



## Reader ROI

- Value-Based Compliance Management (VBCM) is the name of a unique methodology for reducing the overhead of compliance.
- VBCM incorporates a risk-based approach to compliance that balances risk with business value.
- There are many benefits to VBCM. Some provide short-term payback such as eliminating non-value-add activities. Others offer more long-term results such as reducing the cost of compliance.

# The Benefits of Value-Based Compliance Management

Although computer systems compliance (computer systems validation) is recognized as a regulatory requirement, it is generally perceived as an overhead with no added value in terms of system quality. This isn't surprising, since compliance costs can increase the price tag for implementing a new system by 40 percent and extend the implementation timeline by 30 percent. Even after a system is validated, business users can still experience operational and performance problems when the system is finally released. So, where is the value in computer systems validation?

This paper discusses ways to meet regulatory requirements for computer systems validation (CSV) in ways that reduce overall cost and implementation times while improving overall system quality. This results in an increased ROI.

## Approach

Most companies have been performing CSV for over ten years. The approach is generally very conservative, involving large numbers of documents that require many weeks to review and approve. Whether the system is large or small, whether it has the potential to impact product quality or not, the same process is followed and the same documents are produced. If questioned, very few people outside the CSV compliance and quality assurance (QA) areas understand the process. Users tend to replicate documents from previous projects because they were "already approved by QA" rather than tailoring them to fit the current situation. This invariably results in unnecessary overhead and replication of activities.

At the same time, the industry is being forced to cut costs and improve efficiency in order to stay competitive. Even the regulatory authorities are under pressure to speed up drug approvals and work with industry to remove roadblocks. In the area of computer systems compliance, the Federal Drug Administration (FDA) is encouraging companies to take a risk-based approach focusing effort in areas which could impact product quality and patient health and safety.

So how do we continue to implement and maintain compliant computer systems yet reduce costs, shorten implementation time, and improve system quality?

## Available options

Using lower-paid personnel may appear to lower CSV costs in the short term, but may have long-term consequences. Although some tasks (e.g., writing an SOP [Standard Operating Procedure]) appear to be very straightforward, inexperienced personnel may develop inefficient procedures. Today's inefficient CSV approach could have cost repercussions over the long term until procedures are rewritten.

Another option is to implement a risk-based approach to CSV. However, focusing only on risk often leads to over-engineered solutions or very conservative decision-making.

The Value-Based Compliance Management (VBCM) methodology created by EMC incorporates a risk-based approach to compliance that balances risk with business value. In some cases, it is necessary to balance the risk of maintaining a manual solution against the risk of implementing an automated solution. Only qualified personnel who understand pharmacology business processes, regulatory compliance issues, and technology can identify areas of risk and develop appropriate and effective mitigation solutions.

The Value-Based Compliance Management methodology reduces compliance overhead. When applied to computer systems validation, it focuses on the following key strategies:

- Ensuring that business processes are clearly defined at the beginning of the project and incorporated throughout the implementation and validation of the system
- Closely integrating development and validation activities to maximize the reuse of information and eliminate any non-value-add activities
- Planning for long-term support and maintenance during the initial implementation of the system so the amount of re-validation required for upgrades and enhancements is minimized
- Applying a risk-based approach to compliance that focuses attention on the areas of highest risk and continues to identify and manage any new risks during system implementation and ongoing use and maintenance

## The benefits of VBCM

There are many benefits associated with Value-Based Compliance Management. Some provide short-term payback such as eliminating non-value-add activities. Others offer more long-term results such as reducing the cost of compliance. The benefits of applying VBCM to computer systems validation include:

- **Reduced overall cost of computer systems validation.** Focusing on the areas of highest risk and eliminating “non-value-add” activities reduces the overall cost of validation.
- **Faster system implementations and upgrades.** Optimizing development and validation activities eliminates redundancy.
- **Reduced time and cost of re-validation.** Designing user acceptance scripts that can be re-used for revalidation and regression testing eliminates waste.
- **Improved overall system quality.** An optimized CSV approach can identify issues prior to system release.

In the pharmaceutical industry, for example, over 90 percent of systems need to be compliant with regulatory requirements, including computer systems validation. Value-Based Compliance Management meets these requirements without the usual overheads associated with computer systems validation today.



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