Writing sample 5

Excerpt from QA/IT Computer Software Validation Assessment report

1.1.1   Systems noncompliance with 21 CFR Part 11

A serious compliance issue was noted concerning [name of application] and [name of application] with regard to 21 CFR Part 11 Electronic Records; Electronic Signatures. The system as configured violates 21 CFR Part 11.200(i) as follows:

- When using non biometric methods of authentication the regulation requires that two components to be entered, usually user ID and password, at the point of signing when noncontinuous signing sessions are used. Although an exception is permitted during a continuous signing session when on the first signing a signer must enter both components but can enter a single component thereafter, [name of application] and [name of application] populate the user id field and the signer enters only a password, i.e., one component.

  Upon investigation, it has been confirmed that the violation was caused by a configuration error or a coding error and can easily be corrected.

1.1.2   System usage anomalies

- During the change control process, if an additional optional approver is added later in the process, then that additional approver is not included in the approval schedule and is not be part of the approval process. This [name of application] bug is documented and resolution is planned for early January 2015.
- During the change control process, if an optional approver is changed later in the process, the change is not reflected in the approval schedule and the new optional approver is not included in the approval process. The original approver is retained in [name of application] despite the change. This [name of application] bug is documented and resolution is planned for early January 2015.

- A [name of application] user who is logged in has their name automatically populated into the originator field for the following PRs: unplanned deviations, CAPAs, compliance, and laboratory investigations. However, for change control and certain other occurrences, the originator name can be changed to that of another user. This anomaly prevents an originator from asking someone else to raise certain PRs on their behalf. In addition, when the name of the originator can be changed from the name of the person logged in to another name, the audit trail records the change but email notifications are sent to the person whose name was automatically populated into the originator field.

1.2   **Non-validated systems**

Microsoft Access, a Relational Database Management (RDBMS) application, is being used in manufacturing and has not been validated. The application is also not included in the [name of company] CVS Inventory.

Another instance: an Excel spreadsheet was going to be used to enter data from paper records that would be transferred from the spreadsheet to a replacement system as part of a migration. This use of Excel would have violated 21 CFR Part 11 because Excel was not validated. Note: The use of Excel was not implemented upon advice based on discussion of the issue during preparation of this report.