IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY | an informa business
Unlimited Validation Knowledge Awaits...
Published on *IVT Network* (http://www.ivtnetwork.com)

Validation Week EU Think Tank: Strategies for the Advanced Validation Professional

May 7, 2015 6:00 am EDT

In order to meet a need for a forum-based discussion of pressing issues facing professionals, IVT Network convenes senior-level think tanks during industry meetings. These sessions are a major feature at IVT conferences, and they are frequently requested and well attended by conference attenders. Participants in the think tank generally have a sound technical background along with several years of experience in the designated topic. After receiving a series of questions in advance of the meeting, participants submit responses for use during the think tank session. A leader in the particular field of the think tank leads the session, making sure that most of the topics and questions are discussed.

Strategies for the Advanced Validation Professional Think Tank – March 2015, Amsterdam

On March 18 at the 6th Annual EU Validation Week, IVT Network hosted a senior-level think tank entitled, “Strategies for the Advanced Validation Professional.” This session was hosted by Ivan Soto, contributing editor for IVT and associate director of QA Validation at Alexion. Participants were asked to submit answers to the following questions in preparation for the session:

- What is your name, job title, and company?
- In what industry are you?
- How many years of experience do you have in validation and/or quality compliance?
- What do you consider the most challenging task currently on your “to do” list?
- What area of validation is your greatest concern?
- What would you like to take away from this advanced workshop?
- What auditing and inspection trends (related to validation) have you seen at your site and/or company?

With decades of industry experience at their disposal, this panel of professionals provided an ideal ground for dynamic knowledge sharing and benchmarking among top-level professionals. Including fields ranging from beer brewing to pharmaceuticals and experience levels from only a few months in a current position to scores of years, this think tank offered a lively exchange.

More action, less reaction

The think tank began with a participant stating she has worked in validation in many different fields, but in her current field of pharmaceuticals, she believes that the industry has yet to “mature” enough to fully take advantage of risk-based approach to validation. She went on to say that she knows that industries can use validation methodology, not to avert problems, but to drive action and results so that outcomes can be significantly improved. The “immaturity” of not wielding the tools of validation properly is holding the pharmaceutical industry back.

Mr. Soto then interjected that these results can only be driven by more closely following processes, being vigilant of their being carried out, and in the end, simply being less reactionary. By not reacting to each situation as critical, he went on to explain, it

allows for validation professionals to make important distinctions between what is actually critical, what is “not critical,” and what is simply “nice to have.” It is here, Mr. Soto said, that this careful husbanding of validation resources leads to increased productivity and increased profits.

Systems Risk

Mr. Soto went on to suggest that validation professionals should perform a systems risk assessment in order to determine whether the system is high, medium, or low risk. This tool should be succinct and should assess the risk impact to the following:

- Product Quality
- Patient Safety
- Compliance
- Safety
- Business processes
- Complexity

Oftentimes regulators will focus on the last three to provide input to the validation.

When systems risk has been determined, procedures should clearly describe validation deliverables for each level: high, medium, and low system risk. High-risk systems should, of course, have rigorous testing as well as explicit validation deliverables. Medium and low risk require less testing of non-critical aspects, therefore allowing focus to be put on higher-risk projects.

Since 100% testing is not feasible with some *very* complex systems, a risk-based approach to validation allows precious resources, e.g. time, money, materials, equipment, etc., to be directed where they are most needed and not wasted on simpler, low-risk projects.

Objections to a Risk-Based Approach

The session continued with a new participant with many years in medical devices. He said his company has an “old fashioned” approach to validation coupled with a *quite* conservative QA department who is, in large part, mostly averse to moving towards risk-based validation. They are concerned, he said, that the steps required for a risk-based approach would only add more work to their already burdened loads. This line of discussion touched off what proved to be popular topic among the participants: the intransigence of QA in the face of attempting to move towards more efficient systems.

It was apparent from the rest of the participants’ reactions that the speaker was not alone in his feelings.

Mr. Soto asked the panelist *why*, exactly, his company wanted to move towards risk-based validation in the first place. The panelist quickly responded, “because our time to market is suffering because of poor validation.” He went on to explain, “drive for change largely comes from management, and management, when it comes down to it, isn’t *really* behind change.” His organization, at its higher levels, does not want to put in the effort to have true risk-based approach. Instead, he accuses middle management of simply wanting a “checkmark” to show upper management and leave it at that.

A participant who was himself in quality assurance claimed that QA is often afraid; they make risk-based validation overly complex in their minds. In response to this, they often create and demand longer process documents because longer documents better represent to QA the imagined difficulty of the project. In actuality, this only creates double work since fewer people read and follow the longer process documents, and the length of the documents only exposes them to errors in compliance. A succinct, tight process document is much better.

Mr. Soto, who is also in quality, continued the thread by adding that often QA departments feel insecurities about their jobs. They feel the need to have a say at every step of the process or else they are no longer necessary. To allay QA’s fears yet streamline processes further, Mr. Soto suggested attempting to reduce the number of approvers for new processes from a typical seven-person team down to a three-person team. This would save money and a great deal of time. Often only a few of QA approvers have any facility in the subject matter because these are highly technical documents. Why not limit the

approvers to those who are knowledgeable in the subject.

To give an example towards Mr. Soto's point, another speaker brought to the group's attention that he often has little trouble getting QA to approve new documents, as long as they are familiar with the subject matter. Otherwise, he finds their approval a complete waste of time that is only accomplished for form's sake.

A participant went on to say that the key to getting whole organizations on board, from upper management to QA to colleagues, was to show that *results* are improved—that it is not extra work and, in fact, improves the bottom line. Mr. Soto contributed to the thought with his dictum, "you must husband your resources better than this this. It can be expensive [initially], but risk assessment will improve outcomes, execution, and most importantly, the bottom line." To close out the topic, he gave as an example that most people believe a vendor audit to be necessary in all cases. No, he said. A vendor audit should only be executed based on a risk assessment.

Ripe Ground for Implementation

As we progressed to a new speaker, she brought up that she often found QA to have the notion, "if it's hard, it's worthwhile," which she found to be ridiculous. For instance, her company got a machine to clean technicians' and researchers' shoes before they enter the laboratory. Before the machine was installed, she had to create a validation for the usage of the shoe cleaner, but no one was really sure *if* the cleaner even improved lab conditions at all. If risk-based validation were implemented better, she posited, she could find out if the shoe cleaner was effective, determine risk, and then move on to create validation from there. The way she was forced to validate this shoe cleaner, no shoes at all were cleaned for a good deal of time and much more work was created that might not have been necessary at all.

In closing, most participants agreed that proceeding with validation based on the risk of the particular system was highly desirable. Many, however, were tentative to introduce these changes as expansively as they would like because of poor reactions from QA. They believed QA could see apportioning resources based on risk not as a money-saving efficiency and improvement of outcomes but as a laxity. Their challenges going forward were not so much implementation, as they saw it, but of changing institutional culture.

Check outpictures from Validation Week EU.

Join us for our21st Validation Week this October!

Source URL: http://www.ivtnetwork.com/article/validation-week-eu-think-tank-strategies-advanced-validation-professional