Validation Views

Perspectives on Good Validation Practices

Len Grunbaum

Len Grunbaum is the Vice President of Validation Consulting Services at META Solutions, Inc. He has over 25 years of experience in software development, computer auditing, security, and systems validation.

Welcome to *Validation Views: Perspectives on Good Validation Practices.* The purpose of this section of **The Compliance Advisor** is to promote ***"good validation practices"***; that is, practices that are technically sound, practical, cost-beneficial and compliant with industry standards.

We will analyze validation issues through the prism of the knowledge, insights and experiences of individuals who are involved with, responsible for and/or affected by computer systems validation.

MISSION: IMPOSSIBLE ? *

Developing a Practical Validation Strategy

Len Grunbaum

All right! OK! Let's not panic! The mission, should I decide to accept it, is to develop a *practical validation strategy.* But isn't this an oxymoron? I mean, a practical validation strategy? Isn't validation *impractical* by definition? If not, how come so many people think it is? And who actually has a strategy for this stuff? But enough with the questions. The mission can be accomplished. It can be done!

Let's start with the basics. With a wink and a nod to Webster, I'll define a validation strategy as *"planning and directing the effort to ensure that all computer systems are validated in an appropriate manner."* Now, what is a practical validation strategy?

Once again winking and nodding to Webster, I'll define this as *"one that can be used in practice and which deals efficiently with everyday activities."* So, the objective of the mission becomes identifying specific validation requirements in the context of relevant business practices and developing recommendations that are in harmony with these practices.

Now, I must answer the following questions to achieve this objective:

1. What are the relevant business practices (i.e., the practices that require validation)? These will be the automated processes supporting the business functions that are directly affected by regulations pertaining to good manufacturing, laboratory or clinical prac-

tices ("GxPs"). This category will include specific departments (e.g., Clinical Data Management, QAU, Biostatistics), specific application systems (e.g., Adverse Events Reporting, electronic document management) as well as the information services organization(s) responsible for developing, maintaining or supporting the GxP-impacted computer systems. I need to identify all of these processes to ensure:

- The completeness of the validation activity (i.e., all validation that needs to be done is done).
- That no unnecessary validation is undertaken (e.g., validating the corporate general ledger or payroll system).

Of course, a prerequisite for accomplishing this effectively and efficiently is having a good understanding of the organization and the applicable business functions.

2. What is the nature of the regulatory impact on the respective process? Each affected process should be evaluated in terms of the following issues:
   - Status of SOPs (e.g., Do they exist? Are they current?)
   - Status of each computer system (e.g., Has it been validated? Does appropriate documentation exist? Was the development methodology appropriate?)
   - Status of staff training (e.g., Has appropriate training in the respective function been performed? Is training documented? Has validation training been performed? Is such training documented?)
   - Future plans (e.g., Will a new business process be implemented? Will a new computer system be implemented? Will an existing system be extensively modified?)
   - Timing of planned activities.

"For each impacted process, compliance risks and/or business risks may exist . . . Using appropriate business judgment, Management must weigh the existing risks and determine priorities."

3. What are the risks? For each impacted process, ***compliance risks*** and/or ***business risks*** may exist:
   - Compliance risks are issues that could lead to a finding of non-compliance with applicable regulations.
   - Business risks are issues relating to potential inefficiencies, unnecessary use of resources, etc., that could result from existing conditions.

   These risks can result from conditions such as the use of non-existent or obsolete SOPs, submissions supported by invalidated systems, insufficient resources to perform required activities, lack of proper training, etc. Ultimately, the validation requirements will be defined in terms of these risks.

4. What is the impact of each risk? Each risk must be evaluated in terms of the potential for increased costs, decreased profits, legal liabilities, negative public image, etc. The result of this evaluation will be the basis for determining validation priorities.

5. What are the priorities; what must be done? What should be done first? What would be nice to do but is not totally necessary? Using appropriate business judgment, Management must weigh the existing risks and determine priorities. As an example, a model such as the following might be appropriate:

   <u>High Risk/High Priority</u>

   - System currently in use - data from system has been submitted to regulatory agency.
   - System retired - data from system has been submitted to regulatory agency.

Medium Risk/Medium Priority

- System currently in use - no data submitted yet.
- System retired - data will be submitted.

Low Risk/Low Priority

- Systems to be implemented in the future.

Recommendations to address specific risks will be developed and assigned an implementation status based on relative priority.

6. How can the recommendations (e.g., training, SOP development, retrospective evaluations, prospective validation activities) be developed in harmony with existing business practices?

The specific recommendations and implementation plan should be developed in conjunction with the individuals responsible for the respective business unit, system, process, etc.

These individuals, if they understand the existing risks and the need for the recommended actions, will have a vested interest in ensuring that the recommended actions are practical. This is because they will be responsible for the implementation.

Therefore, the implementation plan for a given recommendation should take the following issues into account:

- Roles and responsibilities (i.e., who will be accountable for, and/or perform, the respective activity).
- Internal resource availability or ability to perform the required activity(ies).
- Availability of external resources should internal resources not be sufficient.
- Additional priorities/activities of the affected group.

If I perform these activities properly, I will have a practical validation strategy. I will know what has to be validated, what additional validation-related activities will have to be undertaken, the relative priorities of these activities, how the validation activities will be performed and who will perform them.

Additionally, the participation of impacted individuals in developing the implementation plan will help ensure that the specific validation activities deal efficiently with everyday activities.

Alrighty then, I'll accept the mission.