# *Do It Right the First Time:*

# A Handbook for Controlling Technology Through Good Validation Practices

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# *Do It Right the First Time:* A Handbook for Controlling Technology Through Good Validation Practices

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As someone involved in the pharmaceutical industry, you are constantly confronted with systems and processes that are increasingly technological in nature. Data acquisition systems, instantaneous data capture/verification/transmission, integrated clinical trial management systems, data warehouses, automated document management, web-based systems, and the use of e-mail to communicate data represent just a small sampling of the technology that you face every day.

For our purposes here, we will consider all of these systems to be representative of "technology."

**"This article explains how good validation practices can help you gain and maintain control over the technology with which you have to deal with."**

The process of providing documented evidence that any element of technology operates as intended and will continue to do so is called "validation." This is also the essence of good business practice. You must be able to establish, maintain, and substantiate control over technology to ensure that it is working for you and not undermining your stability and growth potential. This article explains how good validation practices can help you gain and maintain control over the technology that you have to deal with.

Technology that is controlled will be effective. Things will be done right. Processes will also be efficient; they will be done right the first time. You won't have to experience horrors, such as the instance in which a system developed to support a pilot plant operation had to be redeveloped because the system owners and users were not involved in its design. Or the situation where the lone developer resigned without completing the system and without leaving behind any documentation. Or the circumstance where an unplanned and unbudgeted performance qualification had to be developed and implemented in a crisis atmosphere to allow a company to achieve strategic goals.

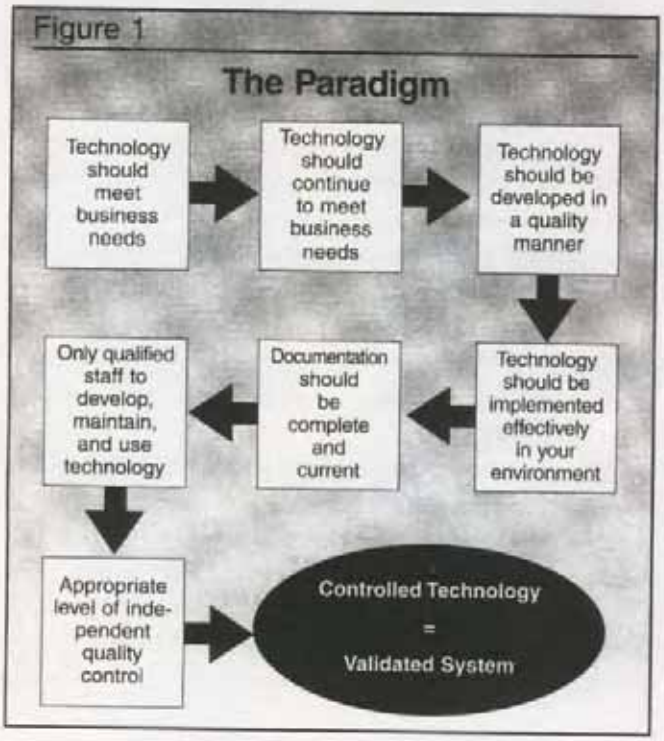
When your systems are properly validated, your company will maintain stability and viability and maximize competitiveness and the ability to grow.

## What are Good Validation Practices?

Good validation practices are controls that furnish the basis for ensuring that appropriate technology is developed, deployed, and maintained in an appropriate manner. They represent the means for providing documented evidence that a system or

process operates as intended and will continue to do so. The conceptual framework of good validation practices as well as the details of the controls are illustrated in *Figure 1* and discussed below.

Figure 1




**Ensure that the Technology Meets Business Needs**

In a business context, technology is not an end in itself but is employed to meet a business need. These needs can be stated simply: maintain stability and viability and maximize competitiveness and the ability to grow. This means that you will be looking at technology to help you achieve one or more of the following general objectives:

- Minimize processing times
- Minimize redundancies
- Minimize data handling
- Minimize bottlenecks
- Minimize need for reprocessing
- Maximize delivery of timely information
- Maximize knowledge management capability
- Maximize application of quality measures
- Maximize capacity (e.g., users, customers, studies, data)

Your business needs should be expressed in a formal set of functional requirements. These requirements define what the technology will do, that is, the business objectives that must be satisfied. If technology were a house, this would represent what you want in the house (for example, three bedrooms, gas heat, a two-car garage, three bathrooms, central air conditioning, a single level, etc.). Regarding technology, functional requirements would include information such as:

- Specific functions to be performed (e.g., specific calculations, reports to be generated)
- Capacity requirements (e.g., number of users to be supported, volume of data to be stored)
- Performance requirements (e.g., acceptable response time, availability requirements)
- Physical and logical security requirements (degree of access restrictions required)
- Quality requirements (e.g., audit trails, edit checks)

Formal functional requirements serve as the basis for developing the technology and for the development of a plan to test the effectiveness of the technology. Without such information, you will have no way of ensuring or substantiating the effectiveness of technology.

Technical specifications provide the details of how the technology works and how the functional requirements will be addressed. Again using the house analogy, this documentation would be the architectural drawings showing what the house will look like and how it will be built. It would show where the rooms are, their size, how they are laid out, materials used for construction, etc. The following represents the information normally included in technical specifications:

- Required hardware and software configuration
- Required communication capabilities
- Components/functions (e.g., data entry, reporting, maintenance, security)
- Deliverables (e.g., reports, screens, analyses)
- Definition and characteristics of the data utilized
- Error conditions and messages

Technical specifications will also allow you to assess the impact of the technology on your environment.

Formal testing is required to confirm that the technology functions as expected, both per the functional requirements and as described in the technical specifications. Continuing with the example of a house, this activity equates to the engineering inspection, the pre-closing walk-through and the municipality's "certificate of occupancy" inspection. Each component of the technology should be tested. This is known as structural or construction testing. All components should then be tested in an integrated fashion. This is known as functional or system testing. Finally, the owner/user of the technology should conduct acceptance testing, which exercises the technology in its intended environment. The testing process should be formal in that test plans and results should be documented and retained to permit review, evaluation and reperformance.

**Ensure that the Technology Continues to Meet Business Needs**

Proper implementation alone will not assure that the technology will continue to function appropriately. Staff turnover, uncontrolled processing corrections/enhancements, new business needs, and increased demand are just some of the reasons why the effectiveness of technology can degrade over time. Therefore, you must also have an effective methodology to assess changing business conditions and to evaluate the impact of such changes on the technology.

Again considering technology as a house, we are referring to the relationships established with the utilities company to maintain and service the heating system, the lawn service to cut the grass, the roofer to periodically check the roof for leaks, and the like. When considering technology, such policies and procedures should address the following:

- Recording any preventive and emergency maintenance to hardware and software to document who did what and when
- Performing applicable tests to confirm that the technology continues to operate properly and that no unintended problems have been introduced
- Backing up and archiving of data such that it can be easily recovered without compromising the integrity of the data
- Recovering backed-up data without compromising the integrity of the data
- Using alternate facilities should access to your facility be restricted as a result of weather problems, fire, etc.
- Limiting physical and logical access to hardware and software to authorized individuals
- Identifying and controlling changes to all hardware and software elements of the technology
- Performing regression testing when fixes/enhancements are made to ensure that no unintended problems are introduced
- Performing daily operations completely, accurately, and consistently
- Monitoring significant conditions and indicators (e.g., temperature, humidity, performance statistics)
- Maintaining qualifications and training commensurate with changing conditions for staff who develop, maintain, support, and use the technology

**Ensure that the Technology is Developed in a Quality Manner**

Technology that is developed in a quality manner will likely have limited risks associated with its deployment and use, relative to technology developed in an uncontrolled manner. Quality in terms of technology development means that the development approach will have the following characteristics:

- Functional and technical specifications, as described above, will be documented and approved by appropriate representatives of management.
- Program development will be performed in accordance with established programming standards to provide clarity and consistency.
- Version and change control procedures will be formalized.
- Structural and functional testing, as described above, will be performed in accordance with formal and approved test plans, and the results will be retained.
- Technical and user documentation will be developed and approved as part of the development effort.

- Staff involved in development, testing, and documentation activities will be appropriately qualified.

When a third party develops technology, you have the obligation to ensure that the vendor's development process is controlled as described above. Unless you know precisely what the system does and how it was built, its limitations, and what its potential organizational impact may be, you may be buying into trouble. Therefore, you should include an evaluation of the vendor's development process and the respective technology in your planning.

**Ensure that the Technology is Implemented Effectively in your Environment**

Technology that cannot be implemented effectively will not be useful. Therefore, when you implement a technology-based system or process, it is imperative to fully understand the scope and impact of what you're dealing with. For example, in the computer systems that support the preclinical or clinical segment of the pharmaceutical industry, such systems normally consist of the following elements:

- The application system itself, which the user interacts with directly. Examples of application systems are Recorder for data acquisition, Documentum for document management, and Microsoft Outlook for e-mail.
- The hardware platform that the application system resides upon. The DEC VAX and Hewlett Packard 9000 are examples of a hardware platform.
- The operating system, such as Windows 95 or Windows NT, which provides the backbone for using any software on the selected hardware platform.
- The configurable software, which provides capabilities for customization. SAS and Microsoft Excel are examples of software that can be configured.
- The network software, such as Internet Explorer and Netscape Navigator, and the communication software, such as TCP/IP, that provide for functionality such as e-mail and internet capabilities.
- The database management system that is required when databases are used in the application. Examples of such systems include Oracle and Interbase.

Additionally, you have to anticipate the impact that technology will have on your environment. For example,

- Do you have the space for a new piece of equipment?
- Can you support a new system or process without reducing the effectiveness or efficiency of existing systems and processes?
- Does your staff have the requisite skills to operate and maintain the new technology?

Therefore, formal "qualification" procedures are needed to ensure that the technology can be deployed properly. These procedures include:

- Installation qualification – establishes documentary evidence that the technology is installed and configured to manufacturers' specifications and user requirements
- Operational qualification – establishes documentary evidence that the technology functions according to provider (manufacturer, developer, or vendor) design intentions and throughout its intended operating range
- Performance qualification – establishes documented evidence that the technology performs according to user-critical requirements, procedures, and processes in its normal operating environment

**Ensure that Documentation is Complete and Current**

Have trouble programming that VCR? Most of us can accomplish this task using the owner's manual, but some of us still have trouble even if the manual is thorough and well-written. The same issues arise when dealing with technology in our industry. The analytical devices and computer systems can be quite complex and not necessarily intuitive. Therefore, an ineffective "owner's manual" can lead to inefficient and/or improper use of the technology.

The documentation that should support technology includes:

- User documentation (e.g., a user manual, operational procedures) provides instructions for effectively using the technology and training new users.
- Technical documentation (e.g., reference manuals) provides a detailed understanding of the system as a whole and of the individual components. This will allow you to better troubleshoot problems and assess the full impact of the technology on your environment.

**Ensure that Qualified Individuals are Involved in Development, Maintenance, and Use of Technology**

An important aspect of controlling technology is to ensure that only qualified individuals are involved in its development, maintenance, and use. This is consistent with regulatory requirements that people should be qualified to do the jobs to which they are assigned. Qualifications of new hires should be confirmed through thorough reference checks, and continued qualification should be supported through effective training programs. Characteristics of effective control over staff qualification include:

- Qualifications should be recorded in CVs that are kept current.
- Training records should be retained for all individuals.
- Training records should reflect all courses, classes, etc., and provide the agenda, training materials, dates provided, and list of attendees.

**Ensure an Appropriate Level of Independent Quality Control**

An independent quality assurance function is a management control to help ensure that applicable policies and procedures exist and that they are being followed. The existence in our industry of the "Quality Assurance Unit," by whatever name, is a widely recognized necessity. However, this group must be able to understand what they are reviewing in order to be an effective independent check and balance. This means that quality assurance representative(s) must possess sufficient technical abilities to understand how the technology was developed and will be used.

## What Can Happen If I Don't Control Technology?

Controlling technology will help you do it right the first time. Your processes will be effective, that is, done right. They will also be efficient; that is, they will be done right the first time. The specific risks are:

**If Technology Is Not Developed Properly...**

The following types of problems will tend to occur if technology is not developed properly:

- You may implement processes that are not appropriate to your business because requirements may not exist or may be ineffective when used as a basis for the development.
- The processes may not function as intended or as designed because requirements were not available or ineffective when used as a basis for development, or the technology was not tested properly.
- Processes that you expect to be performed may not be included in the technology.
- Performance may be inconsistent because it may be affected by variables such as the number of users, volume of data, etc.
- Maintenance may be complex because the programming may be difficult, and/or documentation may not exist or be difficult to understand.
- Unanticipated problems will occur; that is, new problems will keep cropping up.

The impact of these problems will be that processes will have to be reperformed, alternative methods may need to be developed to compensate for limitations, and/or the technology will not keep up with demand. The major concern here is that these issues will prevent your company from supporting growth; if current processing cannot be effectively or efficiently performed, increased demands on resources will not be feasible.

**If Technology Is Not Maintained Properly...**

The following types of problems will tend to occur if technology is not maintained properly:

- New business conditions will not be supported because they are not incorporated in the technology.
- The processes that were initially functioning effectively may not continue to do so because fixes/enhancements were not specified and/or tested properly.
- Performance may be inconsistent because significant increases in the variables, such as the number of users and volume of data, cannot be supported.
- Maintenance may be difficult because the documentation has not been kept current.

The impact of these problems is the same as stated above: Processes will have to be reperformed; alternative methods may need to be developed to compensate for limitations; and/or the technology will not keep up with demand. Again, these concerns will prevent your company from supporting growth; if current processing cannot be effectively or efficiently performed, increased demands on resources will not be feasible.

**If the Staff Is Not Qualified or Trained Properly and/or Documentation Is Not Complete or Current...**

Unqualified/poorly trained staff or staff having to depend on incomplete/out-of-date documentation will tend to beget the following problems:

- Individuals may do the wrong things.
- Individuals may do things at the wrong time.
- Individuals may not do the same things the same way all of the time.
- Individuals may overlook activities.
- Individuals may "spin wheels" or have to do an activity multiple times until the activity is done properly.
- Different individuals may not be consistent in performing similar activities.
- Bottlenecks may occur in the process.

The impact of these problems will be that information will not be disseminated in a timely fashion or may not be disseminated at all, improper actions may be taken, improper decisions may be made, and new employees will not be adequately trained. Again, this will tend to limit your abilities to assimilate new systems and processes that might be needed to support growth.

**If QA Involvement Is Inappropriate...**

If the quality assurance involvement is not effective, any or all of the problems identified above can exist. This is because the absence of an effective quality assurance group weakens the level of management control that is designed to prevent and detect such shortcomings.

## What Should I Do?

If you are affected by technology and want to establish control over it, you should do the following:

- Evaluate your status with respect to the existence of, and compliance with, controls. Using the control objectives described above as a basis, you may have to perform an evaluation of existing practices to identify the "gaps" or areas of noncompliance.
- Assess your risks and the impact of the risks. Each "gap" represents a risk in terms of effectiveness and/or efficiency. You will need to apply certain criteria, such as, but not necessarily limited to, the following:
  - Is the technology of strategic importance to the company?
  - How effective are the development process and supporting procedures?
  - Is this technology new or new to the company, or has its stability been proven over time?
  - What is your company's inspection history with FDA?
  - Is the applicable area one of the FDA's "hot buttons?"
  - What is the likelihood of an inspection?

- Evaluate the cost/benefit of investing resources. A cost/benefit analysis should be done to ensure that "good money will not follow bad." For example, if the system is not critical and will be replaced soon, it may not pay to spend any time or resources to implement corrective measures. However, a mission-critical system that is likely to be inspected deserves a more conservative treatment.
- Develop a plan to address the "gaps" that you deem must be addressed. The plan should include specific activities, roles and responsibilities, and milestones against which to measure progress and deliverables.

## Summary

Effective use of technology is necessary to satisfy clients/customers and regulators. You will avoid client/customer dissatisfaction as well as negative audit findings (and you know how quickly word spreads via the Freedom Of Information Act). You will minimize loss of clients/customers while maximizing your ability to attract new clients/customers. As we've seen, effective use of technology is dependent on effective control of technology. Effective control of technology, in turn, is the very essence of computer systems validation, and employing the means discussed will help to ensure a successful validation of computerized systems.

And don't forget... Efficient operations stay in business. So do it right the first time. Get control of your technology, and keep it. ❑

## About the Author

*Len A. Grunbaum is the President of META Solutions, Inc. He is responsible for all aspects of the company, including the operation and management of the validation and SOP Consulting Services to the pharmaceutical industry. This includes technical and functional computer systems validation, quality assurance, internal controls, computer security, contingency planning, and computer systems development. Len has a Bachelor of Arts degree and a Masters of Business Administration degree from Long Island University. He can be reached by phone at 908-791-1900 by fax at 908-791-9977 and by e-mail at len_g@metasol.com.*