Designing of Bulletproof Documentation; a Review System to avoid Common Audit Observations

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Abstract

- Compliance with GLP standards requires systematic planning and management of various aspects of laboratory operation, including resource planning, scheduling of studies, training management, documentation, quality control, quality assurance, and reporting of final reports. The most common audit observations frequently reported by internal Quality Assurance, GLP inspector's, sponsor's auditors, or regulators are results of poor system management and documentation practices. Incomplete information on the calibration or validation status of equipment, certified chemicals and standards as well as availability of trained and competent personnel results in imperfect planning of studies and subsequently noncompliance. Similarly incomplete or no documentation of pre-study qualification of test systems, test items, reference standards, facilities, equipments and training also play a major role in the noncompliance status of GLP studies.
- Multiple studies on the same test item or single study with several parameters, involve a number of personnel, equipment, chemicals, facilities, raw data, computerized system and quality/acceptance criteria demands an uniform and in-depth documentation from planning to scheduling, auditing and reporting of each study and its phase(s). This complexity demands the designing of an effective and practicable documentation system, either paper based or electronic based, or hybrid system for each relevant action, observation and decision associated with GLP studies.

- Document is information and its supporting medium, in form of paper, CD, Computer file, microfilm, x-Ray film etc.
- Documents provide information or evidence or may serve as an official record.
- Record is a document stating results achieved and provide evidence of activities performed.
- Guidelines is a set of procedure that provides recommended practices and instructions.
- Policy is a plan or adopted course or principle of action intended to influence and determine the decisions or actions of an organization.

Types of Documentation & Records in a GLP Laboratory

- Standard Operating Procedures
- Study Plan/Protocol and Amendment
- Inventory of Test Item/Reference Standards
- Study Raw Data
- Laboratory Environmental Records
- Corrective Action Preventive Action (CAPA)
- Lab staff training records
- Equipment qualification records

For a Robust GDP System in GLP Test Facility Management should ensure:

- Data management policies and procedures are in place
- Allocate adequate human and technical resources
- Make staff aware of the importance of their role in ensuring data integrity
- Establish and maintain a quality culture
- Transparent and open reporting of deviations, errors, omissions and aberrant result
- Prevent, detect and correct weaknesses in systems
- Rejected results recorded, documented with justification, reviewed and retained
- Control the issuance of uncontrolled templates
- Restrict user access rights to automated systems

Common Documentation Errors

- Missing signature and dates at the time of activity performed
- The write-over
- Non-uniformity in date and signature
- Writing a note for the activity was performed on one day and signed on other day
- Blank spaces
- Illegible writing
- Too many corrections / overwritting

Principles Of GDP

- Never destroy the original documents .
- Never falsify information
- Never use a White-out and cover-over-tapes
- Never obliterate information or record
- Never use pencil
- No spaces, lines or fields left blank

What constitutes Good Documentation ?

Attributable: Attributable to the person generating the data
Legible: Readable and permanent
Contemporaneous: Record the result, measurement or data when the work is performed
Original: Referred as source data recorded for the first time
Accurate: Data free from errors, complete, truthful and reflective of the observation
Complete: All data including any repeat or reanalysis performed
Consistent: All elements of the analysis such as the sequence of events follow on and are date or time stamped in the expected sequence
Enduring: Recorded in authorized and approved notebooks or electronic media in the data systems of instruments
Available: Can be accessed for review and audit or inspection over the lifetime of the record

Benefits of Good Documentation Practice

- Build confidence in the Laboratory Quality System
- Reduce efforts to compliance with regulatory bodies
- Allows the achievements of required results
- Correct, complete, current and consistent information
- Effectively meets customer's and stakeholder's requirements
- Enables the laboratory activities are arranged into functional patterns for specific action
- Create structures so that staff can systematically coordinate to conduct business
- Training of Laboratory staff
- Solve complicated problems
- Reduce or eliminate assumptions and second-guessing
- Eliminate the need of rectify the same questions
- Giving clear instructions for staff

Conclusion

Despite numerous regulatory guidelines poor documentation practice has become more and more a global problem and in most cases it leads to severe violations of data integrity principles. As such, Good Documentation Practices are key to ensuring data integrity, and a fundamental part of a well designed Quality Management System.