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QUESTION: What are the characteristics a standard operating procedure (SOP) system should meet for implementing a successful GLP compliance?

2) List 10 benefits the SOPs will provide to the laboratory if properly designed with the appropriate characteristics.

ANSWER

1.

– **Total integration** into the laboratory’s system of master documentation (i.e. not a separate system in potential conflict with memos or other official means of conveying directives to laboratory personnel).

– **Comprehensive coverage of**:

• all critical phases of study design, management, conduct and reporting;

• “scientific” administrative policy and procedures (e.g. formats, safety and hygiene, security, personnel management systems, etc.);

• standard scientific techniques.

– **Readability**. A standard format should be adopted (one standard format is presented

in the WHO/TDR document “Handbook for Quality in Basic Biomedical Research”). The procedures should be written in clear, uncomplicated sentences and with appropriate vocabulary so that all personnel can understand the instructions unambiguously. All personnel should be encouraged to constructively discuss procedures. Ideally, SOPs should be written by the people who perform the work, thus making them responsible for the work they do.

– **Usability and traceability.** For reasons of traceability and easy use, a two-tier system of SOPs is often the preferred approach. The first tier reflects general policies and procedures; the second covers operational instructions. It is advisable to use a method for binding and/or protecting procedures (SOP manuals) with an up-to-date table of contents, logical chapter divisions and selective distribution. In some laboratories SOPs are available directly from a computer screen, but in such cases special rules about printing SOPs (expiry dates, etc.) and rules about electronic signatures must be implemented.

– **Procedures should be fully understood and adhered to.** If deviations occur, easy communication routes with the study director and management is essential to ensure GLP requirements are met and to conserve the credibility of the system.

– **A responsible person should be identified for each SOP** to ensure that queries are dealt with and that each procedure is kept up to date. Periodic review of each SOP should be conducted.

– A **formal change control** system that ensures historical reconstruction. A working SOP system appears to be perpetually incomplete because of additions, deletions and modifications reflecting the normal rate of improvements or changes. Ease and rapidity of updating should be ensured.

– **Centralized organization** of formatting, numbering, issuance, modification and destruction is necessary in order to avoid duplication of effort, incoherence, delays, lack of traceability and incomplete distribution.

– Procedures should be immediately available to the people performing the work.

2.

1. Standardized, consistent procedures (person-to-person, test-to-test variability reduced).

2. A means of study reconstruction, if needed.Optimum efficiency.

3. Capture of technical and administrative improvements.

4. Demonstration of management commitment to quality as part of theSOP approval process.

5. Ease of documenting complicated techniques (a simple reference to the procedure should often suffice).

6. Continuity in case of personnel turnover.

7. Training manual.

8. Means of communication in case of audit, visits, technology transfer, etc.