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CQV #6 - Validation Approval Committee Problems

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Compliance in Quality and Validation — CQV — presents real-life stories reflecting compliance problems in the pharmaceutical, medical device, and related industries. Previous discussions have included:

- CQV #1: Overview and Invitation to Participate, published in Journal of GXP Compliance (JGXP), Volume 22, #5, and Journal of Validation Technology (JVT), Volume 24, #5
- CQV #2: Like-for-Like Problems JVT, V24, #3
- CQV #3: More Like-for-Like Problems. JVT, V24, #5
- CQV #4: Animal Tales, JGXP, V22, #6
- CQV #5: Problems in Aseptic Technique Qualification. JGXP, V23, #1. JVT V25, #4.

Readers are invited to contribute content, suggestions, comments, and ideas to improve this feature. All published content will be anonymous — there will be no connection to companies or organizations. CQV will be most useful when the quality and validation communities submit experiences that will help colleagues improve actual work situations. Please contact coordinators Paul Pluta at paul.pluta@comcast.net or Stacey Bruzzese atstacey.bruzzese@informa.com with content, suggestions, or topics for discussion.

INTRODUCTION

This discussion addresses Validation Approval Committee (VAC) problems in a pharmaceutical manufacturing plant. Content discussed has been provided by multiple validation and quality managers from multiple companies. This discussion is focused primarily on the VAC; future discussions will address issues with validation documents and the site validation quality system.

The site VAC has a company-vital responsibility – review and approval of site validation documents – that is critical to the success of the site validation program. Members of the VAC must be an experienced and competent group. Their responsibilities must be clearly defined and accepted by all members. Depending on the site organizational structure, the VAC may be a sizeable group. The more people involved, the more difficult to ensure a unified and appropriate focus in all members. With potentially many individuals, many technical functions, and multiple complex projects, the VAC requires special attention from QA and validation management. If the VAC function is overlooked, problems will occur.

VAC Members, Competencies, and Responsibilities

The site Validation Approval Committee (VAC) traditionally is a multidisciplinary committee with responsibility for approving all validation documents processed through the site. Members of the VAC should include all major functional organizations at the site such as Manufacturing, Packaging, Engineering, Analytical, and other groups. Further, there may be specific ad hoc

representatives from associated organizations such as Regulatory, R&D, Microbiology, and other groups who are consulted on specific projects.

The VAC has critical responsibilities in the manufacturing site. These include three primary responsibilities regarding validation document approval: Technical / scientific excellence supporting validation projects, compliance with associated regulations and policies, and document general quality. VAC members should also serve as internal company consultants on validation projects. Finally – a critical responsibility -- the VAC must function as an internal regulatory agency auditor.

- Technical / Scientific Justification. The VAC must insure that the validation / qualification and all associated activities are conducted with consideration for scientific and technical principles, be data-based, a generally consistent approach based on risk to patient, product, and process, and provide reference documentation as needed to support technical excellence.
- Compliance With Regulations. The VAC must ensure that the validation / qualification is compliant with relevant company policies, government regulatory standards, local regulations, and industry expectations.
- Document Quality. The VAC must ensure that validation documentation must demonstrate the technical and compliance aspects of the validation in a logical and grammatically correct manner
- Site Internal Consultant. The VAC should also serve as an internal consultant to company personnel working on validation projects and should help site staff to prepare acceptable documents. The VAC will be the ultimate approvers of these documents.
- Site Internal Regulatory Auditor. The VAC must also function as an internal regulatory agency auditor. They must critically evaluate and challenge validation documents in the manner of a regulatory auditor and not automatically approve documents through the system. This is a key responsibility for the site. If a regulatory auditor finds deficiencies in a validation document, VAC members have not done their job.

Members of the VAC must have the wisdom, knowledge, experience, foresight, maturity, interpersonal effectiveness, and training to fulfill responsibilities of the VAC position. VAC members should be respected as experts within the company. VAC membership is not appropriate for new or inexperienced personnel

VAC Problem Topics Discussion

The following are specific problem topics expressed by multiple validation and quality managers from multiple companies. These are problems specific to the VAC. Related problems such as problems with validation documents will be discussed in a future issue of CQV. Specific VAC categories discussed include the following:

- VAC responsibilities
- Competing business priorities
- VAC member focus
- Approval process logistics.

VAC RESPONSIBILITIES

VAC members must embrace their validation responsibilities as outlined above. Their most important responsibility: Evaluate validation documents in the manner of a regulatory auditor.

“Get Docs Through the System”

One manager described an engineering VAC member who was appropriately critical on documents submitted by non-engineering functions but was a “rubber stamp” on engineering documents. Engineering documents that were poorly written, not sufficiently supported by data, or with other deficiencies were argued to be acceptable -- “documents were good enough” -- by the VAC engineering member. When confronted about his attitude, the engineering member stated this his boss told him that his job was to “get docs through the system.”

Data Integrity

Another example was previously described in CQV #2 as a “like-for-like” compliance problem. An engineering technician was assigned to complete five IQ and PQ protocols on five new identical machines. The first machine was successfully completed based on a thorough ad carefully prepared report. Machines #2 and #3 were submitted a few weeks later. When requested to present the data for machines #2 and #3, the technician submitted pages of machine #1 data. His response: “The machines

are all the same; there is no need to repeat same testing on all machines." When confronted about not testing all machines, the technician responded that he was doing as instructed by his engineering VAC representative – that no one will notice the duplication of data. The technician was also asked to present original data (not typewritten data in report). The technician responded that he discarded the original data since data were now in the report. The report was the only record of data – there were no original data.

Validation managers reported numerous instances of original data problems including original data recording, data retrieval, and other documentation practices problems. These will be discussed in a future issue of CQV.

VAC Member Inexperience

Another validation manager noted that one new member of the VAC was obviously inexperienced about regular and relatively simple plant operations. The new person did not contribute to discussions evaluating submitted validation documents. When his boss was confronted about his assignment to the VAC, the boss stated that he always assigned new people to the VAC because it was an excellent training ground for the range of activities in the facility discussed by the VAC. While it is recognized that participating in the validation process is excellent for training new personnel, those assigned to the VAC should have proven their expertise by successfully participating in numerous validation projects.

Technical Writing Skills

VAC members complained that they receive documents that are technically correct and meet technical requirements but are not grammatically acceptable. Managers commented that some authors of documents do not have acceptable technical writing skills. Personnel with English as a second language may have difficulty with acceptable technical writing. Some VAC members may also not have acceptable writing skills or the ability to evaluate grammar. Some organizations use designated technical writers to help with technical writing. A policy describing minimal writing standards may be useful.

COMPETING BUSINESS PRIORITIES – APPROVAL TIME PRESSURE

The VAC responsibility requires adequate time to review, correct, and approve documentation without pressure to release product to meet business goals. VAC members complained that they are forced to approve documents under excessive time pressure. Multiple managers related stories whereby completed documents were submitted for approval on the same day as commercial product would be out-of-stock or on back-order. The VAC was required to approve documents to avoid these business issues. If they did not approve the validation documents, product will be on back-order or site management would not meet personal financial goals. Substandard documents were reluctantly approved to meet company business goals. Project prioritization is always a challenge; validation document review must be given adequate time.

VAC MEMBER FOCUS – COMPETING JOB PRIORITIES

VAC members may be too busy with other site responsibilities to adequately focus on validation document review and evaluation. Managers commented that VAC members requested repeated corrections on validation documents. For example, documents are submitted, and changes are requested by a VAC member; corrections are made, and documents are re-submitted; more changes are then requested by the same VAC member; corrections are made, and documents are re-submitted; more corrections are requested, and so on – frustrating for the document author and other VAC members. VAC members must have adequate time to thoroughly review documents and not be too busy with competing job responsibilities. A good practice would be for the VAC role to be assigned as a core job responsibility to those acting in that role to insure appropriate time is allocated to perform the job correctly.

APPROVAL PROCESS LOGISTICS

The validation document approval process – initiation, submission, evaluation, correction, and so on – may not be optimally designed or administered. Company policies and procedures should be thoughtfully crafted, and the process mapped to avoid wasting resources.

Too Many Approval Signatures

Several managers commented that their system required an excessive number of signatures resulting is time delays for complete approval. Worse yet, many of the signatures represented functions that did not have expertise to comment on the validation project. For example, most regulatory people are not qualified to comment on the technical details of equipment

qualification and are not relevant at this stage of equipment qualification. More signatures and more approvals do not equal better documents.

Pre-Work Before Validation Execution

Validation protocols may be approved with the “promise” to provide procedures, drawings, maintenance, calibration, or other information before initiating validation work. These commitments are then overlooked and otherwise not completed due to other priorities. These absence of these pre-work commitments renders subsequent validation invalid - systems and supporting documentation are inconsistent.

Validation Post-Work

Validation may require specific post-validation work to be completed to close the validation package. For example, procedure updates, new diagrams, new preventive maintenance, and similar activities may be required post-validation. These requirements may not prevent product release, equipment use, or other business needs – so they are judged to be of lesser priority and never done. One manager reported beginning a new validation manager job with ~300 open validation packages – validation completed but required supporting documentation or activities still outstanding.

PROBLEM SOLUTIONS

Although this discussion addresses problems of the VAC, often these problems were caused by personnel executing protocols or submitting validation documents. Problem solutions must then involve more than just the VAC. Validation and quality managers described the activities initiated in response to the above problems – training to all involved individuals (VAC, technicians, authors, project managers), more training, repeated training, and continued training – especially when new VAC members are appointed and when the site hires new people who participate in validation. Key considerations:

- VAC training. VAC responsibilities and expectations must be clearly stated and embraced by members of the VAC. The role of the VAC as internal regulatory auditor must be emphasized. This role is a key responsibility of the VAC – they must not think short term approval of a document, but rather log term review of documents by regulatory auditors. All associated personnel must understand the responsibilities of the VAC.
- Basic validation training for everyone related to validation – technicians, writers, project managers, and VAC. Everyone involved must have a basic understanding of validation.
- Validation document writer training. Expectations for must be clearly stated for authors of validation documents. Writers must know VAC expectations. Templates, outlies, and model documents are helpful to develop a standardized format and content for validation documents.
- Documentation practices / data integrity training. This is an absolute necessity. A validation function must require impeccable documentation practices by all involved.

The VAC should contribute significantly to the development of the above to ensure 100% consistency between VAC expectations and training of respective groups who submit documents to the VAC. The above should be repeated annually to review requirements, make changes, and generally reinforce site expectations for the VAC and validation program.

Time pressures and other validation management problems will be addressed in a future discussion. In brief, these are addressed through better planning of validation work, advance communication to management when deadlines may be missed, assignment of multiple people including proficient technical writers to assist in document preparation, and other measures. One manager described a literal 24-hour VAC validation document approval session to meet an FDA approval-date commitment – this should not happen. Validation managers and site management must anticipate these problems.

FINAL THOUGHTS – MANAGEMENT AND SITE CULTURE

While this discussion has focused primarily on the specific role and responsibility of the VAC and associated problems, its scope encompasses the entire technical organization. VAC goals must be clearly identified. Personnel writing validation documents must further support the objectives of the VAC in their documents. Technicians performing validation activities must have the same goals as the VAC. Documents submitted to the VAC should be ready for approval without changes or modifications. Authors properly writing validation documents and technicians properly executing protocols will result in validation packages acceptable to the VAC. All involved must feel they are partners in a joint effort – they are not competing groups. The VAC is not the enemy of individuals writing documents or doing the work.

Management Role

The VAC will not be successful without the visible and demonstrated support of site senior management and functional management. Training will only go so far. Examples discussed above showed site managers telling their people to ignore VAC standards to minimize work, reduce time spent, meet goals, and other supposed short-term benefits. Goals, deadlines, backorders, personal financial bonuses, and other factors may compete with VAC objectives. Management must resist these potential impediments to develop a site culture of quality and compliance. VAC members must not be conflicted in their understanding of objectives. Months of time and effort to develop a quality and compliant culture can be quickly destroyed by contradictory acts like the actual problem events described above. Management must be unwavering in quality and compliance standards for the organization. Developing a culture based on trust and credibility between management and employees, with clear standards, expectation levels, and consistent predictable performance, is important in solving VAC and other problems described above.

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