



Where's the Value... In Computer Validation?

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Some of you may remember from the mid-1980s senior citizen actress Clara Peller, who played a crusty old lady who slapped the counters of neighborhood hamburger joints and loudly asked the probing question, “Where’s the beef?!” A compelling question is now being asked every day in a similar manner about computer validation: “Where’s the value?!”

Since computer validation began to emerge as an important issue in the late 1980s, and with the enactment in 1997 of 21 CFR Part 11 (the FDA’s regulation for electronic records and electronic signatures), computer validation has been a commonly misunderstood activity. In many cases, computer validation has been a seemingly mindless paper chase that drains value from a project and consequently is the source of blame for schedule delays and project cost overruns. There are many reasons for this problem, including that project teams fail to follow a process until late in the project; project teams must follow an overly restrictive process that may be applicable for high-risk systems but not for lower-risk systems; validation team members write documents with the notion that the only audience is the FDA; and quality assurance representatives offer “moving targets” of what they will approve, which increases the number of cycles and time needed for document review. However, the largest problem is that the project team fails to properly ask and understand at the beginning of the project, “Where’s the value?”

Specifically, what must be understood is the value component of the new technology to the business (e.g., validation should do more with less, reduce process variability and errors, reduce cycle time and labor costs, and improve opportunities to serve new markets) and the value of applying good systems practices (GSPs) to the acquisition, development, implementation, and production control of a system. These GSPs must be applied with a focus on managing safety risk (e.g., what can go wrong to harm the health of a patient, health care worker, or operator) and managing project risk (e.g., what can go wrong to negatively impact the ability to achieve the cost, schedule, and quality goals of the project).

Along with managing risks, these GSPs must focus on communicating the status of a project. We need to be able to frequently answer questions as to how close we are to delivering the value that the project team originally promised. For accurate answers to this question, we need the right ingredients of a clear mission and value proposition, a functioning team, and a process appropriate for the risk and reward of the project. As many of you have probably experienced, attaining a fully functional team performing at

its peak (as opposed to a dysfunctional team) is very difficult. The following is an approach to accelerate the team-building process.

In many of our projects and in our training programs, we conduct a preliminary risk-management exercise. We will select a system and discuss many of the risks related to regulatory interest, safety, financial aspects, and the specific project (e.g., cost, schedule, and quality). When we get to the project risks, we give each participant a five-page paper that lists virtually all the generic risks that could impact a project schedule. We ask each participant to scan the list and pick out risks that may apply to their project and write them on 3" x 5" cards. In a training session, we limit each person to four risks, but on a real project, each participant can have as many as they want and they usually conceive unique risks that are not on the original sheet. We then have each participant present their risks, and they offer an initial estimate on the probability of occurrence (low, medium, or high) and the impact to the organization (low, medium, or high, usually defined in relative financial terms). As each person presents their risks, the other participants get a chance to ask questions and provide input into further refining the risk and whether the probability of occurrence and/or impact estimates should be revised. As each person takes their turn, we begin to cluster similar risks on a board on the wall. After the final risk is presented, we take the clusters and come up with one (or possibly two) risk statements that adequately represent the cluster. We then take all of the risks and begin to place them on a three-by-three grid in which probability (low, medium, and high) represents the x-axis and impact (low, medium, and high) represents the y-axis. We arbitrarily stipulate that risks placed in the three squares in the upper right corner are considered major risks. Risks placed in the three squares in the lower left corner are considered minor risks. Risks placed in the three squares of the remaining diagonal are considered moderate risks.

We then talk about the possible risk-mitigation strategies. These include active acceptance (taking steps and spending resources now to reduce the probability, reduce the impact, or both), passive acceptance (devising a contingency plan in case the risk actually occurs), reactive acceptance (spending no resources now, not even on a plan, but reacting if the risk occurs), transference (shifting the risk to someone else, e.g., buying insurance), and avoidance (taking steps now to avoid the conditions necessary for the risk to occur). With a real project, we usually recommend that the project manager delegates the risk statements to the team members, who are then responsible for researching and reporting back on potential risk-mitigation strategies along with cost estimates. This approach is the best way to get an initial risk-management plan assembled quickly.

However, we have noticed an unintended consequence of performing this risk-analysis exercise. It turns out that team unity is built faster and the team members seem to have a clearer idea of the mission and goals of the project. Why is this so?

First, the stages of development for a project team merit mentioning: "Forming, Storming, Norming, and Performing." Forming refers to selecting team members. Storming refers to conflict between team members because of different agendas and lack of understanding of the mission. Norming refers to the alignment of team members' agendas and commitment to the mission. Performing refers to team members working together as a well oiled "Social Engine" (a term coined by management guru Ram Charan) to achieve the goals of the project. We have all probably experienced projects that fail to deliver on time because the team cannot get out of the storming stage quickly

enough to norm and then really perform. Typically, what happens is that a few “heroes” work night and day at the 11th hour just so something can be delivered.

Why does the risk-analysis exercise help a team rapidly get to the performing stage? I speculate that it is because all the team members get the opportunity to air their concerns in a safe environment and also get to hear the concerns of others. They have an opportunity for debate when talking about each risk relative to others. This activity is a forum that helps team members rapidly build trust and proceed through the storming phase, ultimately aligning attitudes toward the mission, value, and potential pitfalls of the project. Experts agree that the sooner the team achieves the performing stage, the higher the probability that the team will achieve their schedule, cost, and quality goals.

This is just one example in which a computer validation–related activity contributes to information flow and team building. All of us involved in computer validation should be carefully looking at each project activity and resulting document and ask, “Where is the value?” If we can’t find it, it is time to ask, “Why we are doing this?” The answers to these questions will significantly contribute to enabling the teams we support to deliver the value they promised to the business.

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