

## Substandard Data and Documentation Practices— Case Study #5



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Test data and results generated as specified in the validation protocol are critical because they provide the basis for the final validation report and the judgment that the item of interest is validated. Data recording and associated documentation for validation may not meet expected quality standards. Several actual examples involving problems with data and documentation associated with validation are described. These include data recording on scrap paper, erroneous transcribed data, improper error corrections, data inconsistent with protocols, and other examples. Major data and documentation...

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