



Controlling the Impact of Technological Change Through Good Validation Practices

by Leonard A. Grunbaum

As with death and taxes, you can't avoid technology. With the prevalence and sophistication of computer technology — and issues to grapple with such as electronic signatures and Year 2000 computer problems — you may feel that death and taxes are preferable.

However, control over technology must be established, maintained and substantiated to ensure that it is working for and not against you. You also need to ensure that technology is not undermining your company's stability and growth potential. We must understand the needs, objectives and issues surrounding the implementation of controls to help our companies comply with regulatory requirements and expectations.

Good validation practices represent controls that ensure that technology is developed, deployed and maintained appropriately. The basic tenets are:

- The technology must meet the business' needs.
- The technology must continue to meet the business' needs.
- Technology must be developed in a quality manner; standards should govern program development, testing and documentation.
- Technology must be deployed effectively.
- Documentation must be complete and current.
- Only qualified individuals must be involved in developing, maintaining and using technology.
- An independent quality assurance function must be in place and qualified to evaluate information technology.

Technology that is not developed or maintained properly will result in inappropriate processes, incomplete or unperformed processes, inconsistent performance, difficult maintenance and unanticipated problems. Processes will have to be repeated, and "workarounds" may need to compensate for limitations. Otherwise, the technology will not keep up with the demand.

Unqualified or poorly trained staff, or staff dependent on incomplete or out-of-date documentation, will tend to do the wrong things at the wrong times. Information will not be disseminated in a timely fashion (if at all), improper actions may be taken, improper decisions may be made and new employees will not be trained adequately. This will limit your abilities to assimilate new systems and processes that might support growth.

The absence of an effective quality assurance group weakens the level of management control that is designed to prevent and detect such shortcomings.

To establish control over technology:

- Evaluate your status with respect to the existence of and compliance with controls.
- Assess the risks and their impact. Each gap represents a risk in terms of effectiveness and/or efficiency.
- Evaluate the cost-benefit of investing resources to ensure that "good money will not follow bad."
- Develop a plan to address the significant gaps, inclusive of specific activities, roles and responsibilities, and milestones against which to measure progress and deliverables.

Effective use of technology is necessary to satisfy clients or customers and regulators, avoid client-customer dissatisfaction and minimize the risk of negative audit findings. (You know how quickly word spreads via the Freedom of Information Act.)

Don't forget...efficient operations stay in business!

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