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MCB 406

QUESTION

1. 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.

1. The system should include the following characteristics:
2. 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).

1. 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.

1. 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 appro-

priate vocabulary so that all personnel can understand the instructions unambigu-

ously. 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.

1. 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 labo-

ratories 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.

1. 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.

1. 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.

1. 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.

1. 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.

1. Procedures should be immediately available to the people performing the work.
2. If properly designed to ensure the above characteristics, the SOPs will provide the fol-

lowing benefits to the laboratory:

* Standardized, consistent procedures (person-to-person, test-to-test variability

reduced).

* A means of study reconstruction, if needed.– Optimum efficiency.
* Capture of technical and administrative improvements.
* Demonstration of management commitment to quality as part of the SOP approval

process.

* Ease of documenting complicated techniques (a simple reference to the procedure

should often suffice).

* Continuity in case of personnel turnover.
* Training manual.
* Means of communication in case of audit, visits, technology transfer, etc.