

Risk-based Computer System Validation



White Paper

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Introduction

Without careful interpretation of the FDA's 21 CFR Part 11 and other regulations in the context of a company's specific products and systems, compliance and validation efforts are likely to be over-engineered. This could result in an adverse impact on productivity and timelines. In an attempt to reduce this impact and to promote technological progress in regulated environments, the FDA has been recommending a risk assessment based approach to validation. By adopting a well documented, risk based approach to compliance and validation, companies can correctly allocate compliance efforts in areas that are most likely to improve patient safety and satisfaction.

While the risk based approach is applicable to all areas of compliance (systems, processes and people), this paper focuses on computer system validation. Specifically, we will examine the benefits as well as the pitfalls of adopting the risk-based approach to computer system validation and compliance.

Conducting the Analysis

Key points to be considered for the actual process of conducting an effective and efficient risk based analysis and validation are:

- The level at which the analysis will be conducted: System, Module or at the Requirements level. The lower the level, the greater the effort, complexity and benefit. For complex applications such as an ERP this point needs careful consideration. For example at the implementation stage an analysis at the module level may be appropriate while an analysis at the requirements level could be more useful for post go-live changes
- The composition of the team conducting the analysis. Include a cross-functional team with technical, business and regulatory leads
- The components of the risk: Business, technical, regulatory
- The risk ranking/scoring criteria. This should be based on inputs that include the impact of failure, complexity of the solution and likelihood of early detection of the failure
- Risk mitigation actions. These should be documented and followed through in the Validation planning and summarization
- Leveraging the risk score to determine the extent and type of testing: Positive, negative, boundary, stress
- Usage of tools for impact analysis and templates for documenting the analysis to help keep teams focused as well as to provide consistency of approach across the organization

√ **Given the FDA and industry support to a risk based approach to computer system validation, it makes sense for companies to define and adopt a formal risk assessment and mitigation methodology for the validation of computer systems.**

Benefits of Risk-based Approach

A risk-assessment based approach to Computer System Validation brings the following key benefits:

➤ **Bigger bang for the buck**

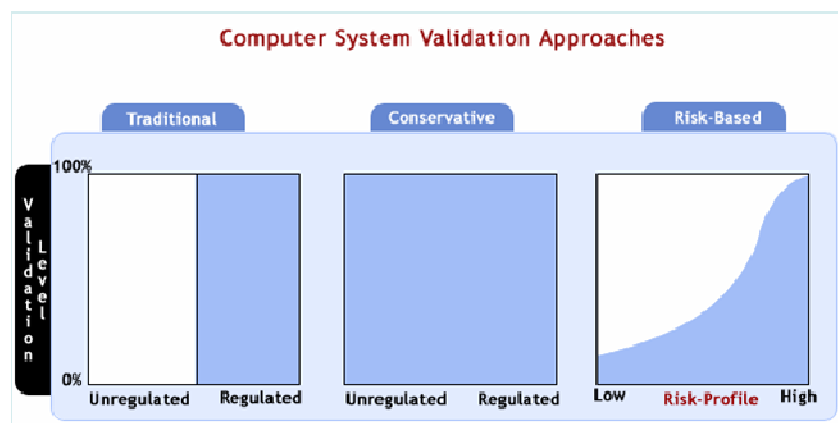
One of the key components of the validation effort is formal test planning, scripting and execution. Given that this forms the key resource and time sink of validation expenses, any improvement in this area has a great impact on the total cost of validation. The risk-based approach allows companies to focus the testing on the critical areas of the system and reduce testing efforts on scenarios that are less likely to occur or whose impact on overall quality is minimal. While the total validation effort and cost may not be significantly reduced and could even be higher in some cases, the money spent is being spent on areas that will improve the quality of the system and potentially reduce downstream cost of re-work and/or regulatory action.

➤ **Better Resource Allocation**

The risk assessment process would ideally bring together a cross-functional team that would simultaneously identify regulatory risks that are relevant to different agencies. The team would identify risks from an FDA, SOX, DEA, HIPAA, EPA, EU and other agency perspectives depending on the scope of the system(s) and the final product. This would result in a unified approach to validation, quality assurance and risk mitigation. Given the commonalities in requirements among many of the regulations, duplicated and inconsistent approaches, effort and documentation would be avoided. The risk assessment process also provides a rationale for prioritization of activities performed by development and testing resources.

➤ **Improved Validation Profile**

Traditional approaches to CSV result in silos of systems that are either fully validated or not validated at all based on whether a given system performs regulated or non-regulated activities. The other extreme condition in the traditional approach is where companies end up validating all systems regardless of whether they perform regulated activities. One of the major benefits of adopting a risk based is a system validation profile in which critical (to patient safety and product quality) aspects of all applications are validated at levels that are commensurate with their criticality. The approach is applicable to systems as well as complex applications such as an ERP. Based on a risk analysis at the module level or at the User Requirements level, the extent of validation can be tailored to the risk profile, resulting in an optimal Quality/Effort ratio.



➤ **Business Continuity**

Existing Business Continuity Plans are rarely examined in light of new IT initiatives. The risk assessment process affords an opportunity to review the business impact of proposed new applications and changes to applications. An early identification of business risk and mitigation approaches would contribute towards minimizing the impact of system or component failure.

➤ **Validation Efficiencies**

The computer system validation process involves many steps, phases and documents. The risk analysis can contribute towards answering some of the questions that can help bring efficiencies to the validation effort: Can some of the steps be reduced in terms of the level of effort? What are the documents that need to be highly detailed? Which ones can be combined or eliminated? What testing activities can be combined (for example User Acceptance Testing and Performance Qualification). Can automated test scripts be leveraged as validation artifacts? Answers to these questions would emerge from a properly conducted risk analysis and thereby help in “right-sizing” the validation effort.

The risk mitigation strategy that would be an important part of the risk analysis, may include procedural or other non-system dependent methods. This could help in further reducing testing efforts in those areas and may even preclude expensive features being required in the system in the first place.

➤ **Build Knowledge Base**

A well documented risk analysis conducted by a cross-functional team is a valuable source of knowledge about the system and its potential weaknesses. The analysis may also provide feedback into the requirements on which the risk analysis is based by identifying changes to the requirements or new requirements based on the selected mitigation.

√ **A risk-based approach applied at appropriate phases in the system lifecycle from selection through retirement, will help in reducing costs, improving system quality and reliability and in meeting cross-agency regulatory compliance requirements.**

The Pitfalls of Risk-based Approach

This section examines some of the major pitfalls to be avoided in implementing a risk-based approach to Computer System Validation.

➤ **Level of Detail**

It is important to conduct the risk analysis at the correct level of detail. While an analysis conducted at too high a level will yield some benefits, important savings in the validation effort would remain unrealized. On the other hand, if the analysis is conducted at an excessively detailed level, the analysis itself could become an expensive and time-consuming exercise, especially when the team spans functional areas (legal, marketing, finance, business, IT and others).

➤ **Team Selection**

Inclusion of the important stakeholders for a given system is important to the success of the risk analysis effort. At the same time, an excessively large team will result in inefficiencies and over-engineering of the analysis and reduce the benefits of the effort.

➤ **Methodology**

A range of risk assessment methodologies and models exist ranging in their level of sophistication from highly complex to simplistic. Apart from the advantages and disadvantages of each, the company's risk tolerance level would be an additional input. In addition the approach for risk analysis may also depend on the stage of the system's life cycle. The approach adopted at the time of implementation may need to be modified for the validation of post go-live changes. Selecting an appropriate methodology and shepherding the analysis from the validation planning stage through summarization are skills best left to internal or external resources that are experienced in this area.

➤ **Documentation of Risk Analysis**

In its guidance document Pharmaceutical cGMPs for the 21st Century: A Risk-based Approach, the FDA stresses the need for documentation of the Risk Analysis effort. Due to the fact that the entire approach to validation and system quality assurance is based on the analysis, the Risk Assessment needs to be documented at an appropriate level of detail with participation, review and approval by the system stakeholders. An approach to validation that is based on an undocumented analysis would be hard to defend in an audit. Additionally, an opportunity to help build a transferable knowledge base about the system would be lost if documentation is inadequate.

√ **An awareness of the potential pitfalls of the risk-based approach can help companies in realizing the full potential of the benefits of the risk-based approach and in reducing audit risks.**



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