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A Matrix for the Development of a Strategic Laboratory Information Management System

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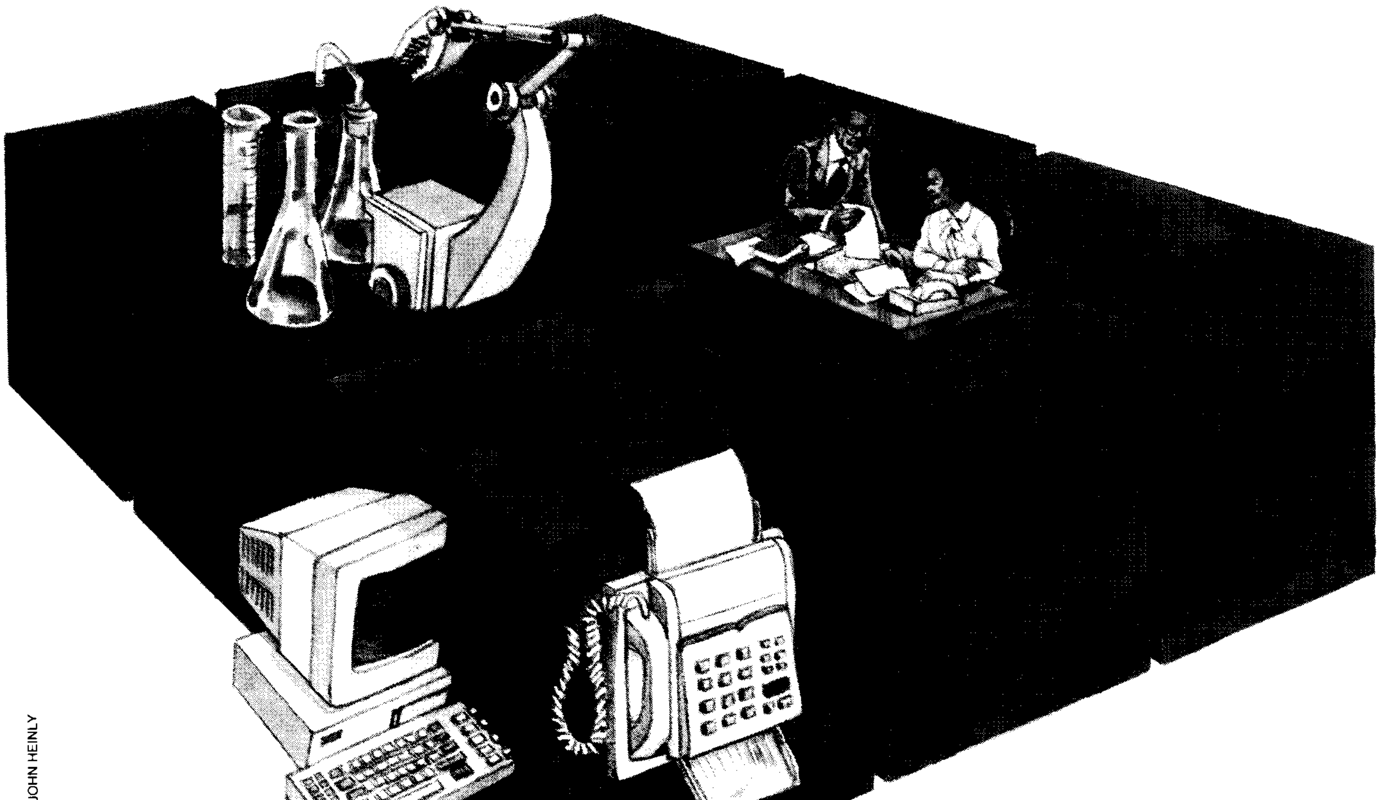

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This is the second in a series of articles addressing the issues of information technology (IT) within the analytical laboratory. In the first article, we considered some of the operational, logistic, and strategic issues that must be addressed to enable an analytical laboratory to meet current and future demands (*1*). Here R. D. McDowall of the University of Surrey concentrates on laboratory information management systems (LIMS) and considers the intent and implementation of LIMS in order to stimulate discussion and debate. He also focuses on the impact that a LIMS should—but rarely does—make on both a laboratory and an organization. To overcome this problem, McDowall proposes a matrix for the development of a strategic LIMS. It can be used to aid system implementation or, alternatively, to evaluate the effectiveness of existing applications and chart their further development. The overall purpose is to give managers and analytical chemists a tool they can use to ensure that any LIMS reaches its full potential.

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The major function of most analytical laboratories is to create and present information in a timely manner that will allow clients to make decisions. A LIMS is one of the primary automation tools at the disposal of analytical chemists to help them achieve this goal (*2*). Although a LIMS does not perform analyses, it can be pivotal in integrating both the laboratory operations and the laboratory itself within an efficient organization. It can provide the means to automate the processes of information creation and presentation and, because it can also be the platform for information dissemination to clients and senior management, a LIMS should serve as a strategic system for any laboratory to add value to the information that is generated.

However, this is not always the case. A large number of systems fail to meet initial expectations, most probably because LIMS are not fully understood (*3*). To address this problem, in 1990 we proposed a LIMS model (*3, 4*) that made it possible to conceptually visualize the requirements of a system (*4, 5*). It has been adopted, modified, and used as the basis of the LIMS concept model in the ASTM LIMS guide that has recently been finalized (*6*). However, the original model focuses on the user functions within the laboratory environment and not on the strategic placement of a system.

In this article, we will review the need for strategic IT planning, discuss the limitations of current LIMS and their implementations, and describe how LIMS fit into the processes of laboratory management and decision making. In addition, we propose a matrix for the development of a strategic LIMS that is formed by plotting three types of information systems versus the scope of laboratory and organizational tasks that can be undertaken. A strategic LIMS will facilitate efficient organizations rather than just the development of operational LIMS.

Strategic IT planning

Strategic IT planning is essential to support business objectives, and yet a dichotomy exists (*7*). Many current IT investments have failed to deliver the anticipated business benefits,

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and some organizations have become concerned about this problem. At the same time, the application of IT by some organizations has provided a competitive advantage.

The lack of a coherent IT strategy can produce problems such as missing business opportunities, duplicating efforts, adopting system priorities that are not based on business needs, selecting incompatible options, and spending considerable resources in an attempt to integrate systems retrospectively. These difficulties illustrate the need to plan IT strategically (*2, 7, 8*).

Most computer applications tend to be planned from the bottom up to solve local needs rather than to deliver the information needed to run the organization. There is an overwhelming tendency to develop solutions in an ad hoc manner with little coordination among systems and little or no sharing of information.

To demonstrate the problems that such an approach creates, imagine the impact of an automation or IT project as a pebble thrown into a pond (*9*). The pebble (project) creates ripples that emanate throughout the pond (organization). The pebble's impact is proportional to its size and the manner in which it was introduced to the pond. When more than one pebble is thrown, their ripples interact; some reinforce each other and others cancel each other or change the shape of the pond itself. Ad hoc IT solutions rarely interact; they become islands of automation or information.

In describing technical center automation, Dessy has stated that work flows in most organizations need feedback loops to make better use of the human, physical, and informational resources (*10*). The primary way to achieve feedback is to integrate IT completely, which may necessitate work flow reengineering.

Formulating an IT/laboratory automation strategy is a creative process (*2, 8*). Assessments must be made about the current status and future goals of an organization and decisions must be made about which methods are best to reach objectives, given the necessary resources and alternative routes. The history of IT within an organization will influence its potential for the future, for better or worse. Whether the strategy will constrain or facilitate development must be considered. A key aspect of any strategy is to build on strengths and overcome weaknesses.

The business situation, the environment in which the organization exists, the competitive pressures, and the company's long-term strategic plan must be understood to enable the IT to focus on critical areas for the future. The IT strategy should also enhance the business strategy. The resulting demands become a portfolio of system requirements that will evolve over time (*2, 8*).

The "old" and "new" LIMS

Current LIMS are actually laboratory data management systems because they manage data rather than information or the laboratory, as Dessy has indicated (*1, 10*). They support only rudimentary management and planning tasks, such as making simple calculations of how many samples of a particular type were assayed in a month or updating information about workload status and sample backlogs.

These are not the only tasks facing laboratory managers. They are also concerned with problems such as organizing future work schedules, planning how to use staff effectively, and justifying resources. Determining future demand for services can be difficult. The ability to extrapolate data or calculate how future workloads will affect resources is virtually nonexistent with present LIMS.

How can this problem be overcome? The solution depends on the attitudes of the LIMS suppliers and customers. If the suppliers do not perceive the need for these functions they will not be added to the repertoire of LIMS. Thus it behooves the customers to demand these capabilities from their suppliers. The difficulty is that the customer is concerned about managing data and not the laboratory. A shift in attitudes is essential.

To demonstrate a true LIMS, one might ask (*11*), "What resources do I need to accommodate 3000 samples for the determination of X that will be submitted during the next three months?" The LIMS should be able to calculate an answer for the manager, basing the decision on the known workload and the current throughput of the assay in question. Priorities would also play a part in the process, and several scenarios would be given. Managers would be able to plan effectively by using this information (*11*).

Other desirable capabilities of the new LIMS include project management and artificial intelligence tools (*3*) as well as the ability to provide combined operational, logistic, and strategic tools for the analytical laboratory (*1*).

LIMS and laboratory management

Most LIMS are used for speeding up tasks within the laboratory; often the use of LIMS is justified on the basis of the ever popular "improvements in laboratory management." This is a fallacy that is often sold by naive sponsors of LIMS to naive senior management. As more seasoned individuals can attest, managing a laboratory is a delicate balancing act involving four main factors: human resources, analytical equipment, analytical methods, and workload (*12*). Each area can be divided further into a number of individual items.

The four areas are interrelated; a change in one can have drastic impacts in one or more of the others. For example, an increase in staff turnover may slow the turnaround time of samples, increase the overall reporting times, and affect the ability to use available equipment fully. In contrast, automation may have effects on sample throughput and backlog, staff motivation, and the need to train or recruit personnel to carry out the new work. This is a dynamic situation that needs careful and continuous management.

Decision making. Making decisions is a complex process that involves information gathering and sifting before the decision can be made. Because it is unusual to have a complete picture of a situation, an element of uncertainty accompanies a decision. How large this uncertainty is depends on the implications of the decision as well as the manager's experience and his or her willingness to take risks.

Four levels of information or knowledge that affect decision making can be distinguished (*13*). Level 1 is a data set with unknown relationships between the data; Level 2 is a reduction of data into characteristic figures (e.g., mean value, standard deviation, or correlation coefficient); Level 3 is a descriptive model that illustrates the relationships between the characteristic figures or blocks of figures; and Level 4 is a predictive model that forecasts the effect of decisions on the value of the characteristic figures.

Levels 3 and 4 are the most advanced tools for decision making because they provide users with direct information on the consequences of alternative decisions. Most laboratory management decisions are based on future trends or workloads; therefore, a predictive model that determines how future workloads would affect resources is needed. Such functions are virtually nonexistent in present LIMS.

Laboratory modeling. Modeling the laboratory can help predict the result of changes in events. This process should be linked to the LIMS database to access the needed information. Some laboratory models that are based on digital filtering, a technique of operations research that can represent analytical procedures and instruments, have been published (*14*). However, they are relatively rudimentary and concentrate on the low operational levels of laboratories. An alternative would be to collect and store operations research data in a LIMS and then formulate and assess different options with an expert system or a suitable model.

Klaessens and co-workers (*15*) have collated historical data stored in a LIMS into a list and, using an algorithm based on fuzzy set theory to incorporate uncertainty into the process, classified the entries into a limited number of clusters called sample types. This classification is completely user-defined and transforms the historical data into a form that can be used to study the performance of a laboratory. Retrospective analysis of the workload (e.g., client/source, tests carried out, or batch size and throughput) is possible by

Organization

Computer system	Laboratory operations	Monitor and control	Laboratory management	Reporting and communication	Analytical decision making	Organizational integration
Strategic LIMS	Integrate with client operations	Compare requests with capacity	Resources based on workload	Integrate with document management software	Decision support system integration	EDI and CANDAs Rapid commercialization
Logistic LIMS	Integrate laboratory operations	Automate regulatory compliance	Monitor test use	Electronic reports to clients	Highlight out-of-specification results	Remote on-line inquiry integration
Operational LIMS	Automate existing operations	Monitor and approve test results	Sample status Billing	Paper reports to clients	Display results vs. specifications	Remote printing of results E-mail between customer and laboratory

System scope

Figure 1. LIMS matrix and functions associated with each cell.

EDI, electronic data interchange; CANDAs, computer-assisted new drug applications.

interrogating the LIMS database. The resulting information is presented in histograms. Although a representation of historical data is possible by using this technique, the selection of the path leading to the optimal representation must be found by trial and error, and hence the need for a user-definable classification is clear.

Klaessens extended this work to include a simulation model of an analytical laboratory in which samples, analysts, and instruments are represented as a production line (*16*). A sample generator represents the flow of samples into the laboratory, and a planner schedules the samples for analysis. SIMULA, a dedicated simulation language, is used to construct an expert system with which to implement rules concerning the flow of data and samples in a laboratory as well as to produce predicative information.

Van de Wijdeven and co-workers have used digital simulation to model an analytical laboratory with information derived from laboratory records and the experience of laboratory staff (*17*). They monitored the flow of samples through the laboratory and the analyses performed there. By changing various factors in the model, the simulation was able to identify bottlenecks and improve scheduling, thus increasing the work capacity of the laboratory.

Constructing a simulation model is both time-consuming and expensive, and it must be weighed against a decision to increase the work capacity without the benefit of the model. Developing simulation models will give managers additional information from which better decisions can be made.

Quo vadis LIMS? As shown above, some of the requirements of the new LIMS are proper laboratory management, prediction capability, and decision support. However, the current generation of systems cannot undertake these functions. To build a LIMS that serves both the laboratory and the organization requires strategic thinking that most analysts lack. Therefore, we propose a LIMS matrix as a tool to help users, implementers, and vendors install effective systems.

The LIMS matrix

The rectangular matrix presented in Figure 1 is simply a plot with information systems on the vertical axis and laboratory and organizational tasks on the horizontal axis. The components of the matrix and details of its construction are explained below.

Classification of information systems. Computer applications have been divided into three hierarchical types (data processing, control, and planning systems) by Anthony (*18*). Each type is responsible for different tasks within an organization. This concept was modified by Nolan (*19*), and the three types of systems are now called operational control, management control, and strategic planning. This concept can be applied to LIMS as well to produce three types of systems: operational, logistic, and strategic. The functions and aims of these systems are described below in more detail and summarized in the box below.

A strategic LIMS integrates information and applications from different functional areas. From this infor-

Impact of the different types of LIMS on laboratories and organizations

Strategic LIMS

Overall impact is on laboratory competitiveness; it has the greatest impact on the business operation

Integrates information and applications from different functional areas and reshapes operations

Logistic LIMS

Overall impact is on laboratory effectiveness; it has intermediate impact on the business operation

Optimizes and enhances operations by providing information to manage and control the functional area

Operational LIMS

Overall impact is on laboratory efficiency; it has the greatest impact on laboratory operations and little impact on the business operation

Improves operational efficiency by automating laboratory processes and is typified by automating the status quo

Scope of LIMS functional areas

Laboratory operations

Overall scope is to automate and structure work

Automate basic laboratory operations such as sample entry, work list generation, and results entry

Rationalize the work performed

Monitor and control

Overall scope is to evaluate performance

Monitor and control laboratory operations by processes such as approving results, using quality control schemes, and checking for transcription errors

Laboratory management

Overall scope is to support intellectual processes

Organize and manage laboratory functions and operations

Plan projects and work

Reporting and communication

Overall scope is to augment human communication

Provide the means to transmit results or reports and communicate with laboratory clients

Analytical decision making

Overall scope is to aid and speed decision making

Provide high-quality information in a timely manner and in the correct format needed to make decisions

Support processes in production, development, or research

Organization integration

Overall scope is to facilitate transactions within and between organizations

Integrate with other functional groups in the corporation and between organizations (e.g., electronic data interchange or computer-assisted new drug applications) mation it may be possible to reshape operations. A strategic LIMS has the greatest impact on the company by increasing the competitiveness of the laboratory.

The main function of a logistic LIMS is to provide users, especially managers, with both management and quality control information and to increase the effectiveness of a laboratory.

An operational LIMS automates basic processes within the laboratory and can be considered to be an operational control system (*19*). The impact of a LIMS, as it is normally implemented, is usually local and increases the efficiency of a laboratory. An operational LIMS would automate functions such as sample entry, work list generation, and report preparation.

System scope. Six areas of system scope comprise the horizontal axis: laboratory operations, monitoring and control of operations, laboratory management, reporting and communication, analytical decision making, and organizational integration. This system scope is derived from the work of Markus (*20*). Analytical decision making has been added to the five areas she described to make the matrix pertinent to the analytical laboratory. Each area of scope is described in the box on p. 899 A with an overview of its function.

Matrix construction. The matrix together with the associated functions of each cell can be viewed as the 3 × 6 block illustrated in Figure 1. The areas of laboratory operations, monitoring and control of operations, and laboratory management on the system scope axis are concerned with functions inside a laboratory. Reporting and communications, analytical decision making, and organizational integration are concerned with organizational functions. A LIMS may be considered a localized tool if it is implemented only in the laboratory area of the matrix. When a LIMS extends beyond this division, the laboratory (via the LIMS) can have a greater effect on the organization.

The third dimension of the matrix. Although the matrix is shown here in two dimensions, it is possible to add a third dimension to resolve a problem that often troubles organizations: prioritizing automation and IT projects (*21*). The third dimension could involve any of many diverse business pressures such as rapid identification of potential products, faster development time, or lower production costs. These factors can be customized for an industry or an individual company.

Impact of the matrix on systems development

The matrix is a tool for visualizing a LIMS and its consequences. Not all systems need to be developed to the full potential of this matrix. Some systems need to interface with other applications that perform required matrix functions. Most LIMS are not developed to their full potential, either as a result of a lack of personnel or limited management vision.

The axes of the matrix represent the effect of the system on the organization (computer system axis) versus the effect of the laboratory on the organization (system scope axis). The further toward the end of each axis that one aims the development, the greater the strategic focus of the system. However, as a direct corollary, the further one develops the system

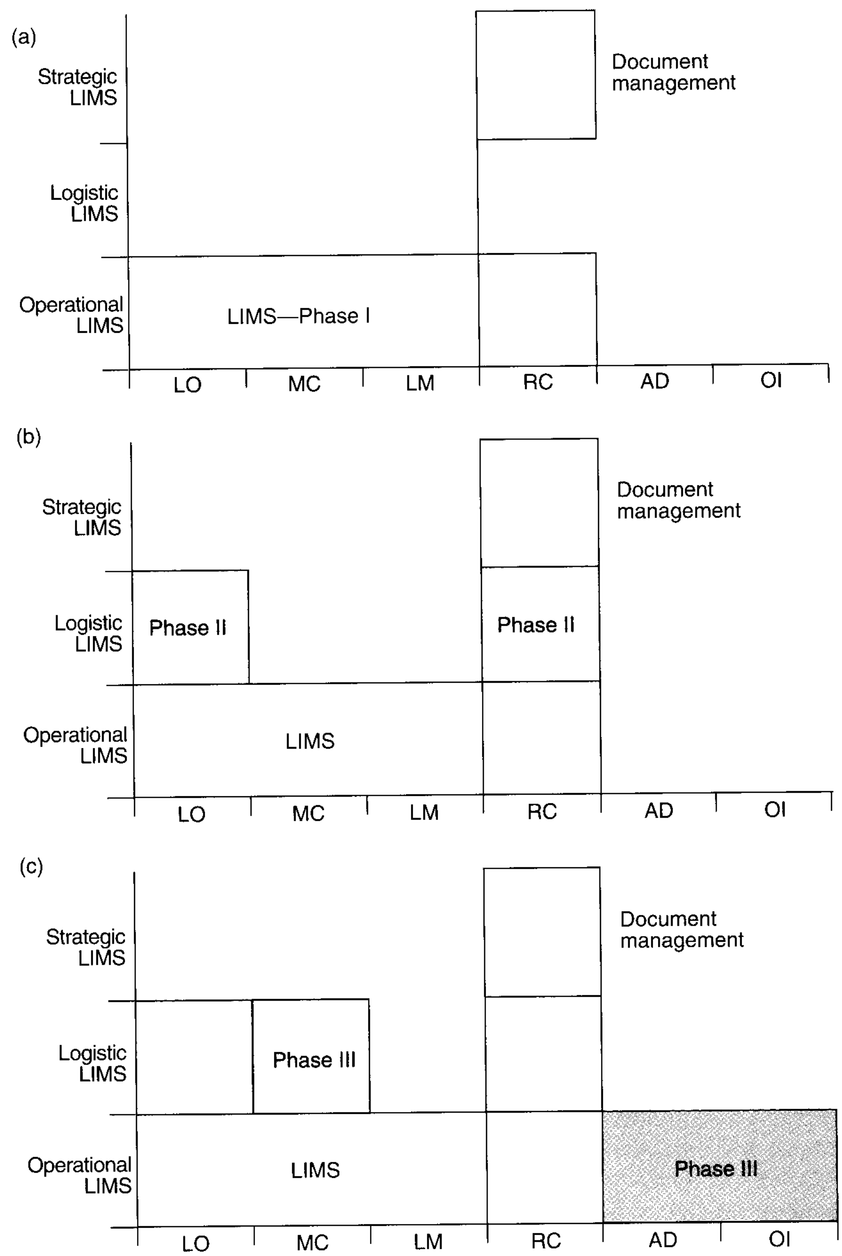

Figure 2. Overall scope of the design for a LIMS in a pharmaceutical company.

(a) First phase of development. (b) Second phase of development. (c) Third phase of development. LO, laboratory operations; MC, monitor and control; LM, laboratory management; RC, reporting and communication; AD, analytical decision making; OI, organizational integration.

along each axis, the greater the risk attached to the overall development.

Strategic LIMS implementation. Prudent implementation of a strategic LIMS should be performed in a staged sequence and be well planned and funded (*8*). It is important to realize that a LIMS cannot be implemented without the involvement of the laboratory that it is intended to automate. Therefore, the foundation of the system must always be based on implementing the LIMS in the laboratory first, and then expanding the system scope into the organization. The 10-year-old statement that the essence of LIMS development is "to provide simple services first with more sophisticated ones following later" (*22*) still holds true and always will.

The overall scope for a LIMS in a pharmaceutical company is shown in Figure 2. The LIMS must interface with a company-wide document management application that will prepare computer-assisted new drug applications (CANDAs). The LIMS will deliver analytical reports to this software.

The first phase of development is to establish the LIMS in the analytical laboratory (Figure 2a). Reports in the first instance will be on paper. The second phase is to build the interface to the document management application and integrate the analytical instruments within the LIMS environment (Figure 2b). The latter task will enable automatic downloading of sample files and methods coupled with instrument control via feedback loops and uploading of analytical results into the LIMS. The third phase is to communicate electronically with clients, which includes having the ability to display results and print reports in remote locations (Figure 2c).

Three LIMS generations. The matrix can also be used to evaluate vendor products. For example, vendor publications have claimed the release of third-, fourth-, or sixth-generation products, but how does one define the degree of change that constitutes a new generation? The matrix can be used to define a new LIMS generation by considering the three types of LIMS on the vertical axis (operational, logistic, and strategic) as just three generations of LIMS. For a LIMS to qualify as a higher order, it must possess at least three functions of the higher system category.

The majority of functions incorporated in a commercial LIMS are driven by existing and potential users. Because users concentrate on laboratory functions rather than on organizational functions, can the vendors be blamed for responding to market forces?

This leads to the LIMS catch-22 situation. Laboratory users and their clients should realize that the organization requires delivery of information to run the business. This necessitates systems that operate conjointly with the objectives of the organization. These systems should provide a means to capture, store, and manipulate a wide range of data to produce information that can be delivered in the places it is needed, in the format that it is needed, and when it is needed. However, to achieve this objective, it is essential that systems be developed with a solid foundation. This foundation is the analytical laboratory.

Impact of the LIMS matrix on the LIMS model

It is natural to compare the roles of the development matrix with the LIMS model (*3, 4*). When conceived, the LIMS model was intended to describe and classify the main user and system functions. By its nature, however, the model is user-based and concentrates mainly on the laboratory rather than on the organization. The model is concerned with reporting methods but barely considers electronic mail or desktop publishing.

In contrast, the LIMS matrix is a tool that has been conceived strategically. It is more business-oriented and encompassing than the model. Therefore it is envisioned that the matrix should be used first to chart the overall scope of a LIMS within an organization, defining the interaction with other IT systems such as process control systems (*23*). Once the breadth of the system has been defined, the LIMS model can be used to determine the scope of the functional components within the laboratory environment.

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