How to Resolve Controversial QA Findings

Scenario: A member of the organization's Quality Assurance unit performs an inspection and submits one or more findings to Management and the Study Director (Principal Investigator). If the findings are straight-forward and undeniable, corrective action is taken quickly and the findings are closed out. End of story.

Problem: If the Study Director/Principal Investigator does not accept the basis of the finding or has an different interpretation of what constitutes compliance, then they will be unwilling to perform corrective action and the finding is not closed out. This leaves an open (unresolved) finding.

Often, the QA personnel are left to negotiate these unresolved findings by themselves, as if they are the primary stake holder. This is a misunderstanding of the process as established by the Good Laboratory Practices regulations. It is helpful to review the process as dictated by 21 CFR part 58:

QA performs an inspection and reports any findings to Management and the Study Director (Principal Investigator)

21 CFR 58.35 (b) (3) *The quality assurance unit shall inspect each nonclinical laboratory study at intervals adequate to assure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for reinspection. Any problems found during the course of an inspection which are likely to affect study integrity shall be brought to the attention of the study director and management immediately.*

At this point, it becomes the responsibility of the Study Director to take corrective action….

58.33 (c) *The study director shall assure that unforeseen circumstances that may affect the quality and integrity of the nonclinical laboratory study are noted when they occur, and corrective action is taken and documented.*

…and it is the responsibility of Management to ensure that this occurs…

58.31 (g) *The testing facility management shall assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.*

Quality Assurance, as a prompt, will periodically remind management of any unresolved findings,

58.35 (b) (4*) The quality assurance unit shall periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.*

So, it is easy to see that the responsibility for ensuring that corrective action is taken falls squarely upon the Study Director (Principal Investigator) and it is the responsibility of Management to ensure that this gets accomplished. This means that when a problem situation arises, such as a controversial finding, then it is Management's job, not QA's, to ensure it gets resolved.

Solution: There are several things that can be done to eliminate this problem.

- QA should ensure that they accurately document the finding, giving specific examples and referencing the appropriate regulation. No finding should be issued without first discussing it with the responsible individual; this will minimize misunderstandings.
- The Study Director (Principal Investigator) should clearly document why they disagree with the finding and provide supporting examples or references to ensure that QA and Management can understand their position.
- A responsible person should be designated who fills the role of "Management" with respect to the GLP requirements, and is responsible for the active follow up on unresolved findings.
- Management should establish a timeframe for following up on all unresolved findings and meet in person with the QA inspector and the Study Director to try to mediate the disagreement.
- QA should report unresolved findings at frequent intervals; preferably once per month. There are organizations that make this report only on an annual basis. This is a bad practice because it allows an unresolved finding can go a very long time before Management is even reminded that it exists. This prolonged reporting interval makes it difficult for Management to follow up on unresolved findings in a timely manner.
- Based upon discussions, Management must reach a decision in how to close out the finding: 1) QA finding stands and the Study Director must take corrective action; 2) the Study Director is correct in their interpretation and QA will have to mark the finding as closed out; or 3) some compromise position may be reached where corrective action is taken, but the original finding is modified.
- Most importantly, everyone involved should use this as an opportunity for improvement. Controversial findings represent the "grey area" of compliance and as such force organizations to review their procedures and systems.