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SOP (Standard Operating Procedure) is a set of written instructions that document a routine or repetitive activity followed by an organization.

The following characteristics should be met for implementing a successful GLP compliance

1. SOPs should be prepared in full compliance with guidelines and organizations and must mirror current organizational practices

2. Comprehensive coverage of

i. All critical phases of study design, management, conduct and reporting.

ii. Scientific & quot administrative policy and procedures ( e.g formats, safety and hygiene, security, personnel management system e.t.c).

iii. Standard scientific techniques.

3. Readability; A standard format should be adopted

4. The procedures should be written in clear, uncomplicated sentences and with appropriate vocabulary 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.

5. 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 the general policies and procedures; the second 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 division and selective distribution.

6. Procedures should be fully understood and adhered to: if deviation occur, easy communication routes with the study director and management are essential to ensure GLP requirements are met and to conserve the credibility of the system.

7. A responsible person should be identified for each SOPs: to ensure that queries are dealt with and that each procedures is kept up to date. Periodic review of each SOP should be conducted.

8. 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 improvement or change. Ease and rapidly of updating should be ensured.

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

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

2. Benefits of an appropriate SOP system to a laboratory

* Safety of Laboratory operations
* Analytical method validation
* It aids personnel training especially if a replacement is needed in short notice
* Maintenance schedules and calibration of different test instruments and weighing balances
* Laboratory environment control, i.e. temperature and humidity
* Qualification of working standards
* Optimum efficiency of workers
* Handling of customer complaints
* Appropriate receipt and distribution of samples for testing
* Consistency and error reduction in procedures