A. What are the characteristics a standard operating procedure (SOP) system should meet for

implementing a successful GLP compliance.

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

1. Total integration into the laboratory 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).

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 ( one standard format is presented in the

WHO/TDR document & quot; Handbook for Quality in Basic Biomedical Research&quot;) The produres 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.

4. Usability and traceability: for reasons of traceability and easy use, a two-tier system of SOPs is often the preffered 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.

5. 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.

6. A responsible person should be identified for each SOPs: to ensure that queries are dealt with and

that each produres is kept up to date.periodic review of each SOP should be conducted.

7. A formal change control system that ensure 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.

8. Contralized 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.

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

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

This benefits include the following

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

2. A means of study reconstruction, if needed.

3. Optimum efficiency.

4. Capture of technical and administrative improvements.

5. Demonstration of management commitment to quality as part of SOP approval process.

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

7. Continuity in case of personnel turnover.

8. Training manual.

9. Means of communication in case of audit, visits, technology transfer e.t.c