the very least. Training to use these packages and potential delays due to technical problems to be solved should be part of the project plan.

Establishing contact with the vendor's technical experts for specialist information and advice may be a way of gaining information to reduce risk or to obtain solutions to actual problems experienced. It is preferable to keep to the corporate standards wherever they are established for easier implementation and maintenance. The choice of packages that do not conform with corporate guidelines must be made carefully:
- Does the database have sufficient flexibility to undertake the tasks now and in the future?
- Is the application development language suitable for the task?

The choice of the wrong data base or development language will have a major impact on the project's ability to deliver the expected benefits.

4.1.2. Type of processing

The greater the complexity of the system the higher the risk that something will go wrong. Management of risk approaches should be adopted to choose the simplest approach consistent with supporting the application effectively. The choice of a pilot system to size the processor, memory and disc I/O accurately before the installation of an operational system, may be one avenue. If distributed processing is required implementing core functions in two locations first could be adopted as preferable to finding the completed package does not work as anticipated. Some applications may require on-line data capture in real time; this requirement may entail having a failure resistant hardware configuration. The need and justification for every requirement should be investigated thoroughly.

4.1.3. Response time

The faster the response time required by the application and the users, the higher the risk. Failure to meet this performance criterion may result in loss of user involvement and interest. The sizing of hardware components and the design for rapid data base searches for urgently required data may be crucial but remember that not all data may be needed rapidly. Ensure that the computer has the expansion capacity for the next three to five years to cope with increased demand either with sufficient capacity purchased at first intent or by planned incremental growth.

4.1.4. System availability

The need for a high system availability should be investigated and justified. If a high degree of availability is placed upon the system hardware, it needs a high level of availability itself. Like the example above, fault tolerant hardware may be justified in cases of near 100% availability being required. Procedures for identifying and solving problems should be developed as should effective and rapid disaster recovery procedures.

4.1.5. Technology mix

The greater the number of technologies that have to be integrated into an application environment the greater the risk becomes. Wherever possible, keep to the simplest approach consistent with the requirement of the application and meeting the needs of the user and organisation. Wherever possible use components, or proven technology, that the organisation has knowledge of and has used successfully before. Here the success rate of the organisation in implementing IT and automation projects plays a role. An organisation with a successful and innovative track record in implementing projects can probably justify the risk involved with a range of technologies. However, a more pedestrian organisation should lower its sights and dwell on the side of caution.

4.2. The application package and the mode of selection

When an application package is chosen there are a number of parties with vested interests within an organisation such as the IT department, the user laboratory, and, in a regulated industry, the quality assurance unit (QAU). With an effective project team approach all should be represented and have their input.

From the IT department's view, the users may have chosen the wrong package for a number of reasons such as non-standard components, new technology or the data base does not appear to fit the requirements. The input of the IT department should be to check the requirements and package to assess the degree of fit from the computer viewpoint. It is possible that the package may not meet the user's expectations or it may take considerably longer to implement than anticipated from an IT perspective. This can be resolved by ensuring the package is tested fully with tests that represent functions carried out by the users.

If the package is selected by the IT department with little input from the users, the greatest risk is that the users will reject the system. The users know their own environment best and appreciate the functions they require. The QAU interest is that the selected system can be validated and that they can use the system to carry out audits effectively.

The closer the package matches the requirements the less risk is incurred by the project. The further the package is from the requirements the more customisation will be required, or the users will have to modify their working practices to use the package. Both instances increase the risk of the project and can lead to excessive time delays or user rejection. It may be appropriate in this instance to consider a custom design system rather than a package. Alternatively redefine the scope of the project and reassess the fit to the modified requirements.

4.3. The vendor

The project will have increased risk if the organisation has no experience in dealing with a specific vendor. Without first-hand knowledge of their contract negotiating techniques and their willingness to modify their package, a laboratory could end up with a package that does not support the business as well as incur expensive delays (see also Section 4.2). This risk is increased if the company is new or has only a relatively small number of installations.

To a certain extent, an indication of the vendor's attitude to existing customers and their problems can be obtained from site visits. However, it is important to remember that a vendor will not usually take potential customers to a site with which they have had many problems. The site most likely to be selected will be one that the vendor has a close relationship with.

To counter this, it may be prudent to insist that all agreements with the vendor are in writing. This may also be true of statements made by sales personnel who are attempting to win an order. Access to the technical specialists can build confidence in dealing with the vendor and be the start of a good working relationship. Communications, both formal and informal, should be established and any issues discussed should be entered into a log as a formal record of progress.

4.3.1. Vendor failure

This risk covers the failure of a vendor due to either commercial failure of the company or, more often, the withdrawal from a market sector for commercial reasons or changes in business direction. If any of these problems occur it is important that the organisation does not suffer loss of investment, both money and time. Contingency plans may be drawn up for the maintenance of the system, at least until a replacement can be found and implemented (possibly a one to three year time period).

To try and avoid failure of this type before any order has been placed, and preferably during the selection process itself, obtain financial statements from each vendor under consideration. Non-disclosure agreements may be essential to obtain information especially if it is not part of a published annual report. Key indicators are the length of time the vendor has been in the business and the growth of the company over that time period. Within the IT area, many companies may have relatively short track records and may be relatively small; the impact the product(s) have had in the time they have been available could be used instead. When considering automation it is more likely that the company will be larger, but this is no guarantee of minimised risk.

While care is needed in vendor selection, a track record and growth with a successful product is ideal but these should not be used as exclusion criteria against smaller companies that may be emerging with a superior product.

Safeguarding the investment can be achieved by the use of clauses in the purchase contract such as all software and documentation should be provided or put into escrow with a third party in the event of failure. Access to source code is a contentious issue but in the event of corporate failure, this may be the only way of maintaining the system. To protect the laboratory, it may be prudent to include a clause allowing the maintenance of the software by a third party if the vendor cannot or will not fulfil the contract. Incorporating items such as those outlined above is a long and complex process that should be undertaken carefully.

5. RISKS ASSOCIATED WITH DEVELOPMENT AND IMPLEMENTATION

Of all areas of the SDLC, development and implementation are the stages that have the highest risk associated with them. To a certain extent, a project can cope with poor sponsorship or the sub-optimal selection of a system. However, the development and implementation phases are where the majority of projects fail. Even a technically perfect system that matches user needs can be lost by user indifference or hostility. Some common risk factors that could occur during development and implementation are presented in Table 6.

There are some factors that are unique to development and implementation. However, it is also the part of the project where many of the earlier risks will have their full effect if they have not been managed properly.

TABLE 6

Risk factors associated with system development and implementation

Risk factor	Low risk	High risk
System scope fixed and prioritized. Changes in organisation or policy implemented	Yes	No
Change control procedures in place	Yes	No
Scope matches working practices or working practices changing to match the scope	Yes	No
Documented development plan available, detailing who, when and where	Yes	No
Sympathetic users identified for prototyping, testing and implementation	Yes	No
Quality assurance unit (QAU) involved for pre-operation audit and GLP/GMP advice	Yes	No
Development documentation to be produced identified	Yes	No
Performance of development system matches expectation	Yes	No
Contingency plan available if performance not good enough	Yes	No
Focused training planned and agreed with the users	Yes	No
Documentation available for users, backup and support staff	Yes	No
Assistance arranged for new users in period after training	Yes	No
Work schedules altered to cope with post training productivity loss	Yes	No
Management of user expectations	Yes	No

5.1. *Fixed system scope*

By the time the development of the system starts it is imperative that the scope of the system is fixed and the functions to be customised are prioritised and agreed by the user management. If the scope is not fixed additional functions could be added by users or managers. This could have a number of results; almost certainly the system will be delayed, the functions added may not produce any meaningful business benefit. During any implementation, the core laboratory functions should be customised first. Additional functions should then be added later according to business need.

5.1.1. System scope matches laboratory working practices

When the development starts, the scope should either match the working practices in the laboratory or changes in the manual practices have been instigated so that they match the new system functions. System credibility can be lost easily amongst the users by an unplanned mismatch of system and working practices. Liaison amongst the user representatives on the project team with the system developers should help to alleviate this problem.

5.1.2. Change control procedures

Once the scope has been fixed, there should be change control procedures set up to debate and approve any additions, deletions or modification to the scope. Without change control procedures in place there is a significant risk in uncontrolled development of a system.

The change control process involves a set of procedures and a review group. This latter can be either a sub-group of the project team or a separate group whose purpose is to review and prioritise any modification of the scope. Submissions, detailing the changes to be made, should be in writing with the business benefit laid out. Change control should avoid the trivial functions being added at the expense of more urgent ones and delaying the project. The corollary is that sometimes important functions are missed from a scope and this mechanism provides the means to have them authorised for inclusion.

Implementation of change control will also be useful when the system is fully operational, as all changes to the system configuration should be proposed and authorized in this manner.

5.1.3. Documentation

The documentation of the system is a key quality issue. The main document required for the development is the scope describing the functions to be customised. Additionally, an outline of the change control procedures, draft testing and validation plans, draft procedures for start-up and shut-down of the system and outlines for the user manuals are needed.

Documentation is required for validation of a system, but more importantly it is essential for the smooth transition from development to operation. The time required to write good quality user and support documentation is usually longer than anticipated. Therefore the tasks should be started well in advance of when they are required and enough time should be allowed for the job to be completed with sufficient quality to be the first line of support for the system.

5.1.4. Involvement of users in prototyping and testing

Before development starts, the project team should have identified a group of sympathetic users, who will be used to test prototypes or functions developed via conventional programming. The users should represent all groups within the laboratory environment. Note the use of the word *sympathetic*. Credibility is easily lost during development by word of mouth and the actual performance of a system. There is little point in selecting a group of users who do not want the system to succeed or are sceptical to the use of automation. What is required is constructive comment and criticism that will allow development of functions to proceed without detrimental comments about the system being made to everyone.

5.2. Implementation

Detailed planning and availability of personnel in this phase of the SDLC are crucial to the credibility of management and success of the overall implementation.

5.2.1. Detailed implementation plan available

Before commencing this phase of work, a detailed plan covering the implementation must be available. Details covered should be as follows:

– The implementation style for a LIMS [7] should

be clearly defined and the implications of each approach thought through before starting.
- Training, which can be carried out in various ways (e.g. internal or external), should be planned and costed. Any external staff from a vendor should be informed of when and where they are required.
- External groups who submit work to the laboratory should know when training will take place and the impact of this upon the work schedules. The latter should be rearranged to include the immediate post-implementation period when productivity will be lower than normal.

The aim of the plan is to remove most of the uncertainty involved during implementation and direct resources to where they are most needed, when they are most required.

5.2.2. Training plans agreed

Once the implementation style has been agreed on, the training schedule can be developed relatively easily. In the implementation plan, the groups of workers who will be trained to use the system and the order of training should be identified along with the support staff who must be on hand to augment training and solve any problems. Obviously risk increases dramatically if staff are not trained to use the system.

Many vendors offer standard courses; however, this may not meet the needs of users whose system has been customised from the core system offered for sale. It may be beneficial to consider customising training courses and also holding them on site if there is sufficient demand to do so or the cost benefit is good.

5.2.3. Implementation delays

There are a number of possible causes of delays such as the vendor fails to deliver a package within an agreed time frame or the writing of in-house software is slower than expected. More problematical are instances where the functions of the LIMS do not match the current working practices in the laboratory necessitating a delay to rewrite software. The lack of suitably qualified staff either in-house or from a vendor may impact at a crucial time on the project. Regardless of the cause, delays in implementation are frustrating, have a bad effect on morale and impact upon the credibility of the system.

Using staff to work on the project in their spare time increases risk due to conflicting interests. It is preferable to have dedicated staff working on a project to ensure implementation in a timely manner.

5.2.4. Poor system performance

This is a classic reason for failure of projects during implementation: the system was sized either by estimation or by a formula. The overall system performance is not sufficient to operate the system effectively and provide adequate performance to the users and ultimately the laboratory customers. Effectively, the system is useless and unable to perform its function. This can be due to a combination of factors:
- hardware related: processor undersized, insufficient memory, insufficient disc input/output capacity;
- software related: inefficient or non-optimised software routines, data base searches slow and not optimised; estimates of laboratory workloads too low.

A number of ways can be used to overcome these problems. One is to define the overall workload of the laboratory accurately together with defining in unambiguous terms what a sample, test, analysis and result means within the context of a specific laboratory. This should allow a vendor to size a system more accurately. Note, however, that vendors work on *average* system sizes. If a laboratory's application is below average, performance should not be affected and may be enhanced. However, if the application is above average, performance will be affected, often quite dramatically.

Visits to existing users are a more practical way of discovering how effective the vendor has been at sizing a system. If this approach is taken, it is imperative that the site visit be to a laboratory in the same industry and, wherever possible, that they use the same software modules as the vendor is proposing for you. Often it can be very difficult to find a laboratory site that operates even in the same industry as your laboratory, or if one is found it is located in a different country. However, site visits are a very useful way of evaluating system performance.

Alternatives exist to avoiding performance problems. The approach taken in the author's laboratory was to purchase a small development computer system, develop the software and carry out performance tests that would predict the size of the computer system required to support the intended user base [8]. Another is to carry out a performance test on the potential system configuration and time the responses obtained. Finally specify the minimum response times required in the contract with any penalties upon failure to achieve them. This is an approach but the author prefers the practical approach to sizing as it removes an area of uncertainty during the most critical phase of a project. This practical approach to hardware sizing should also eliminate the need to seek additional funds, soon after the system is operational, for a CPU upgrade or additional discs.

5.2.5. *Obsolescence*

Given the rapid development and life cycle of hardware and communications components, it will not come as a surprise to find that the system hardware can be replaced in a product line before the organisation's depreciation period is completed. If the equipment has been purchased from a recognised supplier, service support should not be a problem but expansion may be. To reduce, but not completely eliminate, this risk, ensure that the development plans of the hardware supplier are known, especially if the proposed hardware system has been available for over two years.

Obsolescence with commercial LIMS centres around the data base used to support the application. Virtually all commercial LIMS in the past have used either operating system files or network data bases modelled as a hierarchical system. These are usually proprietary data bases with little access to other applications running in an organisation. Now, the trend is towards relational data bases with structured query language (SQL) as standard to retrieve data. The purchase of a LIMS with a data base of operating system files should only be contemplated if the application is a stand-alone one or there is a clear migration path offered by a vendor.

6. CONCLUSIONS

When considering risk assessment and management throughout the lifetime of an automation project a number of common threads emerge:

– Effective planning is needed which includes allowances for slippages and tasks that were not identified at the start of the project. The plan should go to a depth that allows the project to progress on strong technical and human grounds. This is not always done and project plans are usually over-optimistic.

– Communication between all parties: users, vendor, management and IT, is an essential element of reducing risk by transfer of information. Discussion of the benefits of a new system should be realistic to manage user expectations.

– Experience and skills on automation and IT projects are valuable resources within many organisations. Too often they are not used to their full extent by passing experience to different functional groups who are undertaking similar projects. Therefore many projects waste time and resource overcoming the same problems that other groups resolved on other projects.

– Commonsense and flexible management approaches are essential, both from the user management but also the project manager.

– User involvement is essential for a successful project which must be matched by management commitment.

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